UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 000-50768

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**06-1376651**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**
12830 El Camino Real, Suite 400 San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code:

(858) 558-2871

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ACAD**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934:

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $2.9 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2023 of $23.95 per share.

As of February 21, 2024, 164,771,521 shares of the registrant's common stock, $0.0001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission by April 29, 2024 are incorporated by reference into Part III of this report.

ACADIA PHARMACEUTICALS INC.

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PART I

FORWARD-LOOKING STATEMENTS

This report and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or other similar words (including their use in the negative), or by discussions of future matters such as the benefits to be derived from NUPLAZID® (pimavanserin), DAYBUE™ (trofinetide) and our drug candidates, the potential market opportunities for NUPLAZID and DAYBUE and our drug candidates, our strategy for the commercialization of NUPLAZID and DAYBUE, our plans for exploring and developing NUPLAZID and DAYBUE for indications other than Parkinson's disease psychosis (PDP) or Rett syndrome, respectively, and the commercialization of DAYBUE in jurisdictions other than the U.S., our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our drug candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID, DAYBUE and our drug candidates, our strategy for discovering, developing and, if approved, commercializing drug candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, possible changes in legislation, and other statements that are not historical. These statements include but are not limited to statements under the captions "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the caption "Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and cause our results to differ materially from those expressed or implied by our forward-looking statements. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. We undertake no obligation to update any forward-looking statements made in this report to reflect events or circumstances after the date of this report or to reflect new information or the occurrence of unanticipated events, except as required by law.

Summary of Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

- Our prospects are highly dependent on the continued successful commercialization of NUPLAZID and DAYBUE. To the extent we cannot maintain or increase sales of NUPLAZID or DAYBUE, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- The terms of the FDA's approval of NUPLAZID for the treatment of hallucinations and delusions associated with PDP may limit its commercial potential.

- We rely on a limited internal commercial team and a limited network of third-party distributors and pharmacies to market and sell NUPLAZID and DAYBUE. If this approach ceases to be effective, our commercialization of NUPLAZID and DAYBUE may be adversely affected, and NUPLAZID and DAYBUE may not be profitable.
- If we do not obtain regulatory approval of pimavanserin for other indications in addition to treatment of hallucinations and delusions associated with PDP in the U.S., we will not be able to market pimavanserin for other indications in the U.S., which will limit our commercial revenues. Similarly, if we do not obtain regulatory approval of trofinetide outside the U.S. or for indications in addition to Rett syndrome, we will not be able to market trofinetide outside the U.S. or for other indications in the U.S., which will limit our commercial revenues.
- If we are unable to effectively train and equip our sales forces, our ability to successfully commercialize NUPLAZID and DAYBUE will be harmed.
- NUPLAZID and DAYBUE may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.
- Our ability to generate product revenues will be diminished if coverage for our products from payors is decreased or if patients have unacceptably high co-pay amounts.
- Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate product revenues.
- If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.
- We have a history of net losses and we may not be able to predict the extent of future losses.
- If we fail to generate capital, or otherwise obtain the capital necessary to fund our operations, we will be unable to successfully continue the development and commercialization of NUPLAZID and DAYBUE or successfully develop and commercialize our product candidates, if approved.
- We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.
- Our collaborations may be subject to conflicts or disputes, which could have a material adverse effect on our business, results of operations and financial condition.
- We currently depend, and in the future will continue to depend, on third parties to manufacture NUPLAZID, DAYBUE and any product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID, DAYBUE or any product candidates, if approved.
- Our ability to compete may decline if we do not adequately protect our proprietary rights.
- A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.
- Healthcare reform measures may negatively impact our ability to sell NUPLAZID, DAYBUE or our product candidates, if approved, profitably.
- If our competitors develop and market products that are more effective than NUPLAZID, DAYBUE or our product candidates, if approved, they may reduce or eliminate our commercial opportunity.
- Our stock price historically has been, and is likely to remain, highly volatile.

Item 1. ***Business.***

Company Overview

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines that address unmet medical needs in central nervous system (CNS) disorders and rare diseases. We have a portfolio of commercial stage products, in-development product opportunities, and research programs that are designed to address significant unmet needs in CNS disorders and rare diseases. In order to achieve significant long-term growth, we will develop our current portfolio, expand our pipeline of early- and late-stage programs through strategic business development, and invest in targeted internal research efforts.

Our commercial portfolio includes two products. In April 2016, the U.S. Food and Drug Administration (FDA) approved NUPLAZID for the treatment of hallucinations and delusions associated with PDP, which is the first and only drug approved in the United States for this condition. In March 2023, the FDA approved DAYBUE for the treatment of Rett syndrome, which is the first and only drug approved for this condition. DAYBUE became available for prescription in the United States in April 2023.

NUPLAZID is a selective serotonin inverse agonist/antagonist, preferentially targeting 5-HT_{2A} receptors with no appreciable affinity for dopaminergic, histaminergic, or muscarinic receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP without negatively impacting motor function in our Phase 3 pivotal trial. NUPLAZID has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA for the treatment of PDP. We hold worldwide commercialization rights to pimavanserin.

In August 2018, we acquired an exclusive North American license to develop and commercialize DAYBUE for Rett syndrome and other indications from Neuren Pharmaceuticals Limited (Neuren). Rett syndrome is a debilitating neurological disorder that occurs predominantly in females following apparently normal psychomotor development for the first six months of life. Rett syndrome also occurs in males, albeit far less frequently. Sometime between six to eighteen months of age, failure to reach normal developmental milestones is initially observed, which is then followed by a period of development regression with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, hand movements or stereotypies, disorganized breathing patterns, scoliosis and sleep disturbances, among others. The FDA approval of DAYBUE for the treatment of Rett syndrome was based on the positive results from our pivotal Phase 3 LAVENDER™ study which demonstrated statistically significant and clinically meaning improvement over placebo for both co-primary endpoints in the study as well as the key secondary endpoint of the study.

In July 2023, we expanded the 2018 licensing agreement with Neuren to acquire rights to trofinetide outside of North America and global rights to Neuren's development candidate NNZ-2591 in Rett syndrome and Fragile X syndrome.

In addition to the treatment of hallucinations and delusions associated with the PDP, we believe that pimavanserin has the potential as a treatment of the negative symptoms of schizophrenia. Today we are evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia in a Phase 3 clinical development program. The negative symptoms of schizophrenia have been associated with poor long-term outcomes and disability even when the positive symptoms are well-controlled, and today there are no FDA-approved therapies. In the fourth quarter of 2019 we announced positive results from our pivotal ADVANCE study and in the third quarter of 2020, we initiated a second pivotal study, ADVANCE-2. The Phase 3 program is evaluating the efficacy of pimavanserin in patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. We completed enrollment in ADVANCE-2 and expect that top-line results will be available in the first quarter of 2024.

In June 2023, we announced that we added a new Phase 3 development candidate to our rare disease portfolio, ACP-101 (intranasal carbetocin), for the treatment of hyperphagia (an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety) in Prader-Willi syndrome (PWS). We acquired worldwide rights to develop and commercialize ACP-101 with the acquisition of Levo Therapeutics in June 2022. In November 2023, we initiated the Phase 3 COMPASS PWS study evaluating the efficacy and safety of ACP-101 for the treatment of hyperphagia in PWS.

In addition, in August 2022, we announced that we are developing an internally discovered new molecule, ACP-204, which builds upon the learnings of pimavanserin in the treatment of neuropsychiatric symptoms. We completed a Phase 1 study of ACP-204 which demonstrated a favorable safety and tolerability profile, and supports its target product profile as a potential treatment for Alzheimer's disease psychosis (ADP). In November 2023, we initiated a Phase 2 study evaluating the efficacy and safety of ACP-204 for the treatment of hallucinations and delusions associated with ADP. ACP-204 is a new chemical entity for which we hold the worldwide rights.

In January 2022, we entered into a license and collaboration agreement with Stoke Therapeutics, Inc. (Stoke) to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. For the Rett syndrome (MECP2) and the undisclosed neurodevelopmental program, Stoke will lead research and pre-clinical development activities, while we will lead clinical development and commercialization activities.

Corporate Information

We were originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. We reincorporated in Delaware in 1997 and our headquarters are in San Diego, California. We maintain a website at *www.acadia.com*, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission (SEC) are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Interested persons can subscribe on our website to email alerts that are sent automatically when we issue press releases, file our reports with the SEC or post certain other information to our website. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

We own or have rights to various trademarks, copyrights and trade names used in our business, including Acadia®, NUPLAZID® and DAYBUE™. Our logos and trademarks are the property of Acadia Pharmaceuticals Inc. All other brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsement or sponsorship of us, by the trademark or trade dress owners.

Our Strategy

Our strategy is to identify, develop and commercialize innovative therapies that address unmet medical needs in CNS disorders and rare diseases. Key elements of our strategy are to:

- ***Build on the strong commercialization of DAYBUE for the treatment of patients with Rett syndrome in the United States.*** DAYBUE was approved by the FDA in March 2023 for the treatment of Rett syndrome. We launched DAYBUE in the United States in April 2023. We have seen strong revenue numbers since launch, demonstrating what we believe to be a high level of excitement in the Rett community as soon as DAYBUE came to market. We have seen strong early demand for DAYBUE, coupled with persistency rates that have exceeded the same time periods for those seen in patients who were in the placebo group in the Phase 3 LAVENDAR study who then rolled over to treatment with trofinetide in our open-label Lilac study, and relatively broad access for patients regardless of age (>2 years) or gender. We employ U.S. sales specialists that are focused on promoting DAYBUE to physicians who treat Rett syndrome patients, including those at Centers of Excellence, high volume institutions and in the community setting. We also have support services including the Acadia Connect hub for physicians, patients and their families that provide broad resources to help with access, reimbursement and the continual clinical support to help patients start and stay on therapy.
- ***Maximize the successful commercialization of NUPLAZID for Parkinson's disease psychosis in the United States.*** NUPLAZID was approved by the FDA in April 2016 for the treatment of hallucinations and delusions associated with PDP. We launched NUPLAZID in the United States in May 2016 and an important objective is to establish NUPLAZID as the standard of care for PDP. We employ U.S. sales specialists that are focused on promoting NUPLAZID to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. The NUPLAZID franchise has been cash flow positive since 2019, and as such we are focused on maximizing market share, balancing top-line growth with long-term profitability.

- ***Advance our late-stage opportunities to drive further growth.*** We have an ongoing Phase 3 program, ADVANCE-2 evaluating pimavanserin for the treatment of negative symptoms of schizophrenia with top-line results expected in the first quarter of 2024. ADVANCE-2 leverages the same design and optimal therapeutic dose of 34 mg from the previous positive Phase 2 trial of ADVANCE-1. We also initiated a Phase 3 COMPASS study of ACP-101 in PWS and a Phase 2 study of ACP-204 in ADP in the fourth quarter of 2023.
- ***Deliver DAYBUE to the international market for the treatment of patients with Rett syndrome.*** Our early U.S. experience serves as an important reminder to us of a significant unmet medical need with no approved treatments for Rett syndrome outside the United States. In Canada, we expect to file a new drug submission in the first quarter of 2024, with a potential approval around the end of the year. In Europe, we are engaging with the European Medical Authority in the first quarter of 2024, with plans to file a marketing authorization application in the first half of 2025. In Japan, we are engaging with the regulatory agency in 2024.
- ***Develop our early-stage programs and other business development opportunities.*** We have a deep early-stage portfolio that includes disclosed and undisclosed programs focused on neuropsychiatric and rare disorders that represent significant opportunities to continue to build on our current growth. In addition, we continue to remain very active in business development to further expand our portfolio and build on our success with NUPLAZID and DAYBUE in CNS and rare disease.

Our Pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
NUPLAZID® (pimavanserin)	Parkinson's Disease Psychosis					
DAYBUE™ (trofinetide)	Rett Syndrome					
Pimavanserin[1]	Negative Symptoms of Schizophrenia					
ACP-101[2,3]	Hyperphagia in Prader-Willi Syndrome					
ACP-204[3]	Alzheimer's Disease Psychosis					
ACP-2591[3]	Rett Syndrome; Fragile X Syndrome					
ASO Programs[3]	SYNGAP1; Rett; Undisclosed					
Multiple Undisclosed Programs	Neuropsychiatric and Rare Disorders					

NUPLAZID (pimavanserin) is only approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.
DAYBUE (trofinetide) is only approved in the U.S. by the FDA for the treatment of Rett syndrome in adults and pediatric patients two years of age and older.
[1] Safety and efficacy of pimavanserin for the treatment of negative symptoms of schizophrenia have not been established or approved by the FDA. [2] Acadia acquired Levo Therapeutics and its rights/licenses to ACP-101.
[3] The safety and efficacy of these investigational agents have not been established. There is no guarantee these investigational agents will be filed with or approved by any regulatory agency.

NUPLAZID (pimavanserin)

Pimavanserin is a chemical entity that we discovered and that was approved by the FDA in April 2016 for the treatment of hallucinations and delusions associated with PDP. It is the only drug approved in the United States for this condition and is marketed under the tradename NUPLAZID in the United States. NUPLAZID is a selective serotonin inverse agonist/antagonist preferentially targeting the 5-HT_{2A} receptor, a key serotonin receptor that plays an important role in psychosis. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP without negatively impacting motor function in our Phase 3 pivotal trial. NUPLAZID has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA in the treatment of PDP. We hold worldwide commercialization rights to NUPLAZID for all indications and have established a broad patent portfolio, which includes numerous issued patents in the United States, Europe, and several additional countries. NUPLAZID is available in 34 mg capsule and 10 mg tablet dosage forms.

NUPLAZID as a Treatment for Parkinson's Disease Psychosis

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. According to the Parkinson's Disease Foundation, about one million people in the United States and more than 10 million people globally suffer from this disease. Approximately 50% of Parkinson's patients will experience psychosis over the course of their disease. Parkinson's disease is more common in people over 60 years of age and the prevalence of this disease is expected to increase significantly as the population ages.

PDP is a debilitating disorder commonly characterized by visual hallucinations and delusions that afflicts about 40% of the one million Parkinson's disease patients in the United States. The development of psychosis in patients with Parkinson's disease substantially contributes to the burden of Parkinson's disease and deeply affects their quality of life. PDP is associated with a diminished quality of life, nursing home placement, and increased caregiver stress and burden.

As the first and only drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP, NUPLAZID provides an innovative approach to the treatment of PDP without compromising motor control and potentially avoiding many of the debilitating side effects of existing antipsychotics.

In connection with the FDA approval of NUPLAZID, we have agreed to four post-marketing commitments. Three of the four commitments have been fulfilled within the agreed upon timelines. The fourth commitment, a randomized, placebo-controlled eight-week study or studies in predominantly frail and elderly patients that would add to the NUPLAZID safety database by exposing an aggregate of at least 500 patients to NUPLAZID, has been completed and we are awaiting FDA's acknowledgement and acceptance.

Pimavanserin as a Treatment for the Negative Symptoms of Schizophrenia

Schizophrenia is a chronic and debilitating disorder that involves disturbances in cognition, perception, emotion, and other aspects of behavior. These disturbances may include positive symptoms, such as hallucinations and delusions, and a range of negative symptoms, including loss of interest and emotional withdrawal. Schizophrenia is associated with persistent impairment of a patient's social functioning and productivity. Studies show that about 40% to 50% people with schizophrenia suffer from negative symptoms. While currently available antipsychotic treatments for schizophrenia mainly target positive symptoms, many patients remain functionally impaired because of residual negative and cognitive symptoms that are harder to treat with atypical antipsychotics. The residual negative and cognitive symptoms limit social functioning. There is currently no drug approved by the FDA for the treatment of the negative symptoms of schizophrenia. According to the National Institute of Mental Health (NIMH), approximately 1% of the U.S. population suffers from schizophrenia.

Most patients with schizophrenia in the United States today are treated with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than first-generation, or typical, antipsychotics, but still fail to fully address some of the negative symptoms of schizophrenia for a significant portion of patients. In addition, currently prescribed treatments have either negligible effects on cognitive symptoms of schizophrenia or may even further impair cognitive performance. It is believed that the efficacy of atypical antipsychotics is due to their interactions with dopamine and 5-HT_{2A} receptors. Despite their commercial success, current antipsychotic drugs have substantial limitations, including inadequate efficacy and severe side effects. The side effects associated with these atypical agents may include weight gain, type 2 diabetes, metabolic, sexual and cardiovascular side effects, movement disturbances or sedation.

In November 2016, we announced that we initiated ADVANCE, a Phase 2 study to evaluate pimavanserin for adjunctive treatment in patients with negative symptoms of schizophrenia. ADVANCE was a Phase 2, 26-week, randomized, double-blind, placebo-controlled, multi-center, international study designed to examine the efficacy and safety of pimavanserin in patients with schizophrenia who have predominant negative symptoms while on a stable background antipsychotic therapy. 403 patients were randomized to receive once-daily pimavanserin (n=201) or placebo (n=202) as an adjunct treatment to their ongoing antipsychotic in a flexible dosing regimen. The starting daily dose of 20 mg of pimavanserin at baseline could have been adjusted to 34 mg or 10 mg during the first eight weeks of treatment. 53.8% of patients who were randomized to receive pimavanserin completed the trial on 34 mg, 44.7% on 20 mg, and 1.5% on 10 mg. The primary endpoint of the study was the change from baseline to week 26 on the Negative Symptom Assessment-16 (NSA-16) total score. In November 2019, we announced positive top-line results from the ADVANCE study. In this study, pimavanserin demonstrated a statistically significant improvement on the study's primary endpoint, the change from baseline to week 26 on the NSA-16 total score, compared to placebo (p=0.043). A greater improvement in the NSA-16 total score compared to placebo was observed in patients who received the highest pimavanserin dose of 34 mg (n=107; unadjusted

p=0.0065). Pimavanserin did not separate from placebo on the key secondary endpoint, the Personal and Social Performance (PSP) scale.

In the third quarter of 2020, we initiated a second pivotal study, ADVANCE-2. The Phase 3 study will evaluate the efficacy of pimavanserin 34 mg once daily compared to placebo in approximately 454 patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. We anticipate announcing top-line results from the Phase 3 ADVANCE-2 study in the first quarter of 2024.

DAYBUE (trofinetide) as a Treatment for Rett Syndrome

Trofinetide is a novel synthetic analog of the amino-terminal tripeptide of insulin-like growth factor 1 (IGF-1) designed to treat the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function. Trofinetide has been granted FDA Fast Track Status and Orphan Drug Designation in the U.S. and Orphan Designation in Europe.

Rett syndrome is a debilitating neurological disorder that occurs primarily in females following apparently normal development for the first six months of life. Rett syndrome has been most often misdiagnosed as autism, cerebral palsy, or non-specific developmental delay. Rett syndrome is caused by mutations on the X chromosome on a gene called MECP2. There are more than 200 different mutations found on the MECP2 gene that interfere with its ability to generate a normal gene product. Rett syndrome occurs worldwide in approximately one of every 10,000 to 15,000 female births causing problems in brain function that are responsible for cognitive, sensory, emotional, motor and autonomic function. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, disorganized breathing patterns, an abnormal side-to-side curvature of the spine (scoliosis) and sleep disturbances.

In March 2023, the FDA approved DAYBUE for the treatment of Rett syndrome, which is the first and only drug approved for this condition. In addition, we were granted a Rare Pediatric Disease Priority Review Voucher (PRV) following the FDA approval of DAYBUE. DAYBUE became available for prescription in the United States in April 2023.

In connection with the FDA approval of DAYBUE, we are required to conduct post-marketing work, including a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies, and nonclinical in vitro drug interaction studies.

ACP-101 as a Treatment for Prader-Willi syndrome

Carbetocin nasal spray (ACP-101) is an investigational drug being developed for the treatment of hyperphagia in PWS. Carbetocin has improved drug qualities relative to oxytocin, including an extended half-life and greater specificity for the oxytocin receptor compared to vasopressin receptors which could provide meaningful efficacy with an attractive safety profile in patients with PWS. For the treatment of PWS specifically, a central nervous system disorder, an intranasal formulation of carbetocin was developed, which provides direct delivery of the drug to the brain, greatly reducing systemic exposure and the potential for side effects. We acquired Levo Therapeutics and worldwide rights to carbetocin nasal spray in June 2022. Carbetocin nasal spray has been granted Orphan Drug, Fast Track, and Rare Pediatric Disease designations by the FDA.

PWS is a rare neurobehavioral genetic disorder that affects both males and females. PWS is estimated to affect approximately 1 in 15,000 to 1 in 25,000 live births worldwide , or 8,000 to 10,000 patients in the United States. PWS affects the functioning of the hypothalamus and other aspects of the brain with symptoms varying by individual. The most common symptom is hyperphagia, which is an unrelenting lack of satiety, to which a deficiency in oxytocin is believed to be contributory. Oxytocin is a natural hormone that regulates several functions in the body, including hunger, anxiety, social behavior and bonding. Individuals living with PWS have fewer oxytocin-producing neurons in the brain. Other defining features of the syndrome may include altered metabolism, developmental delays, behavioral challenges and moderate cognitive deficits. Patients may also experience bone disorders, high pain tolerance, sleep disturbances, gastrointestinal issues, respiratory and temperature regulation abnormalities. There is no FDA-approved treatment for the hyperphagia associated with PWS.

In the fourth quarter of 2023, we initiated the Phase 3 COMPASS PWS study evaluating the efficacy and safety of ACP-101 for the treatment of hyperphagia in PWS. COMPASS PWS is a 12-week, double-blind, randomized, placebo-controlled global Phase 3 trial evaluating the efficacy and safety of carbetocin nasal spray 3.2 mg three times daily (TID) in approximately 170 children and adults aged five to 30 years with PWS. The primary efficacy endpoint of the study is change from baseline to week 12 on the hyperphagia questionnaire for clinical trials (HQ-CT) score, a caregiver assessment for hyperphagia-related behaviors. Participants who complete the Phase 3 study will be eligible to enroll in a long-term, open-label extension study designed to investigate the safety and tolerability of long-term treatment with ACP-101.

ACP-204 as a Treatment for Alzheimer's Disease Psychosis

An estimated over 6.0 million people in the United States are living with Alzheimer's disease dementia and studies suggest that approximately 30% of them, or 1.8 million people, have psychosis, commonly consisting of delusions and hallucinations. Approximately 900,000 patients in the United States are currently treated for ADP and of those treated, approximately two-thirds are treated with off-label anti-psychotics.

Symptoms of ADP are often persistent and may occur with increasing frequency with progression of disease as patients become more impaired. Serious consequences have been associated with persistent or severe psychosis in persons with dementia such as repeated hospital admissions, earlier progression to nursing home care, severe dementia, and death. There are currently no FDA-approved treatments for ADP. Off-label use of typical and atypical antipsychotics is associated with modest and often equivocal efficacy in these patients. In addition, use of currently available antipsychotics is associated with a significant acceleration in cognitive decline in patients with dementia as well as numerous off-target toxicities, thus negatively impacting the primary illness. The cognitive effects of treatment with an atypical antipsychotic were evaluated in the National Institute of Mental Health Clinical Antipsychotic Trials of Intervention Effectiveness–Alzheimer's Disease (CATIE-AD) study. In this study, patients on any atypical antipsychotic had significantly greater rates of decline in cognitive function compared to patients on placebo. This pronounced negative impact of currently used antipsychotics on cognitive function is believed to be associated with the common pharmacologic property of these drugs, namely blocking of dopamine receptors. Atypical antipsychotics are associated with a number of off-target and dose-limiting side effects, such as extrapyramidal symptoms, orthostatic hypotension, hematologic abnormalities, and metabolic, gastrointestinal and sedative effects. These off-target toxicities are associated with increased risk for falls, infection, aspiration pneumonia, and other serious complications in this vulnerable patient population. With no approved therapies for the treatment of patients with ADP and current off-label use of atypical antipsychotics carrying significant morbidity risks including worsening in cognitive decline and other off target toxicities, we believe that ADP represents an area of high unmet need.

ACP-204 is a new chemical entity which is designed to leverage the learnings from pimavanserin. For several years we have sought to build upon our pimavanserin franchise by investigating and developing other molecules focused on the serotonergic system. Virtually all of the antipsychotics on the market today are thought to work predominantly through blocking dopamine and in particular, the dopamine D2 receptor. Pimavanserin is thought to work entirely through serotonin, which we believe can provide a very different and favorable safety and tolerability profile.

Specifically with ACP-204, we believe we may have an opportunity to maximize the efficacy potential, while reducing the risk of QT prolongation. We completed Phase 1 study of ACP-204 which demonstrated a favorable safety and tolerability profile, and supports its target product profile as a potential treatment for ADP. In the fourth quarter of 2023, we initiated a Phase 2 study of ACP-204 for the treatment of hallucinations and delusions associated with ADP. The Phase 2 study is part of a seamless Phase 2 / Phase 3 program that includes three studies: a single Phase 2 study and two Phase 3 studies which have almost identical design. The Phase 2 study is a global, multi-center, randomized, double-blind, placebo-controlled trial that will enroll approximately 318 patients and evaluate ACP-204 30 mg and 60 mg doses compared to placebo. The primary endpoint is change from baseline to week 6 on the Scale for the Assessment of Positive Symptoms–Hallucinations and Delusions subscales (SAPS-H+D) total score. The clinical trial sites will enroll seamlessly from Phase 2 into Phase 3. Each of the planned Phase 3 studies will enroll approximately 378 patients with ADP. Patients who complete the study will have the option of participating in a long-term open-label extension study.

Antisense Oligonucleotide (ASO) Programs

In January 2022, we entered into a collaboration with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1, MECP2 (Rett syndrome) and an undisclosed CNS target of mutual interest. The programs are currently in various stages of pre-clinical development.

Competition

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors have products or are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

For example, the use of NUPLAZID for the treatment of PDP competes with off-label use of various antipsychotic drugs, including the generic drugs quetiapine, clozapine, risperidone, aripiprazole, and olanzapine.

Pimavanserin for the treatment of negative symptoms of schizophrenia, if approved for that indication, would compete with off-label use of Vraylar, marketed by Allergan, Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., Caplyta, marketed by IntraCellular Therapeutics and various generic drugs, including quetiapine, clozapine, risperidone, aripiprazole, and olanzapine.

Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome. DAYBUE competes indirectly with off-label usage of branded and generic prescription medications targeted at individual symptoms of Rett syndrome, including antiepileptics, antipsychotics, antidepressants and benzodiazepines. In addition, Anavex has a product, Anavex 2-73, in development for the potential treatment of Rett syndrome and Taysha Gene Therapies is conducting clinical trials of a gene therapy to treat Rett syndrome. Neurogene started an early phase clinical trial of its investigational adeno-associated virus gene therapy candidate, NGN-401, delivered using intracerebroventricular administration to treat Rett Syndrome.

Other competitors may have a variety of drugs in development or awaiting approval from the FDA or comparable foreign regulatory authorities that could reach the market and become established before we have a product to sell for the applicable disorder. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities;
- sales and marketing; and
- production and testing facilities.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific, sales and marketing, and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, more

affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

Intellectual Property

We currently hold 59 issued U.S. patents and a significant number of related issued foreign patents. We have also exclusively licensed rights to an additional 35 issued U.S. patents, and a number of related foreign patents. Patents and other proprietary intellectual property rights are an essential element of our business. Our strategy is to file patent applications in the United States and any other country that represents an important potential commercial market to us. In addition, we seek to protect our technology and inventions (and improvements to inventions) that are important to the development of our business. Our patent applications claim proprietary technology, including chemical synthetic or manufacturing methods, drug assays, novel compounds, compositions, formulations and methods of treatment. We also rely upon trade secrets, including technologies that may be used to discover and validate targets, to identify and develop novel drugs, as well as manufacturing or clinical development technologies, among others. We protect our trade secrets by, among other things, requiring employees and third parties who have access to our proprietary information to sign confidentiality and nondisclosure agreements. We are a party to various license agreements that give us rights to use certain technologies in our research and development, subject to certain limitations.

Pimavanserin

We currently hold 36 U.S. patents that relate to pimavanserin, NUPLAZID and methods of use of pimavanserin. Fifteen of these are Orange Book-listed patents that relate to pimavanserin, NUPLAZID and our approved indication, and cover the general formula of the compound, the composition of matter, with claims specifically directed to pimavanserin and salts thereof, the specific polymorph form of pimavanserin, the approved formulations, and the use thereof for treating our approved indication. The composition of matter patent covering pimavanserin and salts thereof currently has an expiration date in 2030, including a patent term extension approved by the U.S. Patent and Trademark Office. The patents covering the polymorph form and the use of pimavanserin or NUPLAZID for our approved indication are currently set to expire between 2024 and 2028. These patent terms include adjustments made by the U.S. Patent and Trademark Office, but not extensions.

In the United States, under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as “Hatch-Waxman,” we are permitted to extend the term of one U.S. patent for pimavanserin or the use thereof. Patent terms may be subject to change not only due to potential patent term extensions but also to any terminal disclaimer that reduces patent term, as well as other factors. Because the U.S. patent laws and judicial interpretations thereof change, modifications or new interpretations of the laws may impact our patent terms.

The remaining 21 U.S. patents relating to pimavanserin that have been issued to us cover methods of use of pimavanserin for, among other things, treating ADP, Alzheimer’s disease indications, schizophrenia, bipolar disorder, Lewy body dementia, sleep disorders, hallucinations and delusions, other indications and methods of manufacturing pimavanserin. We also have a significant number of related issued foreign patents that specifically cover pimavanserin and polymorphs thereof in Europe and Asia as well as in Australia, Canada, Mexico and other countries.

We continue to file and prosecute patent applications directed to pimavanserin, formulations of pimavanserin, methods of manufacturing, and to methods of treating various diseases using pimavanserin, either alone or in combination with other agents, worldwide. For example, in late 2019 and in 2020, we obtained and listed in the Orange Book six additional U.S. issued patents, two patents directed to method of use for our 10 mg tablet, expiring in 2037, and four patents directed to our 34 mg capsule formulation, each expiring in 2038.

Trofinetide

We currently hold the exclusive licenses to 8 U.S. patents from Neuren Pharmaceuticals that relate to trofinetide, methods of manufacturing and methods of use of trofinetide. Two of the U.S. patents are listed in the Orange Book, including a patent claiming the use of trofinetide for treating Rett syndrome. The use patent for treating Rett syndrome has an expiration date in 2032. Subject to a patent term extension request, the expiration date of such patent may be extended to January 2036.

Under the license agreement with Neuren, we continue to file and prosecute patent applications directed to trofinetide, formulations of trofinetide, methods of manufacturing and methods of treating Rett syndrome using trofinetide.

Government Regulation

Our business activities, including the manufacturing and marketing of NUPLAZID, DAYBUE and our potential products and our ongoing research and development activities, are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Before marketing in the United States, any new drug developed by us must undergo rigorous preclinical testing, clinical trials and an extensive regulatory clearance process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act, as amended. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, import, export, sale and distribution of biopharmaceutical products. The regulatory review and approval process, which includes preclinical testing and clinical trials of each product candidate, is lengthy, expensive and uncertain. Moreover, government coverage and reimbursement policies will both directly and indirectly impact our ability to successfully commercialize NUPLAZID, DAYBUE and any future approved products, and such coverage and reimbursement policies will be impacted by enacted and any applicable future healthcare reform and drug pricing measures. In addition, we are subject to state and federal laws, including, among others, anti-kickback laws, false claims laws, data privacy and security laws, and transparency laws that restrict certain business practices in the pharmaceutical industry.

In the United States, drug product candidates intended for human use undergo laboratory and animal testing until adequate proof of safety is established. Clinical trials for new product candidates are then typically conducted in humans in three sequential phases that may overlap. Phase 1 trials involve the initial introduction of the product candidate into healthy human volunteers. The emphasis of Phase 1 trials is on testing for safety or adverse effects, dosage, tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase 2 involves studies in a limited patient population to determine the initial efficacy of the compound for specific targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks. Once a compound shows initial evidence of effectiveness and is found to have an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to more fully evaluate clinical outcomes. Before commencing clinical investigations in humans, we or our collaborators must submit an Investigational New Drug Application (IND), to the FDA.

Regulatory authorities, Institutional Review Boards and Data Monitoring Committees may require additional data before allowing the clinical studies to commence, continue or proceed from one phase to another, and could demand that the studies be discontinued or suspended at any time if there are significant safety issues. Clinical testing must also meet requirements for clinical trial registration, institutional review board oversight, informed consent, health information privacy, and good clinical practices (GCPs). Additionally, the manufacture of our drug product must be done in accordance with current good manufacturing practices (cGMPs).

To establish a new product candidate’s safety and efficacy, the FDA requires companies seeking approval to market a drug product to submit extensive preclinical and clinical data, along with other information, for each indication for which the product will be labeled. The data and information are submitted to the FDA in the form of a New Drug Application (NDA), which must be accompanied by payment of a significant user fee unless a waiver or exemption applies. Generating the required data and information for an NDA takes many years and requires the expenditure of substantial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. The failure to demonstrate adequately the quality, safety and efficacy of a product candidate under development would delay or prevent regulatory approval of the product candidate. Under applicable laws and FDA regulations, each NDA submitted for FDA approval is given an internal administrative review within 60 days following submission of the NDA. If deemed sufficiently complete to permit a substantive review, the FDA will “file” the NDA. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. The FDA has established internal goals of eight months from submission for priority review of NDAs that cover new product candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists, and 12 months from submission for the standard review of NDAs. However, the FDA is not legally required to complete its review within these periods, these performance goals may change over time and the review is often extended by FDA requests for additional information or clarification. Moreover, the outcome of the review, even if generally favorable, may not be an actual approval but a “complete response letter” that describes additional work that must be done before the NDA can be approved. Before approving an NDA, the FDA can choose to inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs. The FDA may also audit sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. The FDA’s review of an NDA may also involve review and recommendations by an independent FDA advisory committee, particularly for novel indications. The FDA is not bound by the recommendation of an advisory committee.

In addition, delays or rejections may be encountered based upon changes in regulatory policy, regulations or statutes governing product approval during the period of product development and regulatory agency review.

Before receiving FDA approval to market a potential product, we or our collaborators must demonstrate through adequate and well-controlled clinical studies that the potential product is safe and effective in the patient population that will be treated. In addition, under the Pediatric Research Equity Act (PREA), an NDA or supplement to an NDA must contain data or a plan to collect such data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a waiver applies. If regulatory approval of a potential product is granted, this approval will be limited to those disease states and conditions for which the product is approved. Marketing or promoting a drug for an unapproved indication is generally prohibited. Furthermore, FDA approval may entail ongoing requirements for risk management, including post-marketing, or Phase 4, studies. Even if approval is obtained, each marketed product, is subject to payment of a significant annual program user fee and continuing review and periodic inspections by the FDA. Discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including labeling changes, warning letters, costly recalls or withdrawal of the product from the market.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a product candidate, known as toxicological studies, or during clinical trials of our potential products. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates. Further, such unacceptable toxicity or side effects could ultimately prevent a potential product's approval by the FDA or foreign regulatory authorities for any or all targeted indications or limit any labeling claims and market acceptance, even if the product is approved.

In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy (REMS). A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

We and our collaborators and contract manufacturers also are required to comply with the applicable FDA GMP regulations. cGMP regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our potential products and must maintain ongoing compliance for commercial product manufacture, testing, storage and distribution. The FDA may conclude that we or our collaborators or contract manufacturers are not in compliance with applicable cGMP requirements and other FDA regulatory requirements, which may result in delay or failure to approve applications, warning letters, product recalls and/or imposition of fines or penalties.

If a product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with advertising and promotion laws enforced by various government agencies, including the FDA's Office of Prescription Drug Promotion, and through such laws as federal and state anti-fraud and abuse laws, including anti-kickback and false claims laws, healthcare information privacy and security laws, post-marketing safety surveillance, and disclosure of payments or other transfers of value to healthcare professionals and entities. In addition, we are subject to other federal and state regulation including, for example, the implementation of corporate compliance programs.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

Outside of the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA marketing approval discussed above. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals and entities.

Coverage and Reimbursement

Sales of NUPLAZID, DAYBUE and our product candidates, if approved, depend and will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Coverage policies and third-party payor reimbursement rates may change at any time. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party payor reimbursement or a decision by a third-party payor to not cover NUPLAZID, DAYBUE or any other future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. NUPLAZID and DAYBUE are available for coverage under Medicare Part D, but the individual Part D plans offer coverage subject to various factors such as those described above. In addition, while Medicare Part D plans have historically included "all or substantially all" drugs in the following designated classes of "clinical concern" on their formularies: anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants, the Centers for Medicare & Medicaid Services (CMS), has in the past proposed, but not adopted, changes to this policy. If this policy is changed in the future and if CMS no longer considers the antipsychotic class to be of "clinical concern", Medicare Part D plans would have significantly more discretion to reduce the number of products covered in that class, including coverage of NUPLAZID and DAYBUE. Furthermore, private third-party payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Healthcare Laws and Regulations

We are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.
- Federal false claims and false statement laws, including the federal civil False Claims Act, and civil monetary penalties laws, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.
- The U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their implementing regulations, imposes obligations on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, the European Union (EU) and United Kingdom (UK) have each established their own data security and privacy legal framework, including but not limited to the EU's General Data Protection Regulation (EU) 2016/79 and the so-called "UK GDPR" (together, the GDPR), which contain provisions specifically directed at the processing of health information, higher sanctions than previously applicable data protection laws and extra-territoriality measures intended to bring non-EU/-UK companies' processing operations under the scope of these regulations in certain circumstances (including where the relevant processing relates to the monitoring of behaviors of individuals in the EU/UK – such as in the context of the conduct of a clinical trial). We currently conduct clinical trials in the EU and the UK and will need to be compliant with these requirements. We anticipate that over time we may expand our business operations to include additional operations in the EU and/or UK. With such expansion, we would be subject to increased governmental regulation in the territories in which we might operate, including the GDPR.
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors by such law), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require drug manufacturers to report information on the pricing of certain drugs, state and local laws that require the registration of pharmaceutical sales representatives, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to significant administrative, civil and/or criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from federal health care programs, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA) was signed into law, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to NUPLAZID, DAYBUE and our product candidates are: (i) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (ii) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (iii) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (iv) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP); (v) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (vii) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA. Through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act, will remain in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to certain providers.

Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs

through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear if and how this program will be implemented and whether it will be subject challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and additional downward pressure on the price that we receive for NUPLAZID, DAYBUE and any future approved products. We cannot predict what healthcare reform initiatives may be adopted in the future.

Manufacturing and Distribution

We currently outsource, and plan to continue to outsource, manufacturing activities for NUPLAZID, DAYBUE and our existing and future product candidates for development and commercial purposes. We believe this manufacturing strategy will enable us to direct our financial resources to our commercial activities and to the ongoing development of pimavanserin, trofinetide and other product candidates without devoting the substantial resources and capital required to build manufacturing facilities.

We licensed worldwide intellectual property rights related to pimavanserin in certain indications to Acadia Pharmaceuticals GmbH, our wholly-owned Swiss subsidiary (Acadia GmbH). Our active pharmaceutical ingredient (API) has been manufactured in Switzerland for over 10 years and we anticipate continuing to manufacture in Switzerland. Acadia GmbH manages the worldwide supply chain of our pimavanserin API, and maintains sufficient materials to manufacture our API.

Acadia GmbH has contracted with Siegfried AG (Siegfried), to manufacture our API to be used in NUPLAZID for commercial sale. Under the manufacturing agreement, Acadia GmbH has agreed to purchase from Siegfried specified percentages of our commercial requirements of API for the United States and Europe. The parties may also agree in the future on additional services under the manufacturing agreement with respect to non-commercial supply or development activities. The term of the manufacturing agreement ended in December 2021 and renewed for a two-year term and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated earlier pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the dissolution or liquidation of the other party, the commencement of insolvency procedures that are not dismissed within a certain period of time, the appointment of any receiver, trustee or assignee to take possession of the properties of the other party or the cessation of all or substantially all of the other party's business operations, upon certain continuing patent infringement, regulatory litigation or other legal proceedings involving the manufacture of our API, upon a continuing force majeure affecting the other party, or if no services are currently being provided under the manufacturing agreement. Additionally, if the parties agree on development services under the manufacturing agreement, the parties may terminate such services by mutual agreement if reasonable efforts to achieve the goals of such services fail. Acadia GmbH also may terminate any services under the manufacturing agreement for any reason on 90 days' prior notice to Siegfried, subject to the requirements of the manufacturing agreement.

We have contracted with Patheon Pharmaceuticals Inc. (Patheon), to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product for commercial use in the United States. We have also contracted with a second contract manufacturing organization to manufacture NUPLAZID 34 mg drug product for commercial use in the United States. Under the manufacturing agreement with Patheon, we have agreed to purchase from Patheon a specified percentage of our commercial requirements of NUPLAZID for the United States. Under the agreement, Patheon will also perform specified validation services. The term of the manufacturing agreement ended in the first quarter of 2023 and renewed for a two-year term and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated early pursuant to its terms. Each party may terminate the manufacturing agreement prior to expiration upon the uncured material breach by the other party, upon the bankruptcy or insolvency of the other party or in the event of a continuing force majeure event affecting the other party. The manufacturing agreement will also terminate if we provide notice to Patheon that we no longer require manufacturing services because NUPLAZID has been discontinued. Additionally, we may terminate the manufacturing agreement, subject to certain limitations, if any regulatory authority takes any action or raises any objection that prevents us from continuing to commercialize NUPLAZID or takes an enforcement action against Patheon's manufacturing site that relates to NUPLAZID or could reasonably be expected to adversely affect Patheon's ability to supply NUPLAZID, if we determine to discontinue commercialization of NUPLAZID for safety or efficacy reasons, or if Patheon uses any debarred person in performing its service obligations under the manufacturing agreement. We also may terminate the manufacturing agreement for any other reason on three years' prior notice to Patheon. Patheon may terminate the manufacturing agreement if we assign the manufacturing agreement or any of our rights under the manufacturing agreement to a Patheon competitor.

We sell NUPLAZID to a limited number of specialty pharmacies (SPs), and specialty distributors (SDs), which we collectively refer to as our customers. SPs subsequently dispense NUPLAZID to patients based on the fulfillment of a prescription and SDs subsequently sell NUPLAZID to government facilities, long-term care pharmacies, and in-patient hospital pharmacies. Four of such customers, each based in the United States, accounted for approximately 73% of our NUPLAZID product revenue and 56% of our total product revenue for the year ended December 31, 2023. We have retained third-party service providers to perform a variety of functions related to the distribution of NUPLAZID, including warehousing, customer service, order-taking, invoicing, collections, and shipment and returns processing.

We have contracted with manufacturers to produce supplies of trofinetide to support the development program and for commercial sale. We have contracted with Corden Pharma Bergamo S.p.A. (Corden), to manufacture the API for trofinetide products. Under the manufacturing agreement with Corden, we have agreed to purchase from Corden the API for trofinetide products at specified price per volume. We and Corden may also agree in the future on additional services under the manufacturing agreement. The term of the manufacturing agreement will end in November 2027 and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated early pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party or the other party ceases for any reason to carry on its business or makes assignment for the benefit of its creditors, or is the subject of any proposal for a voluntary arrangement. Additionally, either party may terminate the manufacturing agreement on 12 months' prior notice to the other party at any time.

We also have contracted with F.I.S. Fabbrica Italiana Sintetici S.p.A. (FIS) to manufacture the API for trofinetide products. Under the manufacturing agreement, we have the right to purchase from FIS the API for the trofinetide products at a specified price per volume. The parties may also agree in the future on additional services under the manufacturing agreement with respect to commercial testing and other manufacturing services. The term of the manufacturing agreement will end in December 2024 and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the manufacturing agreement is terminated earlier pursuant to its terms. Either party may terminate the manufacturing agreement prior to expiration upon an uncured material breach by the other party, upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party or the other party ceases for any reason to carry on its business or makes assignment for the benefit of its creditors, or is the subject of any proposal for a voluntary arrangement. Additionally, either party may terminate the manufacturing agreement on 30 days' prior notice to the other party at any time no services are being rendered under the manufacturing agreement. We also may terminate any services under the manufacturing agreement for any reason on 90 days' prior notice to FIS, subject to the requirements of the manufacturing agreement.

Under the manufacturing agreement with Patheon described above, we also have the right to purchase trofinetide products for commercial use. In addition, we have contracted with CoreRx Inc. (CoreRx) to manufacture trofinetide products for commercial use. We and CoreRx may also agree in the future on additional services under the agreement. The term of the agreement will end in March 2028 and will automatically renew for subsequent two-year terms unless either party provides timely notice of its intent not to renew, or unless the agreement is terminated early pursuant to its terms. Either party may terminate the agreement prior to expiration upon an uncured material breach by the other party or upon the commencement of bankruptcy, reorganization, liquidation or receivership proceedings by or against the other party. In addition, we may terminate the agreement prior to expiration upon timely notice to CoreRx in event (i) any regulatory authority takes an enforcement or other regulatory action against CoreRx's facility which affects CoreRx's ability to process trofinetide products, (ii) any regulatory authority takes an action or raises any objection that prevents us from manufacturing, importing, exporting, purchasing or selling trofinetide products, or (iii) we determine to discontinue commercialization of trofinetide products in the U.S. due to safety or efficacy reasons.

We sell DAYBUE to a single wholesale distributor which performs a variety of functions related to the distribution of DAYBUE, including warehousing, customer service, order-taking, shipment and returns processing.

If any other product candidate is approved by the FDA or other regulatory agencies for commercial sale, we will need to contract with a third party to manufacture such products for commercial sale in the U.S. and/or in such other jurisdictions.

Sales and Marketing

We have U.S. sales specialists that are focused on promoting NUPLAZID to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. This sales force is supported by an experienced sales leadership team. Our experienced commercial team is comprised of experienced professionals in marketing, key account management, patient access services, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, health outcomes, medical affairs, quality control, and compliance.

We launched NUPLAZID in May 2016, and our focus is to continue to establish NUPLAZID as the standard of care for patients with PDP. In order to help us achieve this goal, we are continuing to increase awareness of NUPLAZID's benefits in PDP with a prescriber and patient education campaign consisting of key opinion leader speaker programs, attendance at medical meetings, digital outreach, multimedia campaigns, and direct-to-patient programs.

In addition, we have U.S. sales specialists that are focused on promoting DAYBUE to physicians who treat Rett syndrome patients, including those at Centers of Excellence, high volume institutions and in the community setting. The sales force is supported by an experienced sales leadership team. Our experienced commercial team is comprised of rare disease field-based specialists, patient access services, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, health outcomes, medical affairs, quality control, and compliance.

We launched DAYBUE in April 2023, and our focus is to continue to establish DAYBUE as the standard of care for patients with Rett syndrome. In order to help us achieve this goal, we are continuing to increase awareness of DAYBUE's benefits in Rett syndrome with a prescriber and patient education campaign consisting of key opinion leader speaker programs, attendance at medical meetings, digital outreach, and multimedia campaigns.

We also have support services including the Acadia Connect hub for physicians, patients and their families that provide broad resources to help with access, reimbursement and the continual clinical support to help patients start and stay on therapy. For healthcare providers and practices, Acadia Connect provides access and coverage support services, information on appropriate financial assistance options for eligible patients, and coordination of medication delivery to patients through our specialty pharmacy.

In selected markets outside of the United States in which DAYBUE may be approved, if any, we may choose to commercialize DAYBUE independently or by establishing one or more strategic alliances.

Long-Lived Assets

Our tangible long-lived assets are comprised of intangible assets and property and equipment. Our property and equipment totaled $4.6 million, $6.0 million, and $8.0 million as of December 31, 2023, 2022 and 2021, respectively. All of our tangible long-lived assets are located in the United States. Our intangible assets, comprised of right-of-use assets and other intangibles acquired, totaled $117.3 million, $55.6 million and $58.3 million as of December 31, 2023, 2022 and 2021, respectively.

Employees and Human Capital

Employees. At December 31, 2023, we had a total of 598 employees, 597 of whom were full-time. We employ physicians, scientists and professionals in research and development, clinical, regulatory, manufacturing, marketing, sales, finance, legal and other functions that are important to our business. We also will continue to use temporary workers in certain instances in order to maximize our employment flexibility in light of our business needs. Additionally, when we think it is in the best interest of our business, we will rely upon external advisers and consultants rather than our employees.

Employee Engagement, Benefits & Development. We believe that our future success is dependent upon our ability to recruit, hire and retain exceptional employees. We provide our employees with competitive cash compensation, opportunities to own equity, and an employee benefit program that promotes well-being, including wellness programs, healthcare, retirement planning and paid time off. We also provide employees with opportunities to continue their education and growth, including leadership development and tuition reimbursement. In order to receive feedback from our employees and evaluate our level of employee engagement, we regularly conduct employee surveys.

Diversity, Equity & Inclusion. We value diversity, equity, and inclusion across our workforce, in our communities, and in the work that we do. We will continue to focus on diversity, equity, and inclusion initiatives that support a culture that is centered on belonging while aligning with our shared corporate mission and values.

Item 1A. ***Risk Factors.***

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Business

Our prospects are highly dependent on the continued successful commercialization of NUPLAZID and DAYBUE. To the extent we cannot maintain or increase sales of NUPLAZID or DAYBUE, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

In March 2023, we announced FDA approval of DAYBUE for the treatment of Rett syndrome in adult and pediatric patients two years of age and older, and DAYBUE became available for prescription in the United States in April 2023. NUPLAZID has been approved in the U.S. since April 2016 for the treatment of hallucinations and delusions associated with PDP.

The continued successful commercialization of NUPLAZID and DAYBUE is subject to many risks, and there is no guarantee that we will be able to maintain or increase sales of NUPLAZID and DAYBUE. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial teams and have hired our U.S. sales forces for each of NUPLAZID and DAYBUE, we may need to further expand and develop sales forces as we pursue NUPLAZID and DAYBUE in other indications and pursue DAYBUE in other jurisdictions. Even if we are successful in developing our commercial teams, there are many factors that could negatively impact the sales of our products or cause the continued commercialization of our products to be unsuccessful, including a number of factors that are outside our control. The continued commercial success of NUPLAZID and DAYBUE currently depends on the extent to which patients, caregivers and physicians recognize and diagnose the indications for which NUPLAZID and DAYBUE are approved and accept and adopt NUPLAZID and DAYBUE as a treatment for such indications, and we do not know whether our or others' estimates in this regard will be accurate. In addition, we have changed the price of NUPLAZID in the past, and in the future we may change the price of NUPLAZID and DAYBUE from time to time. Physicians may not prescribe NUPLAZID or DAYBUE

and patients may be unwilling to use NUPLAZID or DAYBUE, due to a number of factors, including if coverage is not provided, coverage changes in the future, reimbursement is inadequate to cover a significant portion of the cost or due to the prevalence and severity of any adverse side effects. Further, with respect to DAYBUE, especially because Rett syndrome is a rare disease with a small physician, patient, caregiver and medical community, the experiences of those adopting DAYBUE earlier could have significant impact on future adoption of DAYBUE by other physicians, patients and caregivers, either favorably or unfavorably, based on clinical benefits and side effects experienced. While we have established our commercial team and have hired our U.S. sales force for DAYBUE, we may need to further expand and develop the team in order to successfully commercialize DAYBUE. Thus, significant uncertainty remains regarding the commercial potential of DAYBUE.

Additionally, any negative publicity related to NUPLAZID or DAYBUE, or negative development in our post-marketing commitments, in clinical development in additional indications, or in regulatory processes in other jurisdictions, may adversely impact our commercial results and potential of NUPLAZID or DAYBUE. Thus, significant uncertainty remains regarding the commercial potential of NUPLAZID and DAYBUE.

If the commercialization of our products and future sales are less successful than expected or perceived as disappointing, our stock price could decline significantly and the long-term success of our products and our company could be harmed.

The terms of the FDA's approval of NUPLAZID for the treatment of hallucinations and delusions associated with PDP may limit its commercial potential.

The scope and terms of the FDA's approval of NUPLAZID may limit our ability to commercialize NUPLAZID and, therefore, our ability to generate substantial sales revenues. The FDA has approved NUPLAZID only for the treatment of hallucinations and delusions associated with PDP, with or without dementia. The label for NUPLAZID also contains a "boxed" warning that elderly patients with dementia-related psychosis (DRP) treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia who experience psychosis unless their hallucinations and delusions are related to Parkinson's Disease. The "boxed " warning may discourage physicians from prescribing NUPLAZID to patients diagnosed with PDP, including those with dementia.

In connection with the FDA approval of NUPLAZID, we agreed to four post-marketing commitments (PMCs). Three of the four commitments have been fulfilled within the agreed upon timelines. The fourth commitment, a randomized, placebo-controlled eight-week study or studies in predominantly frail and elderly patients that would add to the NUPLAZID safety database by exposing an aggregate of at least 500 patients to NUPLAZID, has been completed and we are awaiting FDA's acknowledgement and acceptance. In connection with the FDA approval of DAYBUE, we agreed to the following PMCs: a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies and nonclinical in vitro drug interaction studies. The results of any post-marketing study may cause the FDA to update the label and/or cause the FDA to request additional studies or require risk mitigation plans.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for NUPLAZID and DAYBUE will also continue to be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, good clinical practices, international council for harmonization guidelines and good laboratory practices, each of which are regulations and guidelines enforced by the FDA for all of our nonclinical and clinical development and for any clinical trials that we conduct post-approval.

Discovery of any issues post-approval, including any safety concerns, such as unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, tested, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on NUPLAZID, DAYBUE or on us, including:

- withdrawal of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;

- suspension of any ongoing clinical studies;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or
- seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to discontinue the commercialization of NUPLAZID, limit our sales and marketing efforts, conduct further post-approval studies, and/or discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

As we continue to commercialize NUPLAZID and DAYBUE, each product is becoming available to a larger number of patients, and we do not know whether the results of NUPLAZID and DAYBUE use in such larger number of patients will be consistent with the results from our clinical studies.

As we continue to commercialize NUPLAZID and DAYBUE, each product is becoming available to a larger number of patients. We do not know whether the results, when a larger number of patients are exposed to NUPLAZID and DAYBUE, including results related to safety and efficacy, will be consistent with the results from the clinical studies of NUPLAZID and DAYBUE that served as the basis for their approval. New data relating to NUPLAZID and DAYBUE, including from adverse event reports and applicable post-marketing studies in the U.S., and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of NUPLAZID or DAYBUE from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing NUPLAZID or DAYBUE marketing applications for indications other than in PDP or Rett syndrome, respectively, and/or in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We rely on a limited internal commercial team and a limited network of third-party distributors and pharmacies to market and sell NUPLAZID and DAYBUE. If this approach ceases to be effective, our commercialization of NUPLAZID and DAYBUE may be adversely affected, and NUPLAZID and DAYBUE may not be profitable.

We employ our own internal specialty sales forces to commercialize NUPLAZID and DAYBUE as part of our commercialization strategy in the U.S. If we receive marketing approval for pimavanserin or trofinetide in any other indication, we may need to increase our U.S. sales forces significantly, and also potentially expand our commercial, medical affairs and general and administrative support functions to support commercialization for that indication. In addition, in July 2023, we entered into an expanded license agreement with Neuren under which we have the exclusive worldwide rights to develop and commercialize trofinetide for Rett syndrome. If we obtain marketing approval outside the U.S. using those worldwide rights, we will need to establish one or more sales forces in the additional countries and expand operations to support any new market. Further, we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain such personnel. These efforts will be expensive and time consuming, and we cannot be certain that we will be able to successfully expand, refine and further develop our sales forces and related functional teams.

Additionally, our strategy in the U.S. includes distributing NUPLAZID and DAYBUE solely through a limited network of third-party specialty distributors and specialty pharmacies. While we have entered into agreements with each of these distributors and pharmacies to distribute NUPLAZID and DAYBUE in the U.S., they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors or pharmacies, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. In the event we are unable to maintain, or expand, if needed, our commercial teams, including our U.S. sales forces or any future sales forces in jurisdictions outside the U.S., or maintain and, if needed, expand, our network of third-party specialty distributors and specialty pharmacies, our ability to continue commercializing NUPLAZID and DAYBUE would be limited, and NUPLAZID and DAYBUE may not be profitable.

If we do not obtain regulatory approval of pimavanserin for other indications in addition to treatment of hallucinations and delusions associated with PDP in the U.S., we will not be able to market pimavanserin for other indications in the U.S., which will limit our commercial revenues. Similarly, if we do not obtain regulatory approval of trofinetide outside the U.S. or for indications in addition to Rett syndrome, we will not be able to market trofinetide outside the U.S. or for other indications in the U.S., which will limit our commercial revenues.

While pimavanserin has been approved in the U.S. by the FDA for the treatment of hallucinations and delusions associated with PDP, it has not been approved by the FDA for any other indications. Similarly trofinetide has been approved in the U.S. by the FDA for the treatment of Rett syndrome in adult and pediatric patients two years of age and older, it has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market pimavanserin or trofinetide for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of NUPLAZID by the FDA for the treatment of hallucinations and delusions associated with PDP does not ensure that NUPLAZID will be approved by the FDA for any other indication. Similarly, approval of DAYBUE by the FDA for the treatment of Rett syndrome does not ensure that DAYBUE will be approved by the FDA for any other indication. For example, following the successful completion of our Phase 3 HARMONY study, we submitted an sNDA to the FDA for the treatment of DRP on June 3, 2020. On April 2, 2021, we received a complete response letter (CRL) from the FDA, indicating that the FDA had completed its review of the application and determined that it could not be approved in its present form. In February 2022, we resubmitted the aforementioned sNDA refining the proposed indication to treatment of hallucinations and delusions associated with ADP. On August 4, 2022 we received a CRL from the FDA regarding our ADP sNDA resubmission. At this time, we are not planning to conduct any additional studies for pimavanserin in ADP.

We initiated the Phase 3 ADVANCE-2 study of pimavanserin for the treatment of the negative symptoms of schizophrenia in August 2020. We completed the enrollment with top-line results expected in the first quarter of 2024. There is no guarantee that our ongoing study will be successful, or that the FDA will approve pimavanserin for that indication.

The research, testing, manufacturing, packaging, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit NUPLAZID or DAYBUE for approval for other indications or in other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our existing approvals for NUPLAZID or DAYBUE. If we do not receive marketing approval for NUPLAZID or DAYBUE for any other indication, we will never be able to commercialize NUPLAZID or DAYBUE for any other indication in the U.S. If we do not receive marketing approval for DAYBUE in other jurisdictions, we will never be able to commercialize DAYBUE in other jurisdictions. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to NUPLAZID or DAYBUE do not meet our or others' expectations, the market price of our common stock could decline significantly and the long-term success of the product and our company could be harmed.

If we are unable to effectively train and equip our sales forces, our ability to successfully commercialize NUPLAZID and DAYBUE will be harmed.

NUPLAZID is the first drug approved by the FDA for the treatment of hallucinations and delusions associated with PDP, and DAYBUE is the first drug approved by the FDA for the treatment of Rett syndrome. As a result, we are and will continue to be required to expend significant time and resources to train our sales forces to be credible, persuasive, and compliant with applicable laws in marketing NUPLAZID and DAYBUE to physicians and healthcare providers, and for NUPLAZID, long-term care facilities and other healthcare providers, as appropriate. In addition, we must ensure that consistent and appropriate messages about NUPLAZID and DAYBUE are being delivered to our potential customers by our sales forces. If we are unable to effectively train our sales forces and equip them with current, effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of NUPLAZID and DAYBUE, and their proper administration, our efforts to successfully commercialize NUPLAZID and DAYBUE, could be put in jeopardy, which would negatively impact our ability to generate product revenues.

NUPLAZID and DAYBUE may not gain maximal acceptance among physicians, patients, caregivers and the medical community, thereby limiting our potential to generate revenues.

The degree of market acceptance by physicians, healthcare professionals, patients, caregivers and third-party payors of NUPLAZID, DAYBUE and any other product for which we obtain regulatory approval, and our profitability and growth, will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- the relative convenience and ease of administration;
- the prevalence and severity of any actual or expected adverse side effects;
- the availability of alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, and our ability to increase awareness of our approved products through marketing efforts;
- pricing and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or our collaborators' sales and marketing strategy;
- publicity concerning us, our products or competing products and treatments; and
- our ability to obtain and maintain sufficient third-party insurance coverage or adequate reimbursement levels.

If a product does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide patient benefit, that product will not achieve market acceptance and will not generate sufficient revenues to achieve or maintain profitability.

With respect to NUPLAZID and DAYBUE specifically, successful commercialization will depend on whether and to what extent physicians, patients, caregivers, long-term care facilities and pharmacies, over whom we have no control, determine to utilize NUPLAZID and DAYBUE. NUPLAZID is available to treat hallucinations and delusions associated with PDP, and DAYBUE is available to treat Rett syndrome, both indications for which no other FDA-approved pharmaceutical treatments currently exist. Because of this, it is particularly difficult to estimate NUPLAZID's and DAYBUE's market potential and how physicians, patients, caregivers, long-term care facilities and payors will respond to changes in the price of NUPLAZID and DAYBUE. Industry sources and analysts have a divergence of estimates for the near- and long-term market potential of NUPLAZID and DAYBUE, and a variety of assumptions directly impact the estimates for NUPLAZID's and DAYBUE's market potential, including assumptions regarding the prevalence of PDP and Rett syndrome, the rate of diagnosis of PDP and Rett syndrome, the prevalence and rate of hallucinations and delusions in patients diagnosed with PDP with respect to NUPLAZID, the rate of physician adoption of NUPLAZID and DAYBUE, the potential impact of payor restrictions regarding NUPLAZID and DAYBUE, and patient adherence and compliance rates. Small differences in these assumptions can lead to widely divergent estimates of the market potential of NUPLAZID and DAYBUE.

For example, with respect to NUPLAZID, certain research suggests that patients with Parkinson's disease may be hesitant to report symptoms of PDP to their treating physicians for a variety of reasons, including apprehension about societal stigmas relating to mental illness. Research also suggests that physicians who typically treat patients with Parkinson's disease may not ask about or identify symptoms of PDP. For these reasons, even if PDP occurs in high rates among patients with Parkinson's disease, it may be underdiagnosed. Even if PDP is diagnosed, physicians may not prescribe treatment for hallucinations and delusions associated with PDP, and if they do prescribe treatment, they may prescribe drugs other than NUPLAZID, even though they are not approved in PDP. Further, NUPLAZID may take several weeks to show efficacy. Even if NUPLAZID is prescribed for the treatment of hallucinations and delusions associated with PDP, patients may stop taking NUPLAZID because they may not see results in the timeframe they desire.

Similarly, even if DAYBUE is prescribed for the treatment of Rett syndrome, issues may arise with respect to patient acceptance, adherence and compliance rates for a variety of reasons, including due to the expected or actual side effects a patient might incur. If patients do not adhere to the recommended dosing of DAYBUE, patients and physicians may believe that DAYBUE is less effective, and as a result they may stop taking it and prescribing it.

The label for NUPLAZID also contains a "boxed" warning that elderly patients with DRP treated with antipsychotic drugs are at an increased risk of death, and that NUPLAZID is not approved for the treatment of patients with dementia who experience psychosis unless their hallucinations and delusions are related to Parkinson's Disease. There has also been attention to publicly reported deaths of patients that were prescribed NUPLAZID, and the FDA conducted an evaluation of available information about NUPLAZID. In the past, the FDA has observed potentially concerning prescribing patterns with NUPLAZID, such as the concomitant use of other antipsychotic drugs or drugs that can cause QT prolongation, a potential cause of heart rhythm disorder. The FDA reminded healthcare providers to be aware of the risks described in the NUPLAZID prescribing information and that none of the other antipsychotic medications are approved for the treatment of PDP. Regardless, perceptions that NUPLAZID is unsafe, even if unfounded, may discourage physicians from prescribing or patients from taking NUPLAZID.

The commercial success of NUPLAZID and DAYBUE depends on acceptance by patients, caregivers and physicians, and there are a number of factors that could skew our or others' estimates about prescribing behaviors and market adoption. If we fail to gain the acceptance of patients, caregivers and physicians, or if our estimates are inaccurate, these events could negatively impact our business, results of operations, financial condition and prospects.

Our ability to generate product revenues will be diminished if coverage for our products from payors is decreased or if patients have unacceptably high co-pay amounts.

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others, to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payors is critical to product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when lower cost therapeutic alternatives are already available or subsequently become available. Even with coverage for NUPLAZID, DAYBUE or other products we may market, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use NUPLAZID and DAYBUE if coverage is not provided or reimbursement is inadequate to cover a significant portion of its cost.

In addition, the market for NUPLAZID and DAYBUE depends significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly alternative is available, even if not approved for the indication for which NUPLAZID and DAYBUE are approved.

Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling NUPLAZID or DAYBUE at less than an optimized price would impact our revenues and could impact our overall success as a company. We have changed, and may continue to change, the price of NUPLAZID or DAYBUE from time to time, however, we do not know if the price we have selected, or may select in the future, for NUPLAZID or DAYBUE is or will be the optimized price. Additionally, we do not know whether and to what extent third-party payors will react to any possible future changes in the price of NUPLAZID or DAYBUE. In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Further, one payor's determination to provide coverage and reimbursement for a product does not ensure that other payors will also provide coverage and reimbursement for the product. Therefore, coverage and reimbursement for NUPLAZID and DAYBUE may differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of NUPLAZID and DAYBUE to each payor separately, with no assurance that coverage will be obtained. Coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain coverage of, and adequate payment levels for, NUPLAZID, DAYBUE or any other products we may market to third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize NUPLAZID, DAYBUE or any other products we may market, and thereby adversely impact our profitability, results of operations, financial condition, and future success.

We are solely responsible for the development and commercialization of pimavanserin and trofinetide.

We have full responsibility for the pimavanserin and trofinetide programs throughout the world. We expect our research and development costs for continued development of pimavanserin and trofinetide to be substantial. We are currently undertaking ongoing development work for pimavanserin and trofinetide, including clinical trials of pimavanserin for indications other than in PDP. In the event of approval for additional indications or in jurisdictions outside the U.S., we would need to add significant resources, in order to further commercialize pimavanserin and trofinetide, and to conduct the necessary sales and marketing activities, and to conduct further development activities.

With respect to NUPLAZID, our current strategy is to continue to commercialize NUPLAZID for the treatment of hallucinations and delusions associated with PDP in the U.S. using our specialty sales force that are focused on promoting NUPLAZID to physicians who treat PDP patients, including neurologists, psychiatrists and long-term care physicians. With respect to DAYBUE, our current strategy is to continue to commercialize DAYBUE for the treatment of Rett syndrome in the U.S. and other foreign jurisdictions in which DAYBUE may be approved, if any, using our specialty sales force focused on promoting DAYBUE to physicians who treat Rett syndrome patients, including those at Centers of Excellence, high volume institutions and in the community setting. In selected markets outside of the U.S. in which DAYBUE may be approved, if any, we may choose to commercialize DAYBUE independently or by establishing one or more strategic alliances. Without future additional resources or collaboration partners in selected markets outside of the U.S. for DAYBUE, we might not be able to realize the full value of DAYBUE.

Furthermore, even though NUPLAZID is approved for the treatment of hallucinations and delusions associated with PDP, a failure in a subsequent pimavanserin study for another indication, including our ongoing study in schizophrenia, or any additional studies, or a failure in our post-marketing studies could harm our ability to successfully market NUPLAZID for the treatment of hallucinations and delusions associated with PDP or could lead to it being withdrawn from the market. Similarly, even though DAYBUE is approved for the treatment of Rett syndrome in adult and pediatric patients two years of age and older, a failure in a subsequent trofinetide study for another indication or any additional studies, or a failure in our post-marketing studies could harm our ability to successfully market DAYBUE for the treatment of Rett syndrome in adult and pediatric patients two years of age and older or could lead to it being withdrawn from the market.

If we are unable to develop pimavanserin for other indications, or trofinetide for other indications or in other jurisdictions, we may not be able to maximize the potential of the compounds and that could have a material adverse effect on our future revenues and our success as a company.

Drug development is a long, expensive and unpredictable process with a high risk of failure.

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Preliminary, initial, top-line or interim results of clinical trials do not necessarily predict final results and such results may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final results. In addition, success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials.

Our drug development programs are at various stages of development and the historical rate of failures for product candidates is extremely high. For example, we had an unsuccessful Phase 3 trial with NUPLAZID in 2009 and we have had several clinical studies evaluating pimavanserin in other indications that did not achieve statistical significance on certain endpoints. In addition, following the successful completion of our Phase 3 HARMONY study, we submitted a Supplemental New Drug Application(sNDA) to the FDA for pimavanserin for the treatment of DRP on June 3, 2020. On April 2, 2021, we received a CRL indicating that the FDA had completed its review of the application and determined that it could not be approved in its present form. In February 2022, we resubmitted the aforementioned DRP sNDA with updated labeling for the treatment of hallucinations and delusions associated with ADP to the FDA based on previously submitted studies and new analyses. On August 4, 2022, we received a CRL from the FDA regarding our submission of the sNDA. At this time, we are not planning to conduct any additional studies for pimavanserin for the treatment of hallucinations and delusions associated with ADP.

An unfavorable outcome in any of our ongoing or future development efforts or in the post-marketing studies for NUPLAZID or DAYBUE could be a major set-back for the programs and for us, generally. In particular, an unfavorable outcome in our NUPLAZID program or in the post-marketing studies for NUPLAZID or DAYBUE may require us to delay, devote additional substantial resources to, reduce the scope of, or eliminate this program and could have a material adverse effect on us and the value of our common stock.

We are currently conducting several studies, including our Phase 2 study evaluating the efficacy and safety of an internally-developed compound known as ACP-204, which is akin to pimavanserin, as a potential treatment for the treatment of hallucinations and delusions associated with ADP and our Phase 3 COMPASS study evaluating the efficacy and safety of ACP-101 (intranasal carbetocin) for the treatment of hyperphagia in PWS and may conduct additional studies in the future.

In connection with clinical trials, we face risks that:

- a product candidate may not prove to be efficacious or safe;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not be consistent with positive results of earlier trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies.

If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay our ability to generate product revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining clearance from the FDA to commence clinical trials pursuant to an Investigational New Drug application;
- obtaining approval to conduct clinical trials in countries outside the United States pursuant to evolving regional and local regulations (e.g., EU Clinical Trials Regulation (EU No. 536/2014));
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and
- patient recruitment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including:

- competition for internal and external resources, including clinical sites and study patients, that we may choose to allocate to other programs;
- ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results;
- imposition of clinical holds by regulatory authorities or institutional review boards;
- failure to conduct clinical trials in accordance with regulatory requirements;
- inability to monitor patients adequately during or after treatment;

- difficulty monitoring multiple study sites;
- patient enrollment, which is a function of many factors, most of which is outside our control, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial;
- lower than anticipated screening or retention rates of patients in clinical trials;
- serious adverse events or side effects experienced by participants; and
- insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

In addition, enrollment and retention of patients in, or the ability to receive results from, clinical trials could be disrupted by geopolitical or macroeconomic developments. For example, as a result of the ongoing conflict between Ukraine and Russia, we experienced temporary delays in accessing historical records of certain clinical trial sites located in Russia. It is possible that future enrollment in these studies, or enrollment in future studies, could be impacted due to the same or similar geopolitical or macroeconomic developments. If patients withdraw from our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our trial results are otherwise disrupted or disputed due to such developments, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential future product candidate. If we experience delays, suspensions or terminations in a clinical trial, clinical trial materials or investigational products, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

If we are unable to attract, retain, and motivate key management, research and development, and sales and marketing personnel, our drug development programs, our research and discovery efforts, and our commercialization plans may be delayed and we may be unable to successfully commercialize our products, or develop our product candidates.

Our success depends on our ability to attract, retain, and motivate highly qualified management, scientific, and commercial personnel. In particular, our development programs depend on our ability to attract and retain highly skilled development personnel, especially in the fields of CNS disorders, including neuropsychiatric and related disorders. We are currently hiring, and in the future we expect to need to continue to hire, additional personnel as we expand our research and development efforts for pimavanserin and trofinetide, and commercial activities for NUPLAZID and DAYBUE. We face competition for experienced management, scientists, clinical operations personnel, commercial and other personnel from numerous companies and academic and other research institutions across the U.S. and other jurisdictions in which DAYBUE may be commercialized, if approved. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize products and product candidates, if approved, will be limited. If we are unable to attract and retain the necessary personnel, it will significantly impede our commercialization efforts for NUPLAZID and DAYBUE, and the achievement of our research and development objectives.

All of our employees are “at will” employees, which means that any employee may quit at any time and we may terminate any employee at any time. We do not carry “key person” insurance covering members of senior management.

If we receive approval of NUPLAZID or DAYBUE in additional indications or in jurisdictions outside the U.S., we may need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.

As of December 31, 2023, we employed 598 employees. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, and integrate additional employees and retain existing employees, and may take time away from running other aspects of our business, including development and commercialization of our products and product candidates, if approved.

Our future financial performance and our ability to commercialize NUPLAZID, DAYBUE and any product candidates that receive regulatory approval and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, we will need to support the training and ongoing activities of our sales forces. To that end, we must be able to:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- develop our marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our business, results of operations, financial condition and prospects.

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects would be limited. Even if we obtain rights to other product candidates or products, we will incur a variety of costs and may never realize the anticipated benefits.

A key element of our strategy is to develop, acquire or in-license businesses, technologies, product candidates or products that we believe are a strategic fit with our business. The success of this strategy depends in large part on the combination of our regulatory, development and commercial capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates for the treatment of neurological disorders, or for therapeutic indications that complement or augment our current products and product candidates, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise, and we may not be successful in identifying acquisition targets, completing proposed acquisitions and integrating any acquired businesses, technologies, services or products into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects will be limited. In particular, if we are unable to add additional commercial products to our portfolio, we may not be able to successfully leverage our commercial organization that we have assembled for the marketing and sale of NUPLAZID and DAYBUE.

The process of integrating any acquired business, technology, service, or product may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. As a result, we will incur a variety of costs in connection with an acquisition and may never realize its anticipated benefits. Moreover, any product candidate we identify, select and acquire or license may require additional, time-consuming development or regulatory efforts prior to commercial sale, including preclinical studies, if applicable, and extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risk of failure that is inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective or desired than other commercially available alternatives.

In addition, if we fail to successfully commercialize and further develop NUPLAZID, DAYBUE or our product candidates, if approved, there is a greater likelihood that we will fail to successfully develop a pipeline of other product candidates, and our business and prospects would therefore be harmed.

We have a history of net losses and we may not be able to predict the extent of future losses.

We have experienced significant net losses since our inception. As of December 31, 2023, we had an accumulated deficit of approximately $2.4 billion. We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. Thus, our future operating results, profitability and other financial metrics may fluctuate from period to period, and we will need to generate significant revenues to achieve and maintain profitability and/or positive cash flow on a sustained basis.

We expect that our revenues over the next few years will be entirely dependent on our ability to generate product sales. Substantially all of our revenues since May 2016 were from net product sales of NUPLAZID and DAYBUE. To the extent that we cannot generate significant revenues from the sale of NUPLAZID and DAYBUE to cover our expenses, including the significant expenses associated with commercializing NUPLAZID and DAYBUE and continuing to develop pimavanserin and trofinetide in additional indications and jurisdictions outside the U.S., we may not achieve profitability and/or may have to reduce our commercialization and/or research and development activities to become profitable, which would harm our future growth prospects. Additionally, to obtain revenues from our product candidates, if approved, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, manufacturing and marketing compounds with significant market potential. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

If we fail to generate capital, or otherwise obtain the capital necessary to fund our operations, we will be unable to successfully continue the development and commercialization of NUPLAZID and DAYBUE or successfully develop and commercialize our product candidates, if approved.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents, and investment securities totaled $438.9 million at December 31, 2023. While we believe that our existing cash resources will be sufficient to fund our cash requirements through at least the next twelve months, we may require additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin and trofinetide, and ongoing and planned commercial activities for NUPLAZID and DAYBUE;
- the costs of our development activities for our early-stage pipeline programs and any our product candidates;
- the costs of commercializing NUPLAZID and DAYBUE, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates, if approved;
- the amount of U.S. product sales from NUPLAZID and DAYBUE;
- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S. and in additional indications other than Rett syndrome, for NUPLAZID in additional indications other than in PDP, and for our product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID and DAYBUE for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID in additional indications other than in PDP, or from DAYBUE in jurisdictions other than the U.S. or in additional indications other than Rett syndrome, our early-stage pipeline programs and any product candidates, if approved;
- the costs of acquiring additional products, product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements and supply for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID and DAYBUE or our product candidates.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic collaborations, public or private sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, as a result of geopolitical and macroeconomic developments, including the ongoing conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel and the surrounding areas, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We expect that our results of operations will fluctuate, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include:

- the success of our commercialization of NUPLAZID in the U.S. for the treatment of hallucinations and delusions associated with PDP and DAYBUE in the U.S. for the treatment of Rett syndrome;
- the impact of geopolitical and macroeconomic developments, general political, health and economic conditions, including military conflicts such as the ongoing Ukraine-Russia conflict and the conflicts in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, pandemics or epidemics, economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets on our business;
- the status and cost of our post-marketing commitments for NUPLAZID or DAYBUE;
- the variation in our gross-to-net adjustments from quarter to quarter, primarily because of the fluctuation in our share of the donut hole for Medicare Part D patients;
- the status and cost of development and commercialization of pimavanserin for indications other than for the treatment of hallucinations and delusions associated with PDP, and the status and cost of development and commercialization of trofinetide for indications other than for the treatment of Rett syndrome;
- the status and cost of development and commercialization of our product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved or products;
- whether we generate revenues or reimbursements by achieving specified research, development or commercialization milestones under any agreements or otherwise receive potential payments under these agreements;
- whether we are required to make payments due to achieving specified milestones under any licensing or similar agreements or otherwise make payments under these agreements;
- the incurrence of preclinical or clinical expenses that could fluctuate significantly from period to period, including reimbursement obligations pursuant to our collaboration agreements;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes regarding these collaborations;
- the timing of our satisfaction of applicable regulatory requirements;
- the rate of expansion of our clinical development, other internal research and development efforts, and pre-commercial and commercial efforts;

- the effect of competing technologies and products and market developments;
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID, DAYBUE or our product candidates; and
- general and industry-specific economic conditions.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

From time to time, we provide guidance relating to our expectations for net sales of NUPLAZID and DAYBUE and certain expense line items based on estimates and the judgment of management. If, for any reason, our actual net sales or expenses differ materially from our guidance, we may have to revise our previously announced financial guidance. If we change, update or fail to meet any element of such guidance, our stock price could decline.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Effective January 1, 2022, the Tax Cuts and Jobs Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, the provision may not actually be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use net operating losses and certain other tax attributes to offset future taxable income or taxes may be limited.

Portions of our net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percent change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Tax authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. In 2015, we licensed worldwide intellectual property rights related to pimavanserin in certain indications to Acadia Pharmaceuticals GmbH, our wholly owned Swiss subsidiary (Acadia GmbH), and in July 2020 we licensed additional related rights to Acadia GmbH. Our goals for the establishment of Acadia GmbH, and the licensing of worldwide intellectual property rights for pimavanserin, include building a platform for long-term operational and financial efficiencies, including tax-related efficiencies. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. In addition, future changes in U.S. and non-U.S. tax laws, including implementation of international tax reform relating to the tax treatment of multinational corporations, if enacted, may reduce or eliminate any potential financial efficiencies that we hoped to achieve by establishing this operational structure. Additionally, taxing authorities, such as the U.S. Internal Revenue Service, may audit and otherwise challenge these types of arrangements, and have done so with other companies in the pharmaceutical industry. If any such challenge or disagreement were to occur or change in tax law were enacted, we could be required to pay additional taxes, interest and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including material shortages and related manufacturing and supply chain challenges, geopolitical developments such as ongoing military the conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel and the surrounding areas (as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and manufacturing and supply chain), and the responses by central banking authorities to control inflation, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The geo-political turmoil resulting from Russia's invasion of Ukraine, including the widespread and significant economic sanctions imposed on Russia, has caused significant disruptions of our clinical trial activities in Russia and Ukraine.

We have engaged CROs to conduct clinical trials worldwide. Certain of our trials have a limited number of clinical sites in Russia and Ukraine where patient recruiting and screening were not complete at the time of Russia's military aggression in Ukraine. The resulting geo-political turmoil has caused significant disruptions, including the suspension of further new enrollment of patients at our clinical trial sites in Ukraine and Russia. Existing patients may have been evacuated or relocated far from clinical sites, making it difficult for participation in our clinical trials. Site personnel and/or CRO personnel may be unavailable or otherwise unable to conduct clinical trial activities. Furthermore, the widespread sanctions imposed on Russia have affected clinical sites in Russia managed by our CRO. In addition, clinical sites, their personnel and patients may not be able to continue in the trials and therefore we have terminated the trials in Russia. While we have a limited number of clinical sites in Ukraine, these significant disruptions and the suspension/termination of clinical trial activities could potentially delay the completion of enrollment in our clinical trials and complicate the analysis of data, as affected clinical sites might not be able to have their data be validated or protocol assessments may be missed. Even if data collection can be completed, the FDA may be unable to audit clinical trial sites in Ukraine or Russia. Interruptions of clinical trials may further delay our clinical development and the potential authorization or approval of our product candidates, which could materially increase our costs and adversely affect our ability to commence product sales and generate revenues.

Earthquake or fire damage to our facilities could delay our research and development efforts and adversely affect our business.

Our headquarters and research and development facilities in San Diego are located in a seismic zone, and we face the possibility of one or more earthquakes, which could be disruptive to our operations and result in delays in our research and development efforts. In addition, while our facilities have not been adversely impacted by local wildfires, there is the possibility of future fires in the area. In the event of an earthquake or fire, if our facilities or the equipment in our facilities is significantly damaged or destroyed for any reason, we may not be able to rebuild or relocate our facilities or replace any damaged equipment in a timely manner and our business, financial condition, and results of operations could be materially and adversely affected. We do not have insurance for damages resulting from earthquakes. While we do have fire insurance for our property and equipment located in San Diego, any damage sustained in a fire could cause a delay in our research and development efforts and our results of operations could be materially and adversely affected.

Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do, or interrupt our, business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the generation, storage, use and disposal of hazardous materials, including the components of our products and product candidates and other hazardous compounds and wastes. We and our manufacturers and suppliers are subject to environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, generation, storage, handling, transportation, discharge and disposal of these hazardous materials and wastes and worker health and safety. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination or injury, which could result in an interruption of our commercialization efforts, research and development efforts and business operations, damages and significant cleanup costs and liabilities under applicable environmental, health and safety laws and regulations. We also cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials and wastes generally comply with the standards prescribed by these laws and regulations. We may be held liable for any resulting damages costs or liabilities, which could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental, health and safety laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Failure to comply with these environmental, health and safety laws and regulations may result in substantial fines, penalties or other sanctions. We do not currently carry hazardous waste insurance coverage.

Risks Related to Our Relationships with Third Parties

We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.

We depend on collaborations with third parties to develop certain of our product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. For example, in July 2023, we entered into an expanded license agreement with Neuren under which we have the exclusive worldwide rights to develop and commercialize trofinetide for Rett syndrome and other indications and NNZ-2591 for Rett syndrome and Fragile X syndrome. In January 2022, we entered into a license and collaboration agreement with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. In addition, we may choose to rely on collaborations in the future for certain portions of our pimavanserin and trofinetide programs or other product candidates, or for the commercialization of DAYBUE in selected markets outside of the U.S.

Our collaborators may fail to develop or effectively commercialize products using our product candidates, if approved, or technologies because they:

- do not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as limited cash or human resources or a change in strategic focus;
- may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates, if approved;
- may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement;
- decide to pursue a competitive product developed outside of the collaboration; or
- cannot obtain the necessary regulatory approvals.

Collaborations are complex and time-consuming to negotiate and document. We also will face competition in our search for new collaborators, if we seek a new partner for our pimavanserin or trofinetide programs or other programs. Given the current economic and industry environment, it is possible that competition for new collaborators may increase. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to find new collaborations, we may not be able to continue advancing our programs alone.

Our collaborations may be subject to conflicts or disputes, which could have a material adverse effect on our business, results of operations and financial condition.

Conflicts may arise in our collaborations due to one or more of the following:

- disputes or breaches with respect to payments that we believe are due under the applicable agreements, particularly in the current environment when companies, including large established ones, may be seeking to reduce external payments;
- disputes on strategy as to what development or commercialization activities should be pursued under the applicable agreements;
- disputes as to the responsibility for conducting development and commercialization activities pursuant to the applicable collaboration, including the payment of costs related thereto;
- disagreements with respect to ownership of intellectual property rights;

- unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities, or to permit public disclosure of these activities;
- delay or reduction of a collaborator's development or commercialization efforts with respect to our product candidates, if approved; or
- termination or non-renewal of the collaboration.

Conflicts arising with our collaborators could impair the progress of our product candidates, harm our reputation, result in a loss of revenues, reduce our cash position, and cause a decline in our stock price.

In addition, in our past collaborations, from time to time, we have agreed not to conduct independently, or with any third party, any research that is directly competitive with the research conducted under the applicable program. Any collaborations we establish in the future may have the effect of limiting the areas of research that we may pursue, either alone or with others. Conversely, the terms of any collaboration we may establish in the future might not restrict our collaborators from developing, either alone or with others, products or product candidates in related fields that are competitive with the products or product candidates that are the subject of these collaborations. Competing products and product candidates, either developed by our collaborators or to which our collaborators have rights, may result in the allocation of resources by our collaborators to competing products and product candidates, and their withdrawal of support for our products and product candidates or may otherwise result in lower demand for our potential products and product candidates.

In addition, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, if approved, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the related product candidates, if approved, which would have a material adverse effect on our business

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates, if approved.

Although we design and manage our current preclinical studies and clinical trials, we currently do not have the ability to conduct clinical trials for our product candidates on our own. We rely on CROs, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates. Some of these third parties may experience shutdowns or other disruptions as a result of adverse geopolitical or macroeconomic developments and therefore may be unable to provide the level of service that we have received in the past.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if:

- these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- these third parties need to be replaced; or
- the quality or accuracy of the data obtained by these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons.

Failure to perform by these third parties may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates, if approved. We currently use several CROs to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays, additional expenditures, or at all, any of which could negatively affect our business, results of operations, financial condition and prospects.

Even if we or our collaborators successfully complete the clinical trials of product candidates, the product candidates may fail for other reasons.

Of the large number of product candidates in development, only a small percentage result in the submission of an NDA to the FDA or comparable regulatory filing to regulatory authorities in other jurisdictions, and even fewer are approved for marketing. We cannot assure you that, even if clinical trials are completed, either we or our collaborators will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Even if we or our collaborators successfully complete the clinical trials of product candidates and apply for such required authorizations, the product candidates, such as pimavanserin and trofinetide, may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory clearances required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by competitors.

We currently depend, and in the future will continue to depend, on third parties to manufacture NUPLAZID, DAYBUE and any product candidates. If these manufacturers fail to provide us or our collaborators with adequate supplies of clinical trial materials and commercial product or fail to comply with the requirements of regulatory authorities, we may be unable to develop or commercialize NUPLAZID, DAYBUE or any product candidates, if approved.

We have no manufacturing facilities and only limited experience as an organization in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, NUPLAZID, DAYBUE and our product candidates.

We have contracted with Patheon Pharmaceuticals Inc. to manufacture NUPLAZID 10 mg tablet and 34 mg capsule drug product and DAYBUE for commercial use in the U.S. We have also contracted with a second contract manufacturing organization to manufacture NUPLAZID 34 mg drug product for commercial use in the U.S. Additionally, we have contracted with Siegfried AG to manufacture API to be used in the manufacture of NUPLAZID drug product for commercial use, Corden and FIS to manufacture API to be used in the manufacture of DAYBUE drug product for commercial use, and Patheon and CoreRx to manufacture DAYBUE for commercial use. However, we have not entered into any agreements with any alternate suppliers for 10 mg NUPLAZID drug product or NUPLAZID API. We may face delays or increased costs in our supply chain that could jeopardize the commercialization of NUPLAZID or DAYBUE. While we currently have sufficient API for both NUPLAZID and DAYBUE and NUPLAZID and DAYBUE finished products on hand to continue our commercial and clinical operations as planned, depending on the effects of geopolitical and macroeconomic developments and whether such developments cause disruptions, we may face such delays or costs in future years. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by geopolitical and macroeconomic developments, such as the ongoing military conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain, our supply chain may be disrupted, limiting our ability to manufacture, test and distribute NUPLAZID or DAYBUE for commercial sales and our product candidates for our clinical trials and research and development operations. For example, it takes approximately two years for our third-party manufacturers to produce DAYBUE API, and a supply chain disruption in DAYBUE API would cause delays or increased costs to us that could jeopardize the commercialization of DAYBUE. Additionally, if NUPLAZID is approved for commercial sale in jurisdictions outside the U.S., we will need to contract with a third party to manufacture such products for commercial sale in the U.S. and/or in such other jurisdictions. We may not be able to enter into such contracts in a timely manner or on acceptable terms, if at all.

Even though we have agreements with third parties for the manufacture of NUPLAZID and DAYBUE, the FDA may not approve the facilities of such manufacturers, the manufacturers may not perform as agreed, or the manufacturers may terminate their agreements with us. If any of the foregoing circumstances occur, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, maintain or obtain, as applicable, regulatory approval for or market NUPLAZID, DAYBUE or any product candidates. While we believe that there will be alternative sources available to manufacture NUPLAZID, DAYBUE and any product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts, which would have a negative effect on our business, results of operations, financial condition and prospects.

The manufacturers of NUPLAZID, DAYBUE and any other product candidates, including Patheon, Siegfried, Corden, FIS and CoreRx, are obliged to operate in accordance with FDA-mandated cGMPs, and we have limited control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel to ensure compliance with cGMPs. In addition, the facilities used by our third-party manufacturers to manufacture NUPLAZID and DAYBUE and any product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to any grant of regulatory approval by the FDA. If any of our third-party manufacturers are unable to successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain approval for the manufacturing facilities. Additionally, a failure by any of our third-party manufacturers to establish and follow cGMPs or to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates, or result in issues maintaining regulatory approval of NUPLAZID, DAYBUE and any product candidate that receives regulatory approval, negatively impact our commercialization of NUPLAZID or DAYBUE, or lead to significant delays in the launch and commercialization of any other products we may have in the future. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

The manufacture of pharmaceutical products requires significant capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any issues relating to the manufacture of NUPLAZID, DAYBUE or any product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to commercialize NUPLAZID or DAYBUE, or provide pimavanserin, trofinetide or any other product candidates to patients in clinical trials, would be jeopardized. Any delay or interruption in our ability to meet commercial demand for NUPLAZID, DAYBUE and any other approved products will result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for these products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of NUPLAZID, DAYBUE or any product candidates, if approved, and could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to continue or fully exploit our collaborations with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of CNS disorders. They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates, if approved.

Risks Related to Our Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining intellectual property rights to our products and product candidates, including NUPLAZID and DAYBUE, and technologies, as well as successfully defending these rights against third-party challenges. Successful challenges to, or misappropriation of, our intellectual property could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. To protect our intellectual property, we rely on a combination of patents, trade secret protection and contracts requiring confidentiality and nondisclosure. If our patents are successfully challenged, we may face generic competition prior to the expiration dates of our U.S. Orange Book listed patents. In addition, potential competitors have in the past and may in the future file an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of NUPLAZID, seeking approval prior to the expiration of our patents. In response, we have filed complaints against these companies alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID. For a more detailed description of these matters, see section captioned "Legal Proceedings" elsewhere in this report. While we intend to defend the validity of such patents vigorously, and will seek to use all appropriate methods to prevent their infringement, such efforts are expensive and time consuming. Any substantial decrease in the revenue and income derived from NUPLAZID or DAYBUE would have an adverse effect on our results of operations.

With regard to patents, although we have filed numerous patent applications worldwide with respect to pimavanserin, not all of our patent applications resulted in an issued patent, or they resulted in an issued patent that is susceptible to challenge by a third party. Our ability to obtain, maintain, and/or defend our patents covering our product candidates and technologies is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may develop similar or alternative technologies or design around our patent claims to produce competitive products that fall outside of the scope of our patents;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
- any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or are easily susceptible to challenges by third parties;
- our proprietary technologies may not be patentable;
- changes to patent laws that limit the exclusivity rights of patent holders or make it easier to render a patent invalid;
- recent decisions by the U.S. Supreme Court limiting patent-eligible subject matter;
- litigation regarding our patents may include challenges to the validity, enforceability, scope and term of one or more patents;
- the passage of The Leahy-Smith America Invents Act (the America Invents Act), introduced new procedures for challenging pending patent applications and issued patents; and
- technology that we may in-license may become important to some aspects of our business; however, we generally would not control the patent prosecution, maintenance or enforcement of any such in-licensed technology.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of CNS disorders and the other fields in which we are developing products. These could materially affect our freedom to operate. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. For applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the U.S. Patent and Trademark Office (U.S. PTO), to determine who was the first to invent the invention at issue. It is difficult to determine how such disputes would be resolved. Applications containing a claim not entitled to priority before March 16, 2013, are not subject to interference proceedings due the change brought by the America Invents Act to a "first-to-file" system. However, a derivation proceeding can be brought by a third-party alleging that the inventor derived the invention from another.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. We generally seek to prevent our collaborators from disclosing scientific discoveries until we have the opportunity to file patent applications on such discoveries, but in some cases, we are limited to relatively short periods to review a proposed publication and file a patent application. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality, nondisclosure, and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. We also have not entered into any noncompete agreements with any of our employees. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of future employment with any of our competitors. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to

establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including post-issuance review proceedings before the U.S. PTO or oppositions and other comparable proceedings in foreign jurisdictions.

Central provisions of the America Invents Act went into effect on September 16, 2012 and on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review (IPR), and post-grant review, that allow third parties to challenge the validity of an issued patent in front of the U.S. PTO Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. IPRs permit any person (except a party who has been litigating the patent for more than a year) to challenge the validity of the patent on the grounds that it was anticipated or made obvious by prior art. Patents covering pharmaceutical products have been subject to attack in IPRs from generic drug companies and from hedge funds. If it is within nine months of the issuance of the challenged patent, a third party can petition the U.S. PTO for post-grant review, which can be based on any invalidity grounds and is not limited to prior art patents or printed publications.

In post-issuance proceedings, U.S. PTO rules and regulations generally tend to favor patent challengers over patent owners. For example, unlike in district court litigation, claims challenged in post-issuance proceedings are given their broadest reasonable meaning, which increases the chance a claim might be invalidated by prior art or lack support in the patent specification. As another example, unlike in district court litigation, there is no presumption of validity for an issued patent, and thus, a challenger's burden to prove invalidity is by a preponderance of the evidence, as opposed to the heightened clear and convincing evidence standard. As a result of these rules and others, statistics released by the U.S. PTO show a high percentage of claims being invalidated in post-issuance proceedings. Moreover, with few exceptions, there is no standing requirement to petition the U.S. PTO for inter partes review or post-grant review. In other words, companies that have not been charged with infringement or that lack commercial interest in the patented subject matter can still petition the U.S. PTO for review of an issued patent. Thus, even where we have issued patents, our rights under those patents may be challenged and ultimately not provide us with sufficient protection against competitive products or processes.

We may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. In particular, there are many patents relating to specific genes, nucleic acids, polypeptides or the uses thereof to identify product candidates. Some of these may encompass genes or polypeptides that we utilize in our drug development activities. If our drug development activities are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented genes or polypeptides for the identification or development of drug compounds. There are also many patents relating to chemical compounds and the uses thereof. If our compounds are found to infringe any such patents, and such patents are held to be valid and enforceable, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from making, using or selling the patented compounds.

In addition to the patent infringement lawsuits that we have recently initiated against the filers of ANDAs pertaining to NUPLAZID, we may need to resort to litigation to enforce other patents issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators could lead to:

- payment of damages, which could potentially be trebled if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, or at all.

As a result, we could be prevented from commercializing current or future products.

Furthermore, because of the substantial amount of pre-trial document and witness discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The strength of patents in the pharmaceutical and biotechnology field can be highly uncertain and involve complex legal and factual questions. The U.S. PTO's interpretation of the Supreme Court's decisions and the standards for patentability it sets forth are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings as mentioned above, and U.S. patents may be subject to reexamination and post-issuance proceedings in the U.S. PTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination, post-issuance and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the America Invents Act (2012) included a number of significant changes to U.S. patent law. These included changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. It is still not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

Risks Related to Government Regulation and Our Industry

Healthcare reform measures may negatively impact our ability to sell NUPLAZID, DAYBUE or our product candidates, if approved, profitably.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell NUPLAZID, DAYBUE and any other potential products, as described in greater detail in the Government Regulation section of this Annual Report.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product, including NUPLAZID and DAYBUE. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. There have been legal and political challenges to certain aspects of the ACA. Furthermore, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA. Through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act and the Consolidated Appropriations Act of 2023, will remain in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to certain providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, Congress is considering additional health reform measures as part of the budget reconciliation process.

An expansion in the government's role in the U.S. healthcare industry may increase existing congressional or governmental agency scrutiny on price increases, such as the ones we have implemented for NUPLAZID, cause general downward pressure on the prices of prescription drug products, lower reimbursements for providers using NUPLAZID, DAYBUE or any other product for which we obtain regulatory approval, reduce product utilization and adversely affect our business and results of operations. There have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these

programs are implemented. These provisions will effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services (CMS) Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear if and how this program will be implemented and whether it will be subject challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize NUPLAZID, DAYBUE or any other products for which we may receive regulatory approval.

We are subject, directly and indirectly, to federal, state and foreign healthcare laws and regulations, including healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are directly, and indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our clinical research, sales, marketing, grants, charitable donations, and education programs and constrain the business or financial arrangements with healthcare providers, physicians, charitable foundations that support Parkinson's disease patients generally, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of our products for which we obtain marketing approval. In addition, we and any current or potential future collaborators, partners or service providers are or may become subject to data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, including laws and regulations that apply to our processing of personal data or the processing of personal data on our behalf. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, and civil monetary penalties laws, which impose criminal and civil penalties on individuals or entities for, among other things, knowingly presenting, or causing to be presented to the U.S. federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act (HITECH) and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, individuals or entities that perform certain services involving the use or disclosure of individually identifiable health information on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act (FDCA), which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act", which was enacted as part of the ACA and its implementing regulations and requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value made to physicians (as defined to include doctors of medicine, dentists, optometrists, podiatrists and chiropractors under such law), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and local laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities and/or the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. For example, contributions to third-party charitable foundations are a current area of significant governmental and congressional scrutiny, and we could face action if a federal or state governmental authority were to conclude that our charitable contributions to foundations that support Parkinson's disease patients generally are not compliant. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and/or oversight, and the curtailment or restructuring of our operations. Moreover, while we do not bill third-party payors directly and our customers make the ultimate decision on how to submit claims, from time-to-time, for NUPLAZID, DAYBUE and any product candidates that may be approved, we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of NUPLAZID, DAYBUE or any product candidates that may be approved, outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We are subject to stringent and evolving U.S. and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, financial information and medical information collected by our patient access management team (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA) requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although some U.S. comprehensive privacy laws exempt some data processed in the context of clinical trials, these laws may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more jurisdictions to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), United Kingdom's GDPR (UK GDPR) (collectively, the GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law (PIPL) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million pounds sterling under the UK GDPR or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

The Swiss Federal Act on Data Protection, or the FADP, also applies to the collection and processing of personal data, including health-related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The FADP has been revised and adopted by the Swiss Parliament. Companies must comply with the revised version of the FADP and its revised ordinances from September 1, 2023, which may result in an increase of costs of compliance, risks of noncompliance and penalties for noncompliance.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data to recipients outside Europe for allegedly violating the GDPR's cross-border data transfer limitations. Additionally, companies that transfer personal data to recipients outside of the EEA and/or UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators individual litigants and activist groups.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely on may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price (AMP), for single source and innovator multiple source drugs, effective January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the HHS Office of Inspector General and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP, and best price (BP), for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in significant civil monetary penalties for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the civil False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

We could face liability if a regulatory authority determines that we are promoting NUPLAZID or DAYBUE for any "off-label" uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication or patient population that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of NUPLAZID, DAYBUE and any other products we may be approved to market, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice (DOJ), and various U.S. Attorneys' Offices, the HHS Office of Inspector General, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the FDCA, the civil False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA, DOJ, or any other governmental agency initiates an enforcement action against us, or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

Changes at the FDA and other government agencies could delay or prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities. If repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, and negatively impact other government operations on which we rely, which could have a material adverse effect on our business.

We are subject to stringent regulation in connection with the marketing of NUPLAZID, DAYBUE and any other products derived from our product candidates, which could delay the development and commercialization of our products.

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product, including NUPLAZID and DAYBUE, in the U.S. until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, the FDA and other regulatory agencies may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate, if approved.

Outside the U.S., the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the U.S. and, similarly, approval by regulatory authorities outside the U.S. will not automatically lead to FDA approval.

In addition, U.S. and foreign government regulations control access to and use of some human or other tissue samples in our research and development efforts. U.S. and foreign government agencies may also impose restrictions on the use of data derived from human or other tissue samples. Accordingly, if we fail to comply with these regulations and restrictions, the commercialization of our product candidates, if approved, may be delayed or suspended, which may delay or impede our ability to generate product revenues.

If our competitors develop and market products that are more effective than NUPLAZID, DAYBUE or our product candidates, if approved, they may reduce or eliminate our commercial opportunity.

Competition in the pharmaceutical and biotechnology industries is intense and expected to increase. We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the U.S. and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors have products or are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

For example, the use of NUPLAZID for the treatment of PDP competes with off-label use of various antipsychotic drugs, including the generic drugs quetiapine, clozapine, risperidone, aripiprazole, and olanzapine. Pimavanserin for the treatment of negative symptoms of schizophrenia, if approved for that indication, would compete with off-label use of Vraylar, marketed by Allergan, Rexulti, marketed by Otsuka Pharmaceutical Co., Ltd., Latuda, marketed by Sunovion Pharmaceuticals Inc., Caplyta, marketed by IntraCellular Therapeutics and various generic drugs, including quetiapine, clozapine, risperidone, aripiprazole, and olanzapine. In addition, DAYBUE competes indirectly with off-label usage of branded and generic prescription medications targeted at individual symptoms of Rett syndrome, including antiepileptics, antipsychotics, antidepressants and benzodiazepines. In addition, Anavex has a product, Anavex 2-73, in development for the potential treatment of Rett syndrome and Taysha Gene Therapies is conducting clinical trials of a gene therapy to treat Rett syndrome. Several academic institutions and pharmaceutical companies are currently conducting clinical trials for the treatment of various symptoms of Rett syndrome.

Other competitors may have a variety of drugs in development or awaiting approval from the FDA or comparable foreign regulatory authorities that could reach the market and become established before we have a product to sell for the applicable disorder. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;

- preclinical studies and clinical trials of potential pharmaceutical products;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas: capital resources, research and development resources, manufacturing capabilities, sales and marketing, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of NUPLAZID, DAYBUE or any other product for which we obtain regulatory approval, or development or commercialization of our product candidates, if approved.

We face an inherent risk of product liability as a result of the commercial sales of NUPLAZID and DAYBUE in the U.S. and the clinical testing of our product candidates, and will face an even greater risk following commercial launch of NUPLAZID or DAYBUE in additional jurisdictions, if approved, or if we engage in the clinical testing of new product candidates or commercialize any additional products. For example, we may be sued if NUPLAZID, DAYBUE or any other product we develop allegedly causes injury or is found to be otherwise unsuitable for administration in humans. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates, if approved, that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates, if approved; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of NUPLAZID and DAYBUE, we may need to increase and expand this coverage, including if we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions to operations or clinical trials, reputational harm, litigation, fines and penalties, disruptions of our business operations, and a loss of customers or sales.

In the ordinary course of our business, we, or the third parties upon which we rely, process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets.

Cyberattacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. These threats are prevalent, continue to rise, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," hacktivists, threat actors, personnel misconduct or error (such as through theft or misuse), organized criminal threat actors, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fire, flood, and other similar threats.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials or otherwise affecting our ability to provide our products or product candidates, loss of sensitive data (including data related to clinical trials) and income, significant extra expenses to restore data or systems, reputational harm and the diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments (including, for example, if applicable laws or regulations prohibit such payments). Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections, computers and devices outside our premises, including at home, while in transit or in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, drug suppliers, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices and posture (including whether any unremediated vulnerabilities exist or have been exploited) is limited, and these third parties may not have adequate information security measures in place. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. For example, in May 2021, a key drug supplier notified us of a ransomware attack on our supplier's systems; however, to date we found no indication that our personal data was exposed. Additionally, we have been notified in the past by a third-party identity access provider of a potential exposure to our administrative accounts. Similarly, in November 2023, we were notified of a ransomware attack on a drug substance supplier that interrupted their operations. We have also been made aware of a cyberattack against one of the largest prescription processors in the country as of February 21, 2024 that may impact the ability for our specialty pharmacy partners to have payers provide authorizations for patient refills and new patient starts for certain of our products.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties upon which we rely). We and the third parties upon which may rely may not, however, detect and remediate all such vulnerabilities including on a timely basis. For example, we have identified certain vulnerabilities in our information systems, and we take steps designed to mitigate the risks associated with known vulnerabilities. These steps include implementing compensating controls and other protective measures. Further, we and the third parties upon which we rely may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products.

We may expend significant resources or fundamentally change our business activities and practices (including our clinical trials) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

In addition, our insurance coverage may not be adequate or sufficient in type or amount to protect us from or to mitigate liabilities arising out of our privacy and security practices. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Risks Related to Our Common Stock

Our stock price historically has been, and is likely to remain, highly volatile.

The market prices for securities of biotechnology companies in general, and drug discovery and development companies in particular, have been highly volatile and may continue to be highly volatile in the future. From the period between January 3, 2023 to February 26, 2024, the closing price of our common stock has ranged from a low of $16.32 per share to a high of $33.47 per share. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- the success of our commercialization of NUPLAZID in the U.S. for the treatment of hallucinations and delusions associated with PDP and DAYBUE in the U.S. for the treatment of Rett syndrome;
- the status and cost of development and commercialization of our products and product candidates, if approved, including compounds being developed under our collaborations;
- whether we acquire or in-license additional product candidates or products, and the status of development and commercialization of such product candidates, if approved, or products;
- the status and cost of development and commercialization of pimavanserin for indications other than in PDP, including ADP, and in jurisdictions other than the U.S.;
- any other communications or guidance from the FDA or other regulatory authorities that pertain to NUPLAZID, DAYBUE or our product candidates;
- the status and cost of our post-marketing commitments for NUPLAZID or DAYBUE;
- the initiation, termination, or reduction in the scope of our collaborations or any disputes or developments regarding our collaborations;
- market conditions or trends related to biotechnology and pharmaceutical industries, or the market in general;
- announcements of technological innovations, new products, or other material events by our competitors or us, including any new products that we may acquire or in-license;
- disputes or other developments concerning our proprietary and intellectual property rights;
- fluctuations in our operating results;
- changes in, or failure to meet, securities analysts' or investors' expectations of our financial performance;
- our failure to meet applicable Nasdaq listing standards and the possible delisting of our common stock from the Nasdaq Stock Market;
- additions or departures of key personnel;
- discussions of our business, products, financial performance, prospects, or stock price by the financial and scientific press and online investor communities such as blogs and chat rooms;
- public concern as to, and legislative action with respect to, genetic testing or other research areas of biopharmaceutical companies, the pricing and availability of prescription drugs, or the safety of drugs and drug delivery techniques;
- regulatory developments in the U.S. and in foreign countries;
- changes in the structure of healthcare payment systems;
- the announcement of, or developments in, any litigation matters;

- disruptions caused by geopolitical or macroeconomic developments or other business interruptions, including, for example, the ongoing military conflict between Ukraine and Russia and related sanctions and the ongoing conflict in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain; and
- economic and political factors, including but not limited to economic and financial crises, wars, terrorism, and political unrest.

In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. For example, we, and certain of our current and former officers and directors, are subject to numerous lawsuits related to prior statements about NUPLAZID and our sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with DRP, as described in "Legal Proceedings". If we are not successful in defense of these claims, we may have to make significant payments to, or other settlements with, our stockholders and their attorneys. Even if such claims are not successful, the litigation has resulted in additional costs in the past and could result in further substantial costs and diversion of our management's attention and resources in the future, which could have a material adverse effect on our business, operating results or financial condition.

If we or our stockholders sell substantial amounts of our common stock, the market price of our common stock may decline.

A significant number of shares of our common stock are held by a small number of stockholders. Sales of a significant number of shares of our common stock, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. In connection with our March 2014 public offering of common stock, we agreed to provide resale registration rights for the shares of our common stock held by entities affiliated with one of our principal stockholders and two of our directors, Julian C. Baker and Dr. Stephen R. Biggar, which we refer to as the Baker Entities. In connection with our January 2016 public offering of common stock, we entered into a formal registration rights agreement with the Baker Entities to provide for these rights. Under the registration rights agreement, we have agreed that, if at any time and from time to time, the Baker Entities demand that we register their shares of our common stock for resale under the Securities Act, we would be obligated to effect such registration. On May 25, 2022, we filed a registration statement covering the sale of up to 42,393,855 shares of our common stock, which includes 489,269 shares of our common stock issuable upon the exercise of warrants that were owned by the Baker Entities as of May 16, 2022, and which represented approximately 26 percent of our outstanding shares at the time. Our registration obligations under this registration rights agreement, which cover all shares now held or later acquired by the Baker Entities, will be in effect for up to 10 years, and include our obligation to facilitate certain underwritten public offerings of our common stock by the Baker Entities in the future. If the Baker Entities sell a large number of our shares, or the market perceives that the Baker Entities intend to sell a large number of our shares, this could adversely affect the market price of our common stock. We also may elect to sell from time to time an indeterminate number of shares on our own behalf pursuant to a registration statement or in a private placement. Our stock price may decline as a result of the sale of the shares of our common stock included in any of these registration statements or future financings.

If our officers, directors, and largest stockholders choose to act together, they may be able to significantly influence our management and operations, acting in their best interests and not necessarily those of our other stockholders.

Our directors, executive officers and holders of 5% or more of our outstanding common stock and their affiliates beneficially own a substantial portion of our outstanding common stock. As a result, these stockholders, acting together, have the ability to significantly influence all matters requiring approval by our stockholders, including the election of all of our board members, amendments to our certificate of incorporation, going-private transactions, and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of our other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us more complicated and may make the removal and replacement of our directors and management more difficult.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may delay or prevent a change in control, discourage bids at a premium over the market price of our common stock and adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. These provisions may also make it difficult for stockholders to remove and replace our board of directors and management. These provisions:

- establish that members of the board of directors may be removed only for cause upon the affirmative vote of stockholders owning at least a majority of our capital stock;
- authorize the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares and prevent or delay a takeover attempt;
- limit who may call a special meeting of stockholders;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit our stockholders from making certain changes to our amended and restated certificate of incorporation or amended and restated bylaws except with $66^{2/3}$% stockholder approval; and
- provide for a board of directors with staggered terms.

We are also subject to provisions of the General Corporation Law of the State of Delaware that, in general, prohibit any business combination with a beneficial owner of 15% or more of our common stock for three years unless the holder's acquisition of our stock was approved in advance by our board of directors. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders.

We do not intend to pay dividends on our common stock in the foreseeable future; as such, you must rely on stock appreciation for any return on your investment.

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business. For this reason, the success of an investment in our common stock, if any, will depend on the appreciation of our common stock, which may not occur. There is no guarantee that our common stock will appreciate, and therefore, a holder of our common stock may not realize a return on his or her investment.

General Risk Factors

Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which may cause our stock price to decline.

We have incurred, and expect to continue to incur, significant costs as a result of laws and regulations relating to corporate governance and other matters.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act that was enacted in July 2010, the provisions of the Sarbanes-Oxley Act of 2002 (SOX), and rules adopted or proposed by the SEC and by The Nasdaq Stock Market, have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. In the future, if we are not able to issue an evaluation of our internal control over financial reporting, as required, or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors and board committees, and as our executive officers. We cannot predict or estimate the total amount of the costs we may incur or the timing of such costs to comply with these rules and regulations.

Adverse securities and credit market conditions may significantly affect our ability to raise capital.

Historically, turmoil and volatility in the financial markets (including recent volatility as a result of geopolitical and macroeconomic developments such as the ongoing military conflict between Ukraine and Russia and related sanctions, and the ongoing conflict in Israel and the surrounding areas, as well as any related political or economic responses and counter-responses or otherwise by various global actors or the general effect on the global economy and supply chain) have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. These events, coupled with other factors, may limit our access to financing in the future. This could have a material adverse effect on our ability to access funding on acceptable terms, or at all, and our stock price may suffer further as a result.

Item 1B. ***Unresolved Staff Comments.***

This item is not applicable.

Item 1C. ***Cybersecurity.***

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials and products (Information Systems and Data).

Our information security function and our Chief Information Officer (CIO) help identify, assess and manage the Company's cybersecurity threats and risks. This group works to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods in certain contexts, including, for example, manual tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threat actors, conducting scans of certain environments, evaluating certain threats reported to us, conducting threat and vulnerability assessments, using external intelligence feeds, and using third parties to conduct tabletop incident response exercises and other tests.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response, disaster recovery/business continuity policies, risk assessments, encryption of certain data, network security controls and data segmentation for certain systems, access controls, physical security, asset management and tracking, systems monitoring, employee training, penetration testing, cybersecurity insurance, and dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, (1) cybersecurity risk is addressed as a component of the Company's enterprise risk management program; (2) the information security department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; and (3) our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, outside legal counsel, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, darkweb monitoring services, and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. We have vendor management processes to help manage cybersecurity risks associated with our use of certain of these providers. For certain vendors, these processes include vendor risk assessments, security questionnaires, review of vendors' written security program, and imposition of contractual obligations related to information security on vendors.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors, including: "We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences."; and "If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, interruptions to operations or clinical trials, reputational harm, litigation, fines and penalties, disruptions of our business operations, and a loss of customers or sales."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for overseeing the Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Director of Information Security, who has managed the Security Operations Center for a Fortune 500 company, and led cybersecurity efforts as the Director of IT at another organization.

The Director of Information Security, along with management, including the CIO, is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Management is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our CIO, Chief Accounting Office, Chief Compliance Office, Vice President of People and Performance, and Director of Information Security. This team works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from senior management concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them.

Item 2. ***Properties.***

As of December 31, 2023, our primary facility consists of approximately 67,000 square feet of office space in San Diego, California. We also lease a facility in Princeton, New Jersey that covers approximately 25,000 square feet of office space, which is leased through January 2025. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. ***Legal Proceedings.***

Patent Infringement

On July 24, 2020, we filed complaints against (i) Aurobindo Pharma Limited and its affiliate Aurobindo Pharma USA, Inc. and (ii) Teva Pharmaceuticals USA, Inc. and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, we filed complaints against (i) Hetero Labs Limited and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., (ii) MSN Laboratories Private Ltd. and its affiliate MSN Pharmaceuticals, Inc., and (iii) Zydus Pharmaceuticals (USA) Inc. and its affiliate Cadila Healthcare Limited. These complaints, which were filed in the United States District Court for the District of Delaware, allege infringement of certain of our Orange Book-listed patents covering NUPLAZID (Pimavanserin I Cases). The cases have been assigned to the Honorable Richard G. Andrews. On September 1, 2020, Aurobindo filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 22, 2020, we filed our answer to Aurobindo's counterclaims. On August 31, 2020, Teva filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 21, 2020, we filed our answer to Teva's counterclaims. On October 5, 2020, Hetero filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On October 26, 2020, we filed our answer to Hetero's counterclaims. On September 30, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On November 5, 2020, we filed our first amended complaint against MSN in the United States District Court for the District of Delaware, alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID. On November 19, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On December 10, 2020, we filed our answer to MSN's counterclaims. On November 2, 2020, Zydus filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On November 23, 2020, we filed our answer to Zydus's counterclaims. On December 8, 2020, the parties' joint proposed scheduling order was entered by Judge Andrews. On April 7, 2021, we filed our first amended complaints against Hetero and Teva and our second amended complaint against MSN, to include an additional Orange Book-listed patent covering NUPLAZID. On April 8, 2021, we filed our first amended complaint against Zydus and on April 9, 2021, we filed our first amended complaint against Aurobindo. On April 20, 2021, MSN filed its answer, affirmative defenses, and counterclaims to our second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On April 21, 2021, Teva filed its answer, affirmative defenses, and counterclaims to our first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On April 22, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to our first amended complaint, seeking declaratory judgments of noninfringement and invalidity.

On April 22, 2021, Aurobindo filed its answer, affirmative defenses, and counterclaims to our first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On May 11, 2021, we filed our answer to MSN's counterclaims. On May 12, we filed our answer to Teva's counterclaims. On May 13, we filed our answer to Zydus's counterclaims and its answer to Aurobindo's counterclaims. We entered into an agreement effective April 22, 2021 with Hetero settling all claims and counterclaims in the litigation. The agreement allows Hetero to launch its generic pimavanserin product on February 27, 2038, subject to certain triggers for earlier launch. The Hetero case was dismissed by joint agreement on May 3, 2021.

On August 27, 2021, we filed our second amended complaint against Zydus to include an additional Orange Book-listed patent covering NUPLAZID. On September 10, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to our second amended complaint, seeking declaratory judgments of noninfringement and invalidity. Also on September 10, 2021, the parties filed their Joint Claim Construction Chart. On October 1, 2021, we filed our answer to Zydus's counterclaims. On November 30, 2021, we filed a stipulation and proposed order to dismiss two of our Orange Book-listed patents covering NUPLAZID against Teva, which was ordered by the Court on December 1, 2021. On January 28, 2022, the parties filed their Joint Claim Construction Brief and Appendix. On February 23, 2022, the Court heard oral argument on claim construction. On April 6, 2022, the Court issued a Memorandum Opinion construing several terms at issue, adopting our construction on two terms, Defendants' construction on two terms, and one agreed-upon construction. On February 28, 2022, we filed a stipulation and proposed order to dismiss one patent against MSN, which was ordered by the Court on March 1, 2022. On March 10, 2022, we filed a stipulation and proposed order to dismiss one patent against Teva, which was ordered by the Court on March 10, 2022. On March 22, 2022, we filed a stipulation and proposed order to dismiss seven patents against Aurobindo, which was ordered by the Court on March 22, 2022. On March 30, 2022, we filed a stipulation and proposed order to dismiss two patents against Zydus, which was ordered by the Court on March 31, 2022. On April 22, 2022, we filed a stipulation and proposed order of non-infringement against Aurobindo regarding certain of our Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 22, 2022. On April 26, 2022, we filed a stipulation and proposed order of non-infringement against MSN regarding certain of our Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 26, 2022. On April 26, 2022, we filed a stipulation and proposed order of non-infringement against Teva regarding certain of our Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 27, 2022. On May 10, 2022, we filed our second amended complaint against Teva to include an additional Orange Book-listed patent covering NUPLAZID. On May 18, 2022, we filed a stipulation and proposed order of non-infringement against Zydus regarding certain of our Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on May 19, 2022. On May 24, 2022, Teva filed its answer, affirmative defenses, and counterclaims to our second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On June 1, 2022, we filed our second amended complaint against Aurobindo alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID. On June 2, 2022, we filed our third amended complaint against Zydus alleging infringement of certain of our Orange Book-listed patents covering NUPLAZID. On June 14, 2022, we filed our answer to Teva's counterclaims. June 15, 2022, Aurobindo filed its answer, affirmative defenses, and counterclaims to our second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On June 16, 2022, Zydus filed its answer, affirmative defenses, and counterclaims to our third amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of our Orange Book-listed patents covering NUPLAZID. On July 6, 2022, we filed our answer to Aurobindo's counterclaims.

On September 7, 2022, the consolidated cases were reassigned to the Honorable Judge Gregory B. Williams. On September 30, 2022, we filed a stipulation and proposed order to stay the claims currently asserted against Teva and for Teva to be bound by the result of the litigation rendered against the remaining Defendants, which was ordered by the Court on October 4, 2022. On October 21, 2022, we filed complaints against Aurobindo, MSN and Zydus in the United States District Court for the District of Delaware alleging infringement of an additional Orange Book-listed patent covering NUPLAZID (Pimavanserin II Cases).

On March 29, 2023, following Aurobindo's conversion of various patent certifications from Paragraph IV certifications to Paragraph III certifications in connection with the Pimavanserin I Case, we filed a stipulation and proposed order in the Pimavanserin I Case to dismiss the remaining asserted patents against Aurobindo. This stipulation was ordered by the Court on March 30, 2023.

We entered into an agreement, effective March 31, 2023, with Zydus settling all claims and counterclaims in the Pimavanserin I Cases and Pimavanserin II Cases. The agreement allows Zydus to launch its generic pimavanserin 10 mg products on September 23, 2036 and 34 mg products on February 27, 2038, subject to certain triggers for earlier launch. On April 4, 2023, we filed a stipulation and proposed order to dismiss all claims and counterclaims between us and Zydus in the Pimavanserin I Cases and Pimavanserin II Cases, which was ordered by the Court on April 5, 2023.

As a result of the above, only MSN remained as an active defendant in the Pimavanserin I Cases. On April 6, 2023, we and MSN filed a stipulation and proposed order requesting adjournment of the final pre-trial conference and trial, and requesting resolution of the remaining issue – MSN's validity challenge of the sole patent in suit – through summary judgment briefing by the parties, which was ordered by the Court on April 10, 2023. Briefing was completed on June 28, 2023 and oral argument took place on September 27, 2023. On December 13, 2023, the Court ruled in our favor on the summary judgment motions – denying MSN's motion for summary judgment of invalidity and granting our cross-motion for no invalidity. MSN had previously stipulated to infringement of the patent-in-suit. On January 11, 2024, the District Court entered final judgment in our favor that MSN's submission of ANDA No. 214925 was an act of infringement in the Pimavanserin I Case. On January 18, 2024, MSN filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the December 13, 2023 Memorandum Order of the United States District Court for the District of Delaware, and final judgment entered on January 11, 2024. On February 12, 2024, we filed an Entry of Appearance for the appeal to the United States Court of Appeals for the Federal Circuit. MSN's Opening Appeal Brief is due on March 29, 2024.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. On December 13, 2023, the Court issued a claim construction order finding in favor of us on all disputed terms of the patent-in-suit. Fact discovery closes on March 21, 2024. Trial is scheduled in the matter for December 3, 2024 to December 5, 2024.

Securities Class Action

On April 19, 2021, a purported stockholder of us filed a putative securities class action complaint (captioned Marechal v. Acadia Pharmaceuticals Inc., Case No. 21-cv-0762) in the U.S. District Court for the Southern District of California against us and certain of our current executive officers. On September 29, 2021, the Court issued an order designating lead plaintiff and lead counsel. On December 10, 2021, lead plaintiff filed an amended complaint. The amended complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to disclose that the materials submitted in support of its sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis contained statistical and design deficiencies and that the FDA was unlikely to approve the sNDA in its current form. The amended complaint seeks unspecified monetary damages and other relief. Defendants filed a motion to dismiss the amended complaint on February 15, 2022. On September 27, 2022, the Court issued an order denying Defendants' motion to dismiss. Defendants filed their answer to the amended complaint on October 19, 2022, and filed a motion for reconsideration on October 25, 2022. On February 2, 2023, the Court issued an order denying the motion for reconsideration. On August 21, 2023, plaintiffs filed a motion for class certification. Briefing on that motion concluded on January 12, 2024, and the Court will hear oral argument on the motion on February 28, 2024. The parties are currently engaged in discovery. The cutoff for fact discovery is June 13, 2024.

Derivative Suit

On December 15, 2023, a purported stockholder of us filed a derivative action (captioned *Kanner et al v. Biggar et al.*, Case No. 23-cv-2293) in the U.S. District Court for the Southern District of California against certain of our current directors. We are named as a nominal defendant. The complaint is based on the same alleged misconduct as the Securities Class Action, and asserts state law claims, on behalf of us, against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, waste of corporate assets, and insider trading. The complaint also asserts federal claims under sections 10(b), 21D, and 14(a) of the Securities Exchange Act of 1934, as amended. On December 27, 2023, the action was reassigned to District Judge William Q. Hayes and Magistrate Judge Michael S. Berg due to its relation to the Securities Class Action. On January 30, 2024, the parties jointly requested a stay of the action. The Court granted that request and the action was stayed on February 20, 2024, pending the outcome of our Demand Review Committee's investigation into the underlying claims.

We currently believe that none of the foregoing claims or other actions pending against us as of December 31, 2023 is likely to have, individually or in the aggregate, a material adverse effect on our business, liquidity, financial position, or results of operations. Given the unpredictability inherent in litigation, however, we cannot predict the outcome of these matters. We are unable to estimate possible losses or ranges of losses that may result from these matters, and therefore we have not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

Item 4. ***Mine Safety Disclosures.***

This item is not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.***

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "ACAD".

Holders

As of February 21, 2024, there were 164,771,521 shares of common stock outstanding held by approximately 34 stockholders of record.

Dividends

To date, we have not paid any cash dividends on our common stock, and we do not intend to pay any dividends in the foreseeable future. Instead, we intend to retain any future earnings to fund the development and growth of our business.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

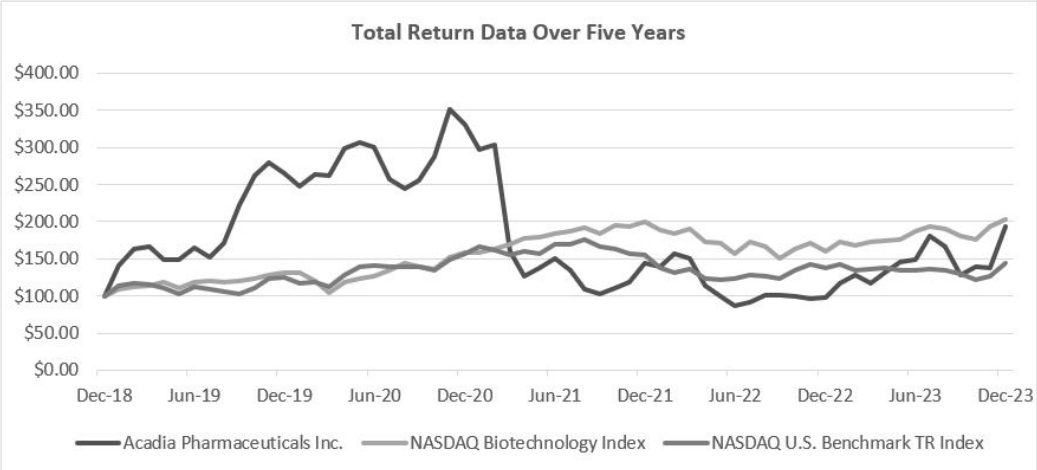
None.

Recent Sales of Unregistered Securities

Not applicable.

Performance Graph

The following graph shows a comparison of the total cumulative returns of an investment of $100 in cash from December 31, 2018 through December 31, 2023 in (i) our common stock, (ii) the Nasdaq Biotechnology Index, and (iii) the Nasdaq U.S. Benchmark TR Index. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of the possible future performance of our common stock. The graph assumes that all dividends have been reinvested (to date, we have not declared any dividends).



Item 6. [Reserved]

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations.***

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. Past operating results are not necessarily indicative of results that may occur in future periods. This discussion contains forward-looking statements, which involve a number of risks and uncertainties. Such forward-looking statements include statements about the benefits to be derived from NUPLAZID® (pimavanserin), DAYBUE™ (trofinetide) and our drug candidates, the potential market opportunities for NUPLAZID and DAYBUE and our drug candidates, our strategy for the commercialization of NUPLAZID and DAYBUE, our plans for exploring and developing NUPLAZID and DAYBUE for indications other than PDP or Rett syndrome, respectively, and the commercialization of DAYBUE in jurisdictions other than the U.S., our plans and timing with respect to seeking regulatory approvals, the potential commercialization of any of our drug candidates that receive regulatory approval, the progress, timing, results or implications of clinical trials and other development activities involving NUPLAZID, DAYBUE and our drug candidates, our strategy for discovering, developing and, if approved, commercializing drug candidates, our existing and potential future collaborations, our estimates of future payments, revenues and profitability, our estimates regarding our capital requirements, future expenses and need for additional financing, the potential or expected impacts of geopolitical and macroeconomic developments, possible changes in legislation, and other statements that are not historical facts, including statements which may be preceded by the words "believes," "expects," "hopes," "may," "will," "plans," "intends," "estimates," "could," "should," "would," "continues," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential" or similar words. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain. For forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We undertake no obligation to update or revise publicly any forward-looking statements. Forward-looking statements are not guarantees of performance. Actual results or events may differ materially from those anticipated in our forward-looking statements as a result of various factors, including those set forth under the section captioned "Risk Factors" elsewhere in this report. Information in the following discussion for a yearly period means for the year ended December 31 of the indicated year.

Overview

Background

We are a biopharmaceutical company focused on the development and commercialization of innovative medicines that address unmet medical needs in CNS disorders and rare diseases. We have a portfolio of commercial stage products, in-development product opportunities, and research programs that are designed to address significant unmet needs in CNS disorders and rare diseases. In order to achieve significant long-term growth, we will develop our current portfolio, expand our pipeline of early- and late-stage programs through strategic business development, and invest in targeted internal research efforts.

Our commercial portfolio includes two products. In April 2016, the FDA approved NUPLAZID for the treatment of hallucinations and delusions associated with PDP, which is the first and only drug approved in the United States for this condition. In September 2023, we announced that the FDA made two changes to the NUPLAZID label clarifying its use in patients with Parkinson's disease-related hallucinations and delusions, with or without dementia, which is consistent with the current indication. In March 2023, the FDA approved DAYBUE for the treatment of Rett syndrome, which is the first and only drug approved for this condition. DAYBUE became available for prescription in the United States in April 2023.

NUPLAZID is a selective serotonin inverse agonist/antagonist, preferentially targeting 5-HT_{2A} receptors with no appreciable affinity for dopaminergic, histaminergic, or muscarinic receptors. Through this novel mechanism, NUPLAZID demonstrated significant efficacy in reducing the hallucinations and delusions associated with PDP without negatively impacting motor function in our Phase 3 pivotal trial. NUPLAZID has the potential to avoid many of the debilitating side effects of existing antipsychotics, none of which are approved by the FDA for the treatment of PDP. We hold worldwide commercialization rights to pimavanserin.

In August 2018, we acquired an exclusive North American license to develop and commercialize DAYBUE for Rett syndrome and other indications from Neuren. Rett syndrome is a debilitating neurological disorder that occurs predominantly in females following apparently normal development for the first six months of life. Rett syndrome also occurs in boys, albeit far less frequently. Typically, between six to eighteen months of age, patients experience a period of rapid decline with loss of purposeful hand use and spoken communication and inability to independently conduct activities of daily living. Symptoms also include seizures, hand movements or stereotypies, disorganized breathing patterns, scoliosis and sleep disturbances, among others. The FDA approval of DAYBUE for the treatment of Rett syndrome was based on the positive results from our pivotal Phase 3 LAVENDER™ study which demonstrated statistically significant improvement over placebo for both co-primary endpoints as well as the key secondary endpoint.

Under the terms of the 2018 agreement, Neuren received an upfront payment of $10.0 million and is eligible to receive milestone payments of up to $400.0 million based on the achievement of certain development and sales milestones for Rett syndrome in North America, of which, $50 million has been paid to date. Neuren is also eligible to receive up to $55.0 million in development and sales milestone for Fragile X syndrome in North America. In addition, Neuren is eligible to receive tiered, escalating, double-digit percentage royalties based on net sales in North America. The following tables provide a summary of milestone and royalty payments that Neuren remains eligible to receive based on the achievement of net sales of trofinetide in North America in any given year:

Sales Milestones Based on Annual Net Sales in North America	
Net Sales ≥$250 million	$50 million
Net Sales ≥$500 million	$50 million
Net Sales ≥$750 million	$100 million
Net Sales ≥$1 billion	$150 million

Tiered Royalty Rates Based on Annual Net Sales in North America	
≤$250 million	10%
>$250 million, but ≤$500 million	12%
>$500 million, but ≤$750 million	14%
>$750 million	15%

In July 2023, we expanded our current licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of $100.0 million and is eligible to receive up to an additional $426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to $831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, we will be required to pay Neuren tiered royalties from the mid-teens to low-twenties percent based on net sales of trofinetide and NNZ-2591. The following table provides a summary of milestone payments that Neuren is eligible to receive based on the achievement of certain sales milestones under the terms of the expanded agreement:

Territory	First Commercial Sales Milestones	Total Sales Milestones
Europe	$35 million (Rett syndrome) $10 million (2nd indication)	Up to $170 million
Japan	$15 million (Rett syndrome) $4 million (2nd indication)	Up to $110 million
Rest of World	—	Up to $83 million

In addition to the treatment of hallucinations and delusions associated with the PDP, we believe that pimavanserin has the potential as a treatment of the negative symptoms of schizophrenia. Today we are evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia in a Phase 3 clinical development program. The negative symptoms of schizophrenia have been associated with poor long-term outcomes and disability even when the positive symptoms are well-controlled, and today there are no FDA-approved therapies. In the fourth quarter of 2019 we announced positive results from our pivotal ADVANCE study and in the third quarter of 2020, we initiated a second pivotal study, ADVANCE-2. The Phase 3 program is evaluating the efficacy of pimavanserin in patients with predominantly negative symptoms of schizophrenia who have achieved adequate control of positive symptoms with their existing antipsychotic treatment. We completed enrollment in ADVANCE-2 and expect that top-line results will be available in the first quarter of 2024.

In June 2023, we announced that we added a new Phase 3 development candidate to our rare disease portfolio, ACP-101 (intranasal carbetocin), for the treatment of hyperphagia (an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety) in PWS. We acquired worldwide rights to develop and commercialize ACP-101 with the acquisition of Levo Therapeutics in June 2022. In November 2023, we initiated the Phase 3 COMPASS PWS study evaluating the efficacy and safety of ACP-101 for the treatment of hyperphagia in PWS.

In addition, in August 2022 we announced that we are developing an internally discovered new molecule, ACP-204, which builds upon the learnings of pimavanserin in the treatment of neuropsychiatric symptoms. We completed Phase 1 study of ACP-204 which demonstrated a favorable safety and tolerability profile, and supports its target product profile as a potential treatment for ADP. In November 2023, we initiated a Phase 2 study evaluating the efficacy and safety of ACP-204 for the treatment of hallucinations and delusions associated with ADP. ACP-204 is a new chemical entity for which we hold the worldwide rights.

In January 2022, we entered into a license and collaboration agreement with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. For the Rett syndrome (MECP2) and the undisclosed neurodevelopmental program, Stoke will lead research and pre-clinical development activities, while we will lead clinical development and commercialization activities.

We have incurred substantial operating losses since our inception due in large part to expenditures for our research and development activities. As of December 31, 2023, we had an accumulated deficit of approximately $2.4 billion. Contingent on the level of business development activities we may complete as well as pipeline programs we may advance, we may continue to incur operating losses for the next few years as we incur significant research and development costs and costs for continued commercialization of NUPLAZID and DAYBUE.

Financial Operations Overview

Product Revenues

Net product sales consist of sales of NUPLAZID and DAYBUE. The FDA approved NUPLAZID in April 2016 for the treatment of hallucinations and delusions associated with PDP and we launched the product in the United States in May 2016. The FDA approved DAYBUE in March 2023 for the treatment of Rett syndrome and we launched the product in the United States in April 2023.

Cost of Product Sales

Cost of product sales consists of third-party manufacturing costs, freight, and indirect overhead costs associated with sales of NUPLAZID and DAYBUE. Cost of product sales may also include period costs related to certain inventory manufacturing services, excess or obsolete inventory adjustment charges, unabsorbed manufacturing and overhead costs, and manufacturing variances. In addition, cost of product sales may include license fees and royalties. License fees and royalties currently consist of milestone payments capitalized and subsequently amortized under our 2018 license agreement with Neuren. License fees and royalties also include royalties of tiered, escalating, double-digit percentages due to Neuren based upon net sales of DAYBUE.

Cost of sales for a newly launched product does not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold. Thus the cost of sales as a percentage of net sales of DAYBUE for the year ended December 31, 2023 was affected by use of the initial pre-launch inventory, which was previously expensed as research and development expense, and is referred to as zero cost inventories. However, we do not expect that the cost of sales as a percentage of net sales of DAYBUE will increase significantly once we commence the sales of full cost inventories.

Research and Development Expenses

Our research and development expenses have consisted primarily of fees paid to external service providers, salaries and related personnel expenses, facilities and equipment expenses, and other costs incurred related to pre-commercial product candidates. We charge all research and development expenses to operations as incurred. Our research and development activities have focused on pimavanserin, trofinetide, ACP-101, ACP-204 and other early-stage programs. We currently are responsible for all costs incurred in the ongoing development of pimavanserin. In connection with the FDA approval of NUPLAZID, we committed to conduct four post-marketing studies. We have fulfilled three of the four studies. The fourth commitment has been completed and we are awaiting FDA's acknowledgement and acceptance. In connection with the FDA approval of DAYBUE, we are required to conduct post-marketing work, including a clinical study of renal impairment in healthy volunteers, nonclinical carcinogenicity studies, and nonclinical in vitro drug interaction studies. We will be responsible for all costs incurred for these post-marketing requirements. In addition, we expect to incur increased research and development expenses as a result of advancement of our early-stage development pipeline programs.

We use external service providers to manufacture our product candidates and for the majority of the services performed in connection with the preclinical and clinical development of pimavanserin, trofinetide, and our early-stage programs. Historically, we have used our internal research and development resources, including our employees and discovery infrastructure, across several projects and many of our costs have not been attributable to a specific project. Accordingly, we have not reported our internal research and development costs on a project-by-project basis. To the extent that external expenses are not attributable to a specific project, they are included in other early-stage programs.

The following table summarizes our research and development expenses for the years ended December 31, 2023, 2022, and 2021 (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Costs of external service providers:			
NUPLAZID (pimavanserin)	$ 55,527	$ 62,746	$ 73,696
DAYBUE (trofinetide)	32,065	62,300	39,814
ACP-101	11,887	2,085	—
ACP-204	43,768	16,898	2,569
Early-stage programs	26,789	45,803	33,395
Upfront and milestone payments*	102,500	88,741	10,999
Subtotal	272,536	278,573	160,473
Internal costs	61,675	60,422	56,973
Stock-based compensation	17,408	22,580	21,969
Total research and development expenses	$ 351,619	$ 361,575	$ 239,415

* Includes upfront and milestone consideration as well as transaction costs associated with acquired in-process research and development.

At this time, due to the risks inherent in regulatory requirements and clinical development, we are unable to estimate with certainty the costs we will incur for the ongoing or additional development of pimavanserin for the negative symptoms of schizophrenia or to support the commercialization of DAYBUE, as well as the further development of our early-stage pipeline programs. Likewise, we are unable to determine with certainty the anticipated completion dates for our current research and development programs. Clinical development and regulatory approval timelines, probability of success, and development costs vary widely. While our current development efforts are primarily focused on advancing the development of pimavanserin for the treatment of the negative symptoms of schizophrenia and the development of ACP-101, ACP-204 and other early-stage programs, we anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical success of each product candidate, as well as an ongoing assessment of the commercial potential of each opportunity and our financial position. We cannot forecast with any degree of certainty which product opportunities will be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree any such arrangements would affect our development plans and capital requirements. Similarly, we are unable to estimate with certainty the costs we will incur for post-marketing studies that we committed to conduct in connection with FDA approval of DAYBUE.

We expect our research and development expenses will continue to be substantial as we conduct studies pursuant to our post-marketing commitments and pursue the development of pimavanserin for the negative symptoms of schizophrenia and the further development of ACP-101, ACP-204 and other early-stage pipeline programs. The lengthy process of completing clinical trials and supporting development activities and seeking regulatory approval for our product opportunities requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist of salaries and other related costs, including stock-based compensation expense, for our commercial personnel, including our specialty sales forces, our medical education professionals, and our personnel serving in executive, finance, business development, and business operations functions. Also included in selling, general and administrative expenses are fees paid to external service providers to support our commercial activities associated with NUPLAZID and DAYBUE, professional fees associated with legal and accounting services, costs associated with patents and patent applications for our intellectual property and charitable donations to independent charitable foundations that support Parkinson's disease patients generally. Changes in selling, general and administrative expenses in future periods are subject to the evolving PDP market dynamics, the Rett syndrome market and our further development of pimavanserin in additional indications other than PDP.

Income Tax Expense

Because we maintain a full valuation allowance against our net deferred tax assets, income tax expense is expected to primarily consist of current federal and state tax expense as a result of taxable income anticipated or incurred in certain jurisdictions. Income tax expense may fluctuate from quarter to quarter due to adjustments related to non-recurring transactions, timing of revenue and expense across different tax jurisdictions and changes in certain tax assessments.

Critical Accounting Policies and Estimates

A summary of the significant accounting policies is provided in Note 2 to our Consolidated Financial Statements.

The preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We evaluate our estimates on an ongoing basis. Our estimates are based on historical experience and on various other assumptions and factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions and conditions.

Management considers an accounting estimate to be critical if:

- it requires a significant level of estimation uncertainty; and
- changes in the estimate are reasonably likely to have a material effect on our financial condition or results of operations.

We believe the following critical accounting policies and estimates describe the more significant judgments and estimates used in the preparation of our consolidated financial statement.

Product Sales, Net

We sell NUPLAZID through SPs and SDs. SPs dispense product to a patient based on the fulfillment of a prescription and SDs sell product to government facilities, long-term care pharmacies, or in-patient hospital pharmacies. We sell DAYBUE through a single wholesale distributor. Product shipping and handling costs are included in cost of product sales.

We recognize revenue from product sales at the net sales price (the "transaction price") which includes estimates of variable consideration for which reserves are established and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the amount payable is settled. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from estimates, we may need to adjust our estimates, which would affect net revenue in the period of adjustment. The following sales discounts and allowances involve a substantial degree of judgment:

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. Our estimates for expected utilization of rebates is based on historical data received from the SPs, SDs and the single wholesale distributor since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates still estimated to be incurred. Allowances for rebates also include amounts due under the Inflation Reduction act of 2022 for Medicare Part D unit sales with applicable period AMP increases that outpace inflation over the benchmark period. The applicable period will be twelve months on October 1 of each year, with the initial applicable period beginning on October 1, 2022. The benchmark period AMP price is January 1, 2021 through September 30, 2021. Our estimates are based Medicare Part D sales as a percentage of gross sales and the rate AMP for the current period will be in excess the benchmark period. We regularly monitor our estimates and record adjustments when rebate trends, rebate programs and contract terms, legislative changes, or other significant events indicate that a change in the estimates is appropriate. To date, our estimates have not differed materially from actual rebates. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to us the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. We also incur group purchasing organization fees for transactions through certain purchasing organizations. We estimate sales with these entities and accrue for anticipated chargebacks and organization fees, based on the applicable contractual terms. To date, our estimates have not differed materially from the actual chargebacks and organization fees. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Research and Development Accruals

We estimate certain costs and expenses and accrue for these liabilities as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include, among other things, costs associated with services provided by contract organizations for preclinical development, manufacturing of our product candidates and clinical trials, and personnel related expenses. We accrue for costs incurred as the services are being provided by monitoring the status of the trial or services provided, and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed materially from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

Stock-Based Compensation

The fair value of each employee stock option and each employee stock purchase plan right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model, which requires us to make a number of assumptions including the estimated expected life of the award and related volatility. The fair value of restricted stock units is estimated based on the market price of our common stock on the date of grant. The estimated fair values of stock options, purchase plan rights, and regular restricted stock units are then expensed over the vesting period. For restricted stock units requiring satisfaction of both market and service conditions, the estimated fair values are generally expensed over the longest of the explicit, implicit and derived service periods. Performance-based stock awards vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these performance-based stock awards is generally recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable. See also Item 15 of Part IV, "Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies" for further discussion of our assumptions and estimates related to our stock-based compensation.

Results of Operations

Fluctuations in Operating Results

Our results of operations have fluctuated significantly from period to period in the past and are likely to continue to do so in the future. We anticipate that our quarterly and annual results of operations will be impacted for the foreseeable future by several factors, including the progress and timing of expenditures related to our commercial activities associated with NUPLAZID and DAYBUE and the extent to which we generate revenue from product sales, our development of pimavanserin for the negative symptoms of schizophrenia, our further development of our early-stage pipeline programs and the progress and timing of expenditures related to studies of DAYBUE pursuant to our post-marketing commitments. Further, we expect our sales allowances to vary from quarter to quarter due to fluctuations in our Medicare Part D Coverage Gap liability and the volume of purchases eligible for government mandated discounts and rebates, as well as changes in discount percentages that may be impacted by potential future price increases and other factors. We cannot predict with certainty what the full impact that geopolitical and macroeconomic developments, including the ongoing military conflict between Ukraine and Russia and the ongoing conflict in Israel and surrounding areas may have on our business, results of operations, financial condition and prospects. Due to these fluctuations, we believe that the period-to-period comparisons of our operating results are not a good indication of our future performance.

Comparison of the Years Ended December 31, 2023 and 2022

Product Sales, Net

Net product sales, comprised of NUPLAZID and DAYBUE, were $726.4 million and $517.2 million for the years ended December 31, 2023 and 2022, respectively.

Net product sales of NUPLAZID were $549.2 million and $517.2 million in 2023 and 2022, respectively. The increase in net product sales of NUPLAZID of $32.0 million was due to the growth in NUPLAZID unit sales as well as a higher average net selling price in NUPLAZID in 2023 compared to 2022. Net product sales of DAYBUE were $177.2 million for 2023. There were no net product sales of DAYBUE during 2022.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2023 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Co-Pay Assistance	Rebates, Data Fees & Returns	Total
Balance at December 31, 2022	$ 10,923	$ (340)	$ 26,046	$ 36,629
Provision related to current period sales	97,797	3,979	113,011	214,787
Credits/payments for current period sales	(85,641)	(4,499)	(26,957)	(117,097)
Credits/payments for prior period sales	(10,923)	340	(26,046)	(36,629)
Balance at December 31, 2023	$ 12,156	$ (520)	$ 86,054	$ 97,690

Cost of Product Sales

Cost of product sales was $41.6 million and $10.2 million in 2023 and 2022, respectively, or approximately 6% and 2% of net product sales, respectively. Cost of product sales as a percentage of net product sales for NUPLAZID remains flat in 2023 as compared to 2022. The increase in cost of product sales was primarily due to the $21.8 million in license fees and royalties expensed during 2023 for DAYBUE, including royalties due to Neuren based on net sales of DAYBUE and the amortization of the milestone payments capitalized under our 2018 license agreement with Neuren. There were no license fees and royalties in the same period of 2022 for either product.

Certain manufacturing related expenses incurred prior to DAYBUE receiving FDA approval were classified as research and development expenses, resulting in zero cost inventory. Prior to receiving FDA approval for DAYBUE in March 2023, we manufactured inventory and recorded approximately $29.9 million related to the zero cost inventory as research and development expense. Utilizing the actual direct costs to manufacture DAYBUE prior to receiving FDA approval, had the previously expensed inventory been capitalized and recognized when sold, the total cost of sales with these manufacturing costs included for the year ended December 31, 2023 would have increased by approximately $9.4 million. We do not expect our cost of product sales for DAYBUE to increase significantly as a percentage of net product sales in future periods as we continue to produce inventory for future sales. We expect to finish selling the zero cost inventories of DAYBUE in 2024.

Subsequent to using our entire zero cost inventories, we estimate our overall cost of product sales as a percentage of total net product sales will be in the range of a mid-single digit to high single digit percentage.

Research and Development Expenses

Research and development expenses decreased to $351.6 million in 2023, including $17.4 million in stock-based compensation, from $361.6 million in 2022, including $22.6 million in stock-based compensation. The decrease in research and development expenses during 2023 was mainly due to trofinetide commercial supply build that was expensed prior to approval. There was a similar level of clinical spend and business development investment year over year.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased to $406.6 million in 2023, including $48.0 million in stock-based compensation expense, from $369.1 million in 2022, including $44.5 million in stock-based compensation expense. The increase in selling, general and administrative expenses was primarily due to increased commercial costs associated with the DAYBUE launch, partially offset by reductions in expenses associated with NUPLAZID.

Comparison of the Years Ended December 31, 2022 and 2021

Product Sales, Net

Product sales, net, comprised of NUPLAZID, were $517.2 million and $484.1 million in 2022 and 2021, respectively. Product sales, net for the year ended December 31, 2022 increased as compared to the year ended December 31, 2021 primarily due to a higher average gross selling price of NUPLAZID in 2022 as compared to 2021.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2022 (in thousands):

	Distribution Fees, Discounts & Chargebacks	Co-Pay Assistance	Rebates, Data Fees & Returns	Total
Balance at December 31, 2021	$ 8,467	$ (202)	$ 15,717	$ 23,982
Provision related to current period sales	80,836	3,087	51,872	135,795
Credits/payments for current period sales	(69,913)	(3,427)	(25,826)	(99,166)
Credits/payments for prior period sales	(8,467)	202	(15,717)	(23,982)
Balance at December 31, 2022	$ 10,923	$ (340)	$ 26,046	$ 36,629

Cost of Product Sales

Cost of product sales was $10.2 million and $19.1 million in 2022 and 2021, respectively, or approximately 2% and 4% of net product sales, respectively. The cost of product sales excluding license fees and royalties, as a percentage of net product sales stayed flat during 2022 as compared to 2021. License fees and royalties were $0 and $8.3 million in 2022 and 2021, respectively, and in 2021 include royalties due to the Ipsen Group of two percent of net sales of NUPLAZID and amortization related to the milestone paid to the Ipsen Group upon FDA approval of NUPLAZID in 2016. The royalty obligation terminated in October 2021 which was the primary reason for the decrease in cost of product sales during 2022 as compared to 2021.

Research and Development Expenses

Research and development expenses increased to $361.6 million in 2022, including $22.6 million in stock-based compensation expense, from $239.4 million in 2021, including $22.0 million in stock-based compensation expense. The increase in research and development expenses was mainly due to the $60 million upfront payment made to Stoke for the license and collaboration agreement and the $10 million milestone to Neuren in 2022 upon acceptance of the trofinetide NDA filing, as well as increased costs of our development activities for trofinetide, ACP-204 and other early-stage programs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased to $369.1 million in 2022, including $44.5 million in stock-based compensation expense, from $396.0 million in 2021, including $40.3 million in stock-based compensation expense. The decrease in selling, general and administrative expenses was primarily related to the continued reduction and optimization of commercial spend related to NUPLAZID, leading to a reduction in overall advertising and promotional costs, offset by investments in preparing for the launch of trofinetide.

Liquidity and Capital Resources

We have funded our operations primarily with revenues from sales of NUPLAZID and DAYBUE since their approvals, and through sales of our equity securities and interest income. We anticipate that the level of cash used in our operations will fluctuate in future periods depending on the levels of spending required for our ongoing and planned commercial activities for NUPLAZID and DAYBUE, our ongoing and planned development activities for pimavanserin for the negative symptoms of schizophrenia, ACP-101 as a treatment for Prader-Willi syndrome and ACP-204 as a treatment for ADP, studies to be conducted pursuant to our post-marketing commitments, our ongoing and planned development activities for other early-stage pipeline programs and strategic business development to further expand our portfolio. We expect that our cash, cash equivalents, and investment securities will be sufficient to fund our planned operations through and beyond the next 12 months.

We may require additional financing in the future to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of acquiring additional product candidates or research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones and other events or developments triggering payments under our collaboration or license agreements, or our collaborators' ability to make payments under these agreements;
- our ability to enter into new collaboration and license agreements;
- the progress in, and the costs of, our ongoing and planned development activities for pimavanserin, post-marketing studies for DAYBUE to be conducted over the next several years, and ongoing and planned commercial activities for NUPLAZID and DAYBUE;
- the costs of our development activities for our early-stage pipeline programs;
- the costs of commercializing NUPLAZID and DAYBUE, including the maintenance and development of our sales and marketing capabilities;
- the costs of establishing, or contracting for, sales and marketing capabilities for our product candidates;

- the amount of U.S. product sales from NUPLAZID and DAYBUE;
- the costs of preparing applications for regulatory approvals for DAYBUE in jurisdictions other than the U.S., for NUPLAZID in additional indications other than PDP and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing NUPLAZID and DAYBUE for commercial use in the U.S.;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, NUPLAZID for the negative symptoms of schizophrenia, or from DAYBUE, and our product candidates;
- the extent to which we are obligated to reimburse collaborators or collaborators are obligated to reimburse us for costs under collaboration agreements;
- the costs involved in filing, prosecuting, enforcing, and defending patent claims and other intellectual property rights;
- the costs of maintaining or securing manufacturing arrangements for clinical or commercial production of pimavanserin, trofinetide or other product candidates; and
- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to NUPLAZID or DAYBUE.

Unless and until we can generate significant cash from our operations, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, public or private sales of our securities, debt financings, or strategic collaborations. In the past, periods of turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. For example, due to geopolitical and macroeconomic developments, including the Ukraine-Russia military conflict and related sanctions, and the ongoing conflict in Israel and surrounding areas, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. These events, coupled with other factors, may limit our access to additional financing in the future. We cannot be certain that additional funding will be available to us on acceptable terms, or at all. If adequate funds are not available when needed, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. We also may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Additional funding, if obtained, may significantly dilute existing stockholders and could negatively impact the price of our stock.

We have invested a substantial portion of our available cash in money market funds, municipal bonds, and government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

Material Cash Requirements

Our material cash requirements in the short and long term consist of the operational, manufacturing, and capital expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with our current financial resources together with our anticipated receipts from product sales. On a long-term basis, we manage future cash requirements relative to our long-term business plans.

Our primary uses of cash and operating expenses relate to paying employees and consultants, administering clinical trials, marketing our products, and providing technology and facility infrastructure to support our operations. We also make investments in our office and laboratory facilities to enable continued expansion of our business.

As of December 31, 2023 we have long-term contractual obligations related to our operating leases of $66.5 million. In May 2023, we subleased our 2nd floor of corporate office space in San Diego with a total minimum sublease income of $18.4 million. In addition to operating leases, we enter into certain other long-term commitments for goods and services that are outstanding for periods greater than one year. We also enter into short-term agreements with various vendors and suppliers of goods and services in the normal course of operations through purchase orders or other documentation, or that are undocumented except for an invoice. Such short-term agreements are generally outstanding for periods less than a year and are settled by cash payments upon delivery of goods and services. The nature of the work being conducted under these agreements is such that, in most cases, the services may be stopped on short notice. In such event, we would not be liable for the full amount of the agreement.

We have entered into various collaboration, licensing and merger agreements which generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of net product sales, with rates that vary by agreement. As of December 31, 2023, we may be required to make milestone payments up to $3.4 billion in the aggregate. These payments are contingent upon achieving future development, regulatory and commercial milestones. We are also required to make royalty payments in connection with the sale of products developed under those agreements.

Cash Flows

At December 31, 2023, we had $438.9 million in cash, cash equivalents, and investment securities, compared to $416.8 million at December 31, 2022. This $22.1 million increase in cash, cash equivalents, and investment securities during 2023 was primarily due to net cash provided by operating activities and increased cash proceeds from the exercise of employee stock options.

Net cash provided by operating activities was $16.7 million in 2023 compared to net cash used in operating activities of $114.0 million in 2022 and $125.7 million in 2021. The increase in net cash provided by operating activities in 2023 relative to 2022 was primarily due to an increase in our net revenues and decreased research and development costs, partially offset by increased sales and marketing costs. The decrease in net cash used in operating activities in 2022 relative to 2021 was primarily due to an increase in our net revenues as well as decreased sales and marketing costs, partially offset by increased research and development costs.

Net cash provided by investing activities totaled $32.0 million in 2023 compared to net cash provided by investing activities of $73.2 million in 2022 and net cash used in investing activities of $71.1 million in 2021. The decrease in net cash provided by investing activities in 2023 compared to 2022 was primarily due to milestone payment of $40 million to Neuren and decreased net sale and maturities of investment securities. The increase in net cash provided by investing activities in 2022 compared to 2021 was primarily due to increased net maturities of investment securities.

Net cash provided by financing activities increased to $25.1 million in 2023 compared to $8.2 million in 2022 and $18.2 million in 2021. The increase in net cash provided by financing activities in 2023 relative to 2022 was primarily due to an increase in proceeds resulting from the exercise of employee stock options. The decrease in net cash provided by financing activities in 2022 relative to 2021 was primarily due to a decrease in proceeds resulting from the exercise of employee stock options.

Off-Balance Sheet Arrangements

To date, we have not had any relationships with unconsolidated entities or financial partnerships, such as entities referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not materially exposed to any financing, liquidity, market, or credit risk that could arise if we had engaged in these relationships.

Recent Accounting Pronouncements

See Item 15 of Part IV, “Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies.”

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Interest Rate Risk

We invest our excess cash in investment-grade, interest-bearing securities. The primary objective of our investment activities is to preserve principal and liquidity. To achieve this objective, we invest in money market funds. U.S. treasury notes, and high quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than one year. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. We do not have any direct investments in auction-rate securities or securities that are collateralized by assets that include mortgages or subprime debt. If a 10 percent change in interest rates were to have occurred on December 31, 2023 and 2022, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to our investment in investment-grade, interest-bearing securities, as of the date of this Annual Report on Form 10-K, we do not expect anticipated changes in interest rates to have a material effect on our interest rate risk in future reporting periods.

Item 8. ***Financial Statements and Supplementary Data.***

The consolidated financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

Item 9. ***Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.***

None.

Item 9A. ***Controls and Procedures.***

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2023, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2023.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision and with the participation of, our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act of 1934, as amended, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
Acadia Pharmaceuticals Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Acadia Pharmaceuticals Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Acadia Pharmaceuticals Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2023, and the related notes and the financial statement schedule listed in the Index at Item 15(a)2 and our report dated February 27, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2024

Item 9B. ***Other Information.***

Insider Trading Arrangements

During the Company's last fiscal quarter, the following officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) adopted or terminated a "Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K, as follows:

- On December 15, 2023, Stephen R. Davis, President and Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale of up to 370,000 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is from March 14, 2024 until July 15, 2024, or earlier if and when all transactions under the trading arrangement are completed.
- On December 15, 2023, Austin D. Kim, our former Executive Vice President, General Counsel and Secretary, adopted a Rule 10b5-1 trading arrangement providing for the sale of up to 10,000 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is from March 14, 2024 until June 14, 2024, or earlier if and when all transactions under the trading arrangement are completed.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.***

Not applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance*****.**

The information required by this Item and not set forth below will be set forth under the proposal captioned "Election of Directors" and the sections captioned "Information Regarding the Board of Directors and Corporate Governance," "Executive Officers" and "Delinquent Section 16(a) Reports," if any, in our definitive Proxy Statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC by April 29, 2024 (our "Proxy Statement") and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer or controller) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.acadia.com* under the Corporate Governance section of our Investors page. Information contained in our website does not constitute a part of this report or our other filings with the SEC. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics from our compliance department c/o Acadia Pharmaceuticals Inc., 12830 El Camino Real, Suite 400, San Diego, CA 92130.

Item 11. ***Executive Compensation*****.**

The information required by this Item will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated in this report by reference.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*****.**

The information required by this Item will be set forth in the section headed "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "Equity Compensation Plan Information" in our Proxy Statement and is incorporated in this report by reference.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence*****.**

The information required by this Item will be set forth in the section headed "Transactions With Related Persons" in our Proxy Statement and is incorporated in this report by reference.

Item 14. ***Principal Accountant Fees and Services*****.**

The information required by this Item will be set forth under the proposal captioned "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules.***

(a) Documents filed as part of this report.

1. The following financial statements of Acadia Pharmaceuticals Inc. and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in this report:

2. List of financial statement schedules:

Schedule II – Valuation and Qualifying Accounts

Schedules not listed above have been omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as Amended (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 6, 2015).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, filed February 25, 2021).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed September 12, 2013).
4.1	Form of common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to Registration Statement No. 333-52492).
4.2	Form of Amended and Restated Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K, filed February 26, 2019).
4.3	Description of the Registrant's Common Stock (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed February 27, 2020).
10.1[a]	Form of Indemnity Agreement for directors and officers (incorporated by reference to Exhibit 10.1 to Registration Statement No. 333-113137).
10.2[a]	2004 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.3 to Registration Statement No. 333-113137).
10.3[a]	2010 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-K, filed August 9, 2022).
10.4[a]	Forms of agreement under the 2010 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed February 29, 2016).

10.5[a]	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under Acadia Pharmaceuticals Inc. 2010 Equity Incentive Plan.
10.6[a]	2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed June 29, 2020).
10.7[a]	Offerings under the 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K, filed February 28, 2017).
10.8[a]	Employment Agreement, dated September 1, 2015, between the Registrant and Stephen Davis (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed September 3, 2015).
10.9[a]	Employment Offer Letter, dated June 26, 2018, between the Registrant and Brendan Teehan (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, filed March 1, 2022).
10.10[a]	Employment Offer Letter, dated July 2, 2018, between the Registrant and Austin D. Kim (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 6, 2018).
10.11[a]	Employment Offer Letter, dated April 28, 2020, between the Registrant and Mark Schneyer (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K, filed March 1, 2022).
10.12[a]	Employment Offer Letter, dated December 19, 2022, between the Registrant and Doug Williamson (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, filed February 28, 2023).
10.13[a]	Employment Offer Letter, dated January 12, 2024, between the Registrant and Jennifer Rhodes.
10.14[a]	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed June 29, 2020).
10.15[a]	Management Severance Benefit Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed December 15, 2015).
10.16[a]	Amended and Restated Change in Control Severance Benefit Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed December 15, 2015).
10.17[c]	Master Manufacturing Services Agreement and Product Agreement, dated August 3, 2015, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.18[c]	First Amendment to Product Agreement, dated April 25, 2016, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.19[c]	Second Amendment to Product Agreement, dated October 6, 2016, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.20[c]	Third Amendment to Product Agreement, dated December 11, 2017, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.21[c]	Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates, and Attachment #1, Attachment #2 and Attachment #3 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).
10.22[c]	Change Order #1 to Master Services Agreement Attachment #1, dated January 3, 2017, by and between Acadia Pharmaceuticals GmbH and Siegfried AG (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).
10.23[c]	Attachment #4, Attachment #5 and Attachment #6, each dated May 12, 2017, to the Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed November 3, 2022).
10.24[c]	Attachment #7, dated September 30, 2020, to the Master Services Agreement, dated December 15, 2016, by and between Acadia Pharmaceuticals GmbH and Siegfried AG and its affiliates (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly report on Form 10-Q, filed November 4, 2020).

10.25	Registration Rights Agreement, dated January 6, 2016, between the Registrant and the investors listed on Schedule A thereto (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed January 7, 2016).
10.26	Assignment of Brann Intellectual Property Rights, dated January 29, 1997, by Mark R. Brann in favor of the Registrant (incorporated by reference to Exhibit 10.17 to Registration Statement No. 333-52492).
10.27[b]	License Agreement, dated August 6, 2018, by and between the Registrant and Neuren Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, filed February 27, 2019).
10.28[b]	Lease Agreement, effective October 4, 2018, by and between the Registrant and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K, filed February 27, 2019).
10.29[c]	First Amendment to Office Lease, dated December 23, 2019, between the Registrant and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly report on Form 10-Q, filed May 8, 2020).
10.30[c]	Second Amendment to Office Lease, dated March 12, 2020, between the Registrant and Kilroy Realty, L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly report on Form 10-Q, filed May 8, 2020).
10.31[a]	Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.1 to Registration Statement No. 333-269611).
10.32[a]	Forms of Stock Option Grant Notice and Stock Option Agreement under Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.2 to Registration Statement No. 333-269611).
10.33[a]	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under Acadia Pharmaceuticals Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 99.3 to Registration Statement No. 333-269611).
10.34[c]	Lease Agreement, effective May 15, 2018, by and between the Registrant and Boston Properties Limited Partnership (incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K, filed February 28, 2023).
10.35[c]	Master Commercial Supply Agreement, dated November 16, 2022, by and between the Registrant and Corden Pharma Bergamo S.p.A.
10.36[c]	Commercial Supply Agreement, dated December 15, 2021, by and between the Registrant and F.I.S. Fabbrica Italiana Sintetici S.p.A.
10.37[c]	Product Agreement, effective May 1, 2022, by and between the Registrant and Patheon Pharmaceuticals Inc.
10.38[c]	Commercial Supply Agreement, dated March 1, 2023, by and between the Registrant and CoreRx Inc., as amended by Amendment No. 1, dated August 1, 2023.
10.39[c]	Joint Venture and License Agreement, dated July 13, 2023, by and between the Registrant and Neuren Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 3, 2023).
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31.1	Certification of Stephen Davis, Chief Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Mark Schneyer, Executive Vice President and Chief Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1[d]	Certification of Stephen Davis, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2[d]	Certification of Mark Schneyer, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Acadia Pharmaceuticals Inc. Dodd-Frank Clawback Policy.
101	The following financial statements from this Annual Report, formatted in iXBRL (Inline Extensible Business Reporting Language), are filed herewith: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Cash Flows, (v) Consolidated Statements of Stockholders' Equity, and (vi) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

[a] Indicates management contract or compensatory plan or arrangement.

[b] We have requested or received confidential treatment of certain portions of this agreement, which have been omitted and filed separately with the SEC pursuant to Rule 406 under the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[c] Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]" or "[…***…]") because the Company has determined that the information is both not material and is the type that the Company treats as private or confidential.

[d] The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

Item 16. ***Form 10-K Summary***

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACADIA PHARMACEUTICALS INC.

Date: February 27, 2024

/s/ STEPHEN R. DAVIS

Stephen R. Davis
Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Stephen R. Davis his true and lawful attorney-in-fact and agent, with full power of substitution, for him and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen R. Davis **Stephen R. Davis**	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2024
/s/ Mark C. Schneyer **Mark C. Schneyer**	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	February 27, 2024
/s/ James K. Kihara **James K. Kihara**	Vice President, Chief Accounting Officer and Controller (Principal Accounting Officer)	February 27, 2024
/s/ Stephen R. Biggar **Stephen R. Biggar**	Chairman of the Board	February 27, 2024
/s/ Julian C. Baker **Julian C. Baker**	Director	February 27, 2024
/s/ Laura A. Brege **Laura A. Brege**	Director	February 27, 2024
/s/ James M. Daly **James M. Daly**	Director	February 27, 2024
/s/ Elizabeth A. Garofalo **Elizabeth A. Garofalo**	Director	February 27, 2024
/s/ Edmund P. Harrigan **Edmund P. Harrigan**	Director	February 27, 2024
/s/ Adora Ndu **Adora Ndu**	Director	February 27, 2024
/s/ Daniel B. Soland **Daniel B. Soland**	Director	February 27, 2024

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
Acadia Pharmaceuticals Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Acadia Pharmaceuticals Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, cash flows and stockholders' equity for each of the three years in the period ended December 31, 2023, and the related notes and financial statement schedule listed in the Index at Item 15(a)2 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 27, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Medicare Part D sales rebate accruals

Description of the Matter	As described in Note 2 to the consolidated financial statements under the caption "Revenue Recognition" the Company establishes provisions for sales rebates and discounts in the same period as the related sales occur. Estimated sales rebates for the purchase of the product covered by Medicare Part D are included within accrued liabilities on the consolidated balance sheet. In order to establish these sales rebate accruals, the Company estimated its rebates based upon the identification of the product subject to a rebate, the historical and expected payor mix, the applicable price, rebate terms and the estimated lag time between the sale and payment of the rebate. Auditing the Medicare Part D sales rebate is complex because of the subjectivity of certain assumptions required to estimate the rebate liabilities and the amounts involved are material to the financial statements taken as a whole. In calculating the appropriate accrual amount, the Company considered historical Medicare Part D rebate payments as well as any significant changes in sales trends, the lag in payment timing, an evaluation of the current Medicare Part D laws and interpretations, the percentage of products that are sold via Medicare Part D, and product pricing. In deriving these estimates and assumptions, the Company used both internal and external sources of information to estimate product in the distribution channels, payor mix, prescription volumes and historical experience. Management supplemented its historical data analysis with qualitative adjustments based upon changes in rebate trends, rebate programs and contract terms, legislative changes, or other significant events which indicate a change in the reserve is appropriate.
How We Addressed the Matter in Our Audit	We obtained an understanding evaluated the design and tested the operating effectiveness of controls over the Company's sales rebate accruals for Medicare Part D rebates. This included testing controls over management's review of the significant assumptions described above and inputs into the rebate calculations. For example, we tested controls over actual sales and the accuracy of forecasting expected utilization and payor mix. The testing was inclusive of management's controls to evaluate the accuracy of its reserve judgments to actual rebates paid, rebate validation and processing, and controls to ensure that the data used to evaluate and support the significant assumptions was complete, accurate and, where applicable, verified to external data sources. To test the sales rebate accruals for Medicare Part D, our audit procedures included, among others, understanding and evaluating the significant assumptions and underlying data used in management's calculations. Our testing of significant assumptions included a lookback analysis to evaluate the historical accuracy of management's estimates by comparing actual rebates to previous estimates and performed sensitivity analyses over the subjective assumptions to evaluate the completeness of the reserves. As a part of our procedures, we evaluated the reasonableness of the Company's assumptions considering recent sales trends and regulatory factors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2015.

San Diego, California
February 27, 2024

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2023	**2022**
Assets		
Cash and cash equivalents	$ 188,657	$ 114,846
Investment securities, available-for-sale	250,208	301,977
Accounts receivable, net	98,267	62,195
Interest and other receivables	4,083	885
Inventory	35,819	6,636
Prepaid expenses	39,091	21,398
Total current assets	616,125	507,937
Property and equipment, net	4,612	6,021
Operating lease right-of-use assets	51,855	55,573
Intangible assets, net	65,490	—
Restricted cash	5,770	5,770
Long-term inventory	4,628	4,924
Other assets	476	7,587
Total assets	$ 748,956	$ 587,812
Liabilities and stockholders' equity		
Accounts payable	$ 17,543	$ 12,746
Accrued liabilities	236,711	112,884
Total current liabilities	254,254	125,630
Operating lease liabilities	47,800	52,695
Other long-term liabilities	15,147	9,074
Total liabilities	317,201	187,399
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 225,000,000 shares authorized at December 31, 2023 and 2022; 164,650,219 shares and 162,064,872 shares issued and outstanding at December 31, 2023 and 2022, respectively	16	16
Additional paid-in capital	2,862,552	2,770,923
Accumulated deficit	(2,430,837)	(2,369,551)
Accumulated other comprehensive income (loss)	24	(975)
Total stockholders' equity	431,755	400,413
Total liabilities and stockholders' equity	$ 748,956	$ 587,812

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Years Ended December 31,		
	2023	2022	2021
Revenues			
Product sales, net	$ 726,437	$ 517,235	$ 484,145
Total revenues	726,437	517,235	484,145
Operating expenses			
Cost of product sales	41,638	10,166	19,141
Research and development	351,619	361,575	239,415
Selling, general and administrative	406,559	369,090	396,028
Total operating expenses	799,816	740,831	654,584
Loss from operations	(73,379)	(223,596)	(170,439)
Interest income, net	17,234	6,610	591
Other income	5,109	3,542	2,329
Loss before income taxes	(51,036)	(213,444)	(167,519)
Income tax expense	10,250	2,531	351
Net loss	$ (61,286)	$ (215,975)	$ (167,870)
Net loss per common share, basic and diluted	$ (0.37)	$ (1.34)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	163,819	161,683	160,493

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Years Ended December 31,		
	2023	2022	2021
Net loss	$ (61,286)	$ (215,975)	$ (167,870)
Other comprehensive income (loss):			
Unrealized income (loss) on investment securities	1,017	(789)	(235)
Foreign currency translation adjustments	(18)	6	7
Comprehensive loss	$ (60,287)	$ (216,758)	$ (168,098)

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2023	2022	2021
Cash flows from operating activities			
Net loss	$ (61,286)	$ (215,975)	$ (167,870)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Stock-based compensation	66,421	68,201	63,615
Amortization of premiums and accretion of discounts on investment securities	(7,533)	(2,736)	2,404
Amortization of intangible assets	4,093	—	1,108
Gain on strategic investment	(5,109)	(3,542)	(2,329)
Depreciation	1,459	2,026	2,236
Loss on sale of investment securities	524	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(36,072)	2,171	(16,119)
Interest and other receivables	(3,198)	93	1,057
Inventory	(28,808)	2,415	(4,210)
Prepaid expenses and other current assets	(17,693)	2,494	1,802
Operating lease right-of-use assets	5,769	6,566	6,287
Other assets	(33)	(48)	10
Accounts payable	4,797	5,870	(1,617)
Accrued liabilities	93,170	24,306	(8,455)
Operating lease liabilities	(5,872)	(7,916)	(5,433)
Long-term liabilities	6,073	2,040	1,854
Net cash provided by (used in) operating activities	16,702	(114,035)	(125,660)
Cash flows from investing activities			
Purchases of investment securities	(369,985)	(363,174)	(492,797)
Sale and maturity of investment securities	429,780	436,415	422,817
Proceeds from sales of strategic investment	12,253	—	—
Net purchases of property and equipment	(50)	—	(1,122)
Intangible assets	(40,000)	—	—
Net cash provided by (used in) investing activities	31,998	73,241	(71,102)
Cash flows from financing activities			
Proceeds from issuance of common stock, net of issuance costs	25,129	8,199	18,162
Net cash provided by financing activities	25,129	8,199	18,162
Effect of exchange rate changes on cash	(18)	6	7
Net increase (decrease) in cash, cash equivalents and restricted cash	73,811	(32,589)	(178,593)
Cash, cash equivalents and restricted cash			
Beginning of year	120,616	153,205	331,798
End of year	$ 194,427	$ 120,616	$ 153,205
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 5,850	$ 2,190	$ 1,038
Supplemental disclosure of noncash information:			
Accrued milestone and contingent payments in connection with asset acquisition	$ 29,583	$ —	$ —

The accompanying notes are an integral part of these consolidated financial statements.

ACADIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	159,637,771	$ 16	$ 2,612,663	$ (1,985,706)	$ 36	$ 627,009
Issuance of common stock from exercise of stock options and units	1,078,074	—	12,850	—	—	12,850
Issuance of common stock pursuant to employee stock purchase plan	296,850	—	5,312	—	—	5,312
Net loss	—	—	—	(167,870)	—	(167,870)
Stock-based compensation	—	—	63,821	—	—	63,821
Other comprehensive loss	—	—	—	—	(228)	(228)
Balances at December 31, 2021	161,012,695	16	2,694,646	(2,153,576)	(192)	540,894
Issuance of common stock from exercise of stock options and units	721,652	—	3,705	—	—	3,705
Issuance of common stock pursuant to employee stock purchase plan	330,525	—	4,494	—	—	4,494
Net loss		—		(215,975)		(215,975)
Stock-based compensation	—	—	68,078	—	—	68,078
Other comprehensive loss	—	—			(783)	(783)
Balances at December 31, 2022	162,064,872	16	2,770,923	(2,369,551)	(975)	400,413
Issuance of common stock from exercise of stock options and units	2,236,849	—	20,309	—	—	20,309
Issuance of common stock pursuant to employee stock purchase plan	348,498	—	4,820	—	—	4,820
Net loss	—	—	—	(61,286)	—	(61,286)
Stock-based compensation	—	—	66,500	—	—	66,500
Other comprehensive income	—	—	—	—	999	999
Balances at December 31, 2023	164,650,219	$ 16	$ 2,862,552	$ (2,430,837)	$ 24	$ 431,755

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Business

Acadia Pharmaceuticals Inc. (the Company), based in San Diego, California, is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders and rare diseases.

In April 2016, the U.S. Food and Drug Administration (FDA) approved the Company's first drug, NUPLAZID® (pimavanserin), for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis (PDP). NUPLAZID became available for prescription in the United States in May 2016.

In March 2023, the FDA approved the Company's second drug, DAYBUE™ (trofinetide), for the treatment of Rett syndrome. DAYBUE became available for prescription in the United States in April 2023.

2. Summary of Significant Accounting Policies

Significant accounting policies followed in the preparation of these financial statements are as follows:

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity date at the date of purchase of three months or less to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in thousands).

	Twelve Months Ended December 31, 2023		Twelve Months Ended December 31, 2022	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 114,846	$ 188,657	$ 147,435	$ 114,846
Restricted cash	5,770	5,770	5,770	5,770
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 120,616	$ 194,427	$ 153,205	$ 120,616

Investment Securities

Currently, all of the Company's investment securities are debt securities. The Company has classified all of its investment securities as available-for-sale as the sale of such securities may be required prior to maturity to implement management strategies, and accordingly, carries these investments at fair value. Unrealized gains and losses, if any, are reported as a separate component of stockholders' equity. The cost of investment securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses, if any, are also included in interest income. The cost of securities sold is based on the specific identification method.

Fair Value of Financial Instruments

The carrying values of the Company's financial instruments, consisting of cash and cash equivalents, trade receivables, interest and other receivables, restricted cash, and accounts payable and accrued liabilities, approximate fair value due to the relative short-term nature of these instruments.

As disclosed in Note 4, the Company classifies its cash equivalents and available-for-sale investment securities within the fair value hierarchy as defined by authoritative guidance:

Level 1 Inputs — Quoted prices for identical instruments in active markets.

Level 2 Inputs — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.

Level 3 Inputs — Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and credit losses. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company adopted FASB Accounting Standards Codification 326-20, *Financial Instruments – Credit Losses* (ASC 326-20) as of January 1, 2020. The Company estimated the current expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about the collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. Based on its assessment, as of December 31, 2023, the Company determined that an allowance for credit loss was not required.

Inventory

Inventory is stated at the lower of cost or net realizable value under the first-in, first-out method (FIFO). The Company uses a combination of standard and actual costing methodologies to determine the cost basis for its inventories which approximates actual costs. Inventory consists of raw material, work in process, and finished goods, including third-party manufacturing costs, freight, and indirect overhead costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of NUPLAZID in April 2016 and DAYBUE and March 2023, all costs related to the manufacturing of NUPLAZID and DAYBUE were charged to research and development expense in the period incurred.

The Company periodically reviews inventory and reduces the carrying value of items to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. During the years ended December 31, 2023, 2022 and 2021, the Company recorded charges of $0.9 million, $0.6 million and $1.3 million, respectively, to reduce certain finished goods and work in process inventory to its net realizable value.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the lease by use of the straight-line method. Construction-in-process reflects amounts incurred for property, equipment or improvements that have not been placed in service. Maintenance and repair costs are expensed as incurred. When assets are retired or sold, the assets and accumulated depreciation are removed from the respective accounts and any gain or loss is recognized. Estimated useful lives by major asset category are as follows:

	Useful Lives
Machinery and equipment	5 to 7 years
Computers and software	3 years
Furniture and fixtures	10 years

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Through December 31, 2023, no such impairment losses have been recorded by the Company.

License Fees and Royalties

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

In connection with the FDA approval of NUPLAZID in April 2016, the Company made a one-time milestone payment of $8.0 million pursuant to its 2006 license agreement with the Ipsen Group in which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID. The Company capitalized the $8.0 million payment as an intangible asset and is amortizing the asset on a straight-line basis over the estimated useful life which ended during the year ended December 31, 2021. The Company recorded no amortization expense related to its intangible asset for the years ended December 31, 2023 and 2022 and recorded amortization expense of $1.1 million for the year ended December 31, 2021. As of December 31, 2021, the intangible asset was fully amortized.

In connection with the first commercial sale of DAYBUE in April 2023, the Company made a milestone payment of $40.0 million pursuant to its 2018 license agreement with Neuren, as disclosed in Note 9. The Company capitalized the $40.0 million payment as an intangible asset and began amortizing the asset in April 2023 on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded amortization expense related to this intangible asset of $2.4 million for the year ended December 31, 2023. As of December 31, 2023, estimated future amortization expense related to the Company's intangible asset was $3.1 million for each subsequent year.

Following the FDA approval of DAYBUE, the Company was granted a Rare Pediatric Disease Priority Review Voucher (PRV). Pursuant to the license agreement, the Company is required to pay Neuren one third of the value of the PRV at the time of sale or use of the PRV. If the PRV is sold, the amount to be paid will be the sale value net of applicable fees. If the PRV is not sold but used by the Company, the amount to be paid will be the average price of the three most recent publicly announced sales of Rare Pediatric Disease PRVs immediately preceding the issuance of the PRV to the Company. The Company capitalized the $29.6 million for the estimated PRV value owed to Neuren as an intangible asset and began amortizing it in April 2023 on a straight-line basis over the estimated useful life of the licensed patents through early 2036. The Company recorded amortization expense related to this intangible asset of $1.7 million for the year ended December 31, 2023. As of December 31, 2023, estimated future amortization expense related to the Company's intangible asset was $2.3 million for each subsequent year.

Royalties incurred in connection with the Company's license agreement with Neuren, as disclosed in Note 9, are expensed to cost of product sales as revenue from product sales is recognized.

Intangible Assets

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If such intangible assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of intangible the assets exceeds the estimated fair value of the intangible assets. No impairment loss was recorded on intangible assets during the years ended December 31, 2023 or 2022.

Acquisitions

The Company accounts for acquisitions of an asset or group of similar identifiable assets that do not meet the definition of a business as asset acquisition using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of their relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets acquired in an asset acquisition for use in research and development activities which have no alternative future use are expensed as in-process research and development on the acquisition date. Intangible assets acquired for use in research and development activities which have an alternative future use are capitalized as in-process research and development. Future costs to develop these assets are recorded to research and development expense as they are incurred. Contingent milestone payments associated with asset acquisitions are recognized when probable and estimable. These amounts are expensed to research and development if there is no alternative future use associated with the asset, or capitalized as an intangible asset if alternative future use of the asset exists.

Advertising Expense

Advertising costs are expensed when services are performed or goods are delivered. The Company incurred $9.4 million, $5.5 million and $41.8 million in advertising costs during the years ended December 31, 2023, 2022 and 2021, respectively. No advertising costs were capitalized as prepaid expenses at December 31, 2023 or 2022.

Revenue Recognition

The Company operates in one business segment. Results of its operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Revenues consist of net product sales to customers, all of which are sales in the U.S. Revenues by product are as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
NUPLAZID	$ 549,248	$ 517,235	$ 484,145
DAYBUE	177,189	—	—
Product sales, net	$ 726,437	$ 517,235	$ 484,145

Product Sales, Net

The Company accounts for contracts with its customers in accordance with *Revenue from Contracts with Customers (Topic 606)*. The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Payment terms differ by customer, but typically range from 31 to 35 days from the date of shipment. Revenue for the Company's product sales has not been adjusted for the effects of a financing component as the Company expects, at contract inception, that the period between when the Company transfers control of the product and when the Company receives payment will be one year or less.

The Company's product sales, net consist of U.S. sales of NUPLAZID and DAYBUE. NUPLAZID was approved by the FDA in April 2016 and the Company commenced shipments of NUPLAZID to SPs and SDs in late May 2016. SPs dispense product to a patient based on the fulfillment of a prescription and SDs sell product to government facilities, long-term care pharmacies, or in-patient hospital pharmacies. DAYBUE was approved by the FDA in March 2023 and the Company commenced shipments of DAYBUE to a single wholesale distributor in April 2023. Product shipping and handling costs are included in cost of product sales.

The Company recognizes revenue from product sales at the net sales price (the "transaction price") which includes estimates of variable consideration for which reserves for sales discounts and allowance are established and reflects each of these as either a reduction to the related account receivable or as an accrued liability, depending on how the amount payable is settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which the Company is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from estimates, the Company may need to adjust its estimates, which would affect net revenue in the period of adjustment. The following are the Company's significant categories of sales discounts and allowances:

Distribution Fees: Distribution fees include distribution service fees paid to the SPs, SDs and wholesale distributor based on a contractually fixed percentage of the wholesale acquisition cost (WAC), fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates, estimated payor mix, and expected utilization. The Company's estimates for expected utilization of rebates are based on historical data received from the SPs, SDs and single wholesale distributor since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates still estimated to be incurred. Allowances for rebates also include amounts due under the Inflation Reduction act of 2022 for Medicare Part D unit sales with applicable period AMP increases that outpace inflation over the benchmark period. The applicable period will be twelve months on October 1 of each year, with the initial applicable period beginning on October 1, 2022. The benchmark period AMP price is January 1, 2021 through September 30, 2021. The Company's estimates are based Medicare Part D sales as a percentage of gross sales and the rate AMP for the current period will be in excess the benchmark period.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual terms.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate for product returns, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

Research and Development Expenses

Research and development expenses are charged to operations as incurred. Research and development expenses include costs associated with services provided by contract organizations for preclinical development, pre-commercialization manufacturing expenses, and clinical trials, salaries and related personnel expenses including stock-based compensation expense, and facilities and equipment expenses. The upfront consideration and transaction costs associated with acquired in-process research and development are also included in the research and development expenses.

The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. When the Company makes payments in advance of services being provided, it records those amounts as prepaid expenses on its consolidated balance sheets and expense them as the services are rendered. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known, the Company adjusts its accruals accordingly.

Concentration Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, investment securities, accounts receivable, and restricted cash. The Company invests its excess cash primarily in money market funds, U.S. treasury notes, and high quality, marketable debt instruments of corporations and government sponsored enterprises in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's. Further, the Company specifies credit quality standards for its customers that are designed to limit the Company's credit exposure to any single party.

The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of NUPLAZID and DAYBUE for commercial use and for the production of its product candidates for clinical trials. For the production of NUPLAZID, the Company has contracts in place with two third-party manufacturers of commercial drug product and one third-party manufacturer of drug substance that is approved for the production of NUPLAZID API. For the production of DAYBUE, the Company has contracts in place with two third-party manufacturers of commercial drug product and two third-party manufacturers of drug substance that is approved for the production of DAYBUE API. Although there are potential sources of supply other than the Company's existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

The Company has entered into agreements for the distribution of NUPLAZID with a limited number of SPs and SDs, and all of the Company's product sales of NUPLAZID are to these customers. The Company has also entered into agreements for the distribution of DAYBUE with a single wholesale distributor, and all of the Company's product sales of DAYBUE and accounts receivable balance at December 31, 2023 are related to this customer.

For the year ended December 31, 2023, the Company's four largest customers, including the single wholesale distributor, represented approximately 69% of the Company's product revenue and 73% of the Company's accounts receivable balance at December 31, 2023. For the year ended December 31, 2022, the Company's four largest customers represented approximately 73% of the Company's product revenue and 74% of the Company's accounts receivable balance at December 31, 2022.

Stock-Based Compensation

The fair value of each employee stock option and each employee stock purchase right granted is estimated on the grant date under the fair value method using the Black-Scholes valuation model. The estimated fair value of each stock option and purchase right is then expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The following weighted-average assumptions were used during these periods:

	Years Ended December 31,		
	2023	2022	2021
Stock Options:			
Expected volatility	66%	68%	64%
Risk-free interest rate	3.9%	2.9%	0.9%
Expected dividend yield	0%	0%	0%
Expected life of options in years	5.4	5.4	5.4

	Years Ended December 31,		
	2023	2022	2021
Employee Stock Purchase Plan:			
Expected volatility	40%-67%	62%-82%	49%-100%
Risk-free interest rate	4.0%-5.3%	1.5%-4.6%	0.0%-0.5%
Expected dividend yield	0%	0%	0%
Expected life in years	0.5-2.0	0.5-2.0	0.5-2.0

Expected Volatility. The Company considers its historical volatility and implied volatility when determining the expected volatility.

Risk-Free Interest Rate. The Company determines its risk-free interest rate assumption based on the U.S. Treasury yield for obligations with contractual terms similar to the expected term of the stock option or purchase right being valued.

Expected Dividend Yield. The Company has never paid any dividends and currently has no plans to do so.

Expected Life. In determining the expected life for stock options, the Company considers, among other factors, its historical exercise experience to date as well as the mean time remaining to full vesting of all outstanding options and the mean time remaining to the end of the contractual term of all outstanding options. The estimated life for the Company's employee stock purchase rights is based upon the terms of each offering period.

Forfeitures. The Company recognizes forfeitures as they occur.

The fair value of restricted stock units (RSUs) is estimated based on the closing market price of the Company's common stock on the date of grant. RSUs generally vest over a four-year period. Certain RSUs also have an accelerated vesting clause based on specified market condition target and continued employment through a minimum vesting period. The fair value of RSUs expected to vest are recognized and amortized on a straight-line basis over the requisite service period, which is generally the vesting period. For those RSUs requiring satisfaction of both market and service conditions, the requisite service period is the longest of the explicit, implicit and derived service periods. The fair value of performance-based stock units (PSUs) is estimated based on the closing market price of the Company's common stock on the date of grant. PSUs vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these PSUs is recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable. During the year ended December 31, 2021, the Company had a change in estimate related to the achievement of certain performance-based criteria for performance-based stock awards which resulted in a reduction in stock-based compensation expenses by approximately $6.8 million.

The table below summarizes the total stock-based compensation expense included in the Company's consolidated statements of operations for the periods presented (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Cost of product sales	$ 1,007	$ 1,106	$ 1,286
Research and development	17,408	22,580	21,969
Sales, general and administrative	48,006	44,515	40,360
	$ 66,421	$ 68,201	$ 63,615

Income Taxes

Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future tax benefit to be derived from tax credits and loss carryforwards. Deferred income tax expense or benefit represents the net change during the year in the deferred income tax asset or liability. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes the impact of a tax position in the financial statements only if that position is more likely than not to be sustained upon examination by taxing authorities, based on the technical merits of the position. Any interest and penalties related to uncertain tax positions will be reflected in income tax expense.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, employee stock purchase rights, RSUs, and PSUs are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be antidilutive. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at December 31, 2023, 2022 and 2021, stock options, employee stock purchase plan rights, RSUs and PSUs covering a total of approximately 21,264,000 shares, 21,185,000 shares and 17,535,000 shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

Segment Reporting

The Company uses "the management approach" in determining reportable operating segments. The management approach considers the internal organization and reporting used by the Company's chief operating decision maker for making operating decisions and assessing performance as the source for determining the Company's reportable segments. The Company's chief operating decision maker is the chief executive officer who reviews operating results to make decisions about allocating resources and assessing performance for the entire Company. Management has determined that the Company operates in one business segment which is the development and commercialization of innovative medicines. All revenues for the years ended December 31, 2023, 2022 and 2021 were generated from customers in the United States.

Recently Issued Accounting Standards

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, *Segment Reporting*. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

3. Investments

The carrying value and amortized cost of the Company's investments, summarized by major security type, consisted of the following (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 75,315	$ 47	$ (28)	$ 75,334
Government sponsored enterprise securities	174,867	119	(112)	174,874
	$ 250,182	$ 166	$ (140)	$ 250,208

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury notes	$ 15,956	$ —	$ (11)	$ 15,945
Government sponsored enterprise securities	81,216	16	(291)	80,941
Municipal bonds	20,873	—	(98)	20,775
Commercial paper	184,923	30	(637)	184,316
	$ 302,968	$ 46	$ (1,037)	$ 301,977

The Company has classified all of its available-for-sale investment securities, including those with maturities beyond one year, as current assets on its consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of December 31, 2023 and 2022, all of the Company's available-for-sale investment securities have contractual maturity dates of less than one year. The Company has classified all equity securities as other assets on its consolidated balance sheets.

At December 31, 2023 and 2022, the Company had 21 and 43 securities, respectively, in an unrealized loss position. The following table presents gross unrealized losses and fair value for those available-for-sale investments that were in an unrealized loss position as of December 31, 2023 and December 31, 2022, aggregated by investment category and length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2023						
U.S. Treasury notes	$ 41,366	$ (28)	$ —	$ —	$ 41,366	$ (28)
Government sponsored enterprise securities	108,587	(112)	—	—	108,587	(112)
Total	$ 149,953	$ (140)	$ —	$ —	$ 149,953	$ (140)
December 31, 2022						
U.S. Treasury notes	$ 15,945	$ (11)	$ —	$ —	$ 15,945	$ (11)
Government sponsored enterprise securities	58,254	(291)	—	—	58,254	(291)
Municipal bonds	20,775	(98)	—	—	20,775	(98)
Commercial paper	135,200	(637)	—	—	135,200	(637)
Total	$ 230,174	$ (1,037)	$ —	$ —	$ 230,174	$ (1,037)

During the first quarter of 2023, the Company made a sale of all of its investments in commercial paper. The proceeds from sales of these securities were $183.0 million and net realized losses from the related sales were $0.5 million. There were no other sales of available-for-sale investment securities in prior periods.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions.

The Company does not intend to sell the investment in unrealized loss position and it is unlikely that the Company will be required to sell the investment before the recovery of its amortized cost basis. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at December 31, 2023.

4. Fair Value Measurements

The Company's investments include cash equivalents, available-for-sale investment securities consisting of money market funds, U.S. treasury notes, and marketable debt instruments of corporations and government sponsored enterprises in accordance with the Company's investment policy, and equity investments. The Company's investment policy defines allowable investment securities and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least Aa3/AA- or better, or P-1/A-1 or better, as determined by Moody's Investors Service or Standard & Poor's.

The Company's cash equivalents, available-for-sale investment securities, and equity securities are classified within the fair value hierarchy as defined by authoritative guidance. The Company's investment securities and equity securities classified as Level 1 are valued using quoted market prices. The Company obtains the fair value of its Level 2 financial instruments from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable. The Company validates the prices provided by the third-party pricing services by reviewing their pricing methods and matrices and obtaining market values from other pricing sources. After completing the validation procedures, the Company did not adjust or override any fair value measurements provided by these pricing services as of December 31, 2023 and 2022, respectively.

In November 2021, the Company established a plan whereby substantially all full-time employees excluding executive management are eligible to receive a series of cash bonuses based on achievement of certain conditions as described in more detail in Note 6 to the consolidated financial statements. The Company estimated the fair value of the cash awards using a Monte Carlo simulation, which utilizes level 3 inputs such as volatility, probabilities of success, and other inputs that are not observable in active markets. The cash awards are required to be measured at fair value on a recurring basis each reporting period, with changes in the fair value recognized as compensation cost over the derived service period of the awards.

The Company has not transferred any investment securities between the classification levels.

The recurring fair value measurements of the Company's cash equivalents, available-for-sale investment securities, and equity securities at December 31, 2023 and 2022 consisted of the following (in thousands):

		Fair Value Measurements at Reporting Date Using		
	December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund	$ 64,586	$ 64,586	$ —	$ —
U.S. Treasury notes	75,334	75,334	—	—
Government sponsored enterprise securities	174,874	—	174,874	—
Total	$ 314,794	$ 139,920	$ 174,874	$ —
Liabilities				
Cash awards	$ 4,506	$ —	$ —	$ 4,506
Total	$ 4,506	$ —	$ —	$ 4,506

		Fair Value Measurements at Reporting Date Using		
	December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market fund	$ 72,578	$ 72,578	$ —	$ —
U.S. Treasury notes	15,945	15,945	—	—
Equity securities	7,180	7,180	—	—
Government sponsored enterprise securities	94,803	—	94,803	—
Municipal bonds	20,775	—	20,775	—
Commercial paper	184,316	—	184,316	—
Total	$ 395,597	$ 95,703	$ 299,894	$ —
Liabilities				
Cash awards	$ 898	$ —	$ —	$ 898
Total	$ 898	$ —	$ —	$ 898

Changes in estimated fair value of contingent cash awards during the twelve months ended December 31, 2023 are as follows (in thousands):

Balance as of December 31, 2022	$ 898
Vesting of awards	772
Expense forfeited	(128)
Change in fair value	2,964
Balance as of December 31, 2023	$ 4,506

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

	December 31,	
	2023	2022
Finished goods	$ 5,001	$ 1,926
Work in process	4,134	4,427
Raw material	31,312	5,207
	$ 40,447	$ 11,560
Reported as:		
Inventory	$ 35,819	$ 6,636
Long-term inventory	4,628	4,924
Total	$ 40,447	$ 11,560

Amount reported as long-term inventory consisted of raw materials as of December 31, 2023 and 2022. The Company has raw materials beyond its one-year production plan that prevent the Company from potential supply interruption. Those raw materials maintained beyond the one-year production plan are classified as long-term inventory.

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2023	2022
Computers and software	$ 5,873	$ 5,873
Leasehold improvements	3,746	3,696
Furniture and fixtures	4,549	4,549
	14,168	14,118
Accumulated depreciation	(9,556)	(8,097)
	$ 4,612	$ 6,021

Depreciation of property and equipment was $1.5 million, $2.0 million, and $2.2 million for the years ended December 31, 2023, 2022, and 2021, respectively. For the year ended December 31, 2023, the Company did not retire any fully depreciated property and equipment. For the year ended December 31, 2022, the Company retired $0.1 million of fully depreciated property and equipment. During 2021, the Company did not retire any fully depreciated property and equipment.

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued sales allowances	$ 90,718	$ 26,046
Accrued compensation and benefits	42,718	28,023
Accrued research and development services	32,883	35,048
Accrued contingent payments	29,583	—
Accrued consulting and professional fees	18,804	11,377
Current portion of lease liabilities	9,405	9,305
Accrued taxes	1,564	377
Other	11,036	2,708
	$ 236,711	$ 112,884

6. Stockholders' Equity

Equity Awards

The Company's 2010 Equity Incentive Plan, as amended to date (the 2010 Plan), permits the grant of options to employees, directors and consultants. In addition, the 2010 Plan permits the grant of stock bonuses, rights to purchase restricted stock, and other stock awards. The exercise price of options granted under the 2010 Plan cannot be less than 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option is 10 years. Options granted under the 2010 Plan generally vest over a four-year period. All shares that remained eligible for grant under the Company's 2004 Equity Incentive Plan (the 2004 Plan) at the time of approval of the 2010 Plan were transferred to the 2010 Plan. The 2010 Plan share reserve also has been, and may be, increased by the number of shares that otherwise would have reverted to the 2004 Plan reserve after June 2010. In June 2015, June 2016, June 2017, June 2018, June 2019 and June 2022, the Company's stockholders approved amendments to its 2010 Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the plan by 5,000,000 shares, 3,000,000 shares, 5,500,000 shares, 6,700,000 shares, 8,300,000 shares and 6,000,000 shares, respectively. At December 31, 2023, there were 30,490,486 shares of common stock authorized for issuance, of which 7,731,848 shares were available for new grants under the 2010 Plan.

Stock Options

The 2010 Plan provided for the grant of options to employees, directors and consultants. The exercise price of options granted under the 2010 Plan was at 100 percent of the fair market value of the common stock on the date of grant and the maximum term of any option was 10 years. Options granted under the 2010 Plan generally vested over a four-year period.

The following table summarizes the Company's stock option activity during the year ended December 31, 2023:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	16,339,465	$ 29.83		
Granted	3,157,634	$ 21.99		
Exercised	(1,046,035)	$ 19.42		
Cancelled/forfeited	(1,825,035)	$ 32.07		
Outstanding at December 31, 2023	16,626,029	$ 28.75	5.6	$ 90,962
Vested and exercisable at December 31, 2023	11,152,607	$ 31.12	4.2	$ 44,951
Unvested at December 31, 2023	5,473,422	$ 23.92	8.4	$ 46,012

The aggregate intrinsic value of options exercisable as of December 31, 2023 is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company's common stock on that date, which was $31.31 per share. The aggregate intrinsic value of options exercised during the years ended December 31, 2023, 2022, and 2021 was approximately $7.9 million, $1.7 million, and $8.0 million, respectively, determined as of the date of exercise. The Company received approximately $20.3 million, $3.7 million and $12.9 million in cash from options exercised during the years ended December 31, 2023, 2022 and 2021, respectively.

The weighted average per share fair value of options granted during the years ended December 31, 2023, 2022, and 2021 was approximately $13.25, $13.66, and $24.07, respectively. As of December 31, 2023, 2022 and 2021, total unrecognized compensation cost related to stock options was approximately $62.1 million, $63.9 million and $66.0 million, and the weighted average period over which this cost is expected to be recognized is approximately 2.6 years, 2.7 years and 2.3 years, respectively.

Restricted Stock

The Company grants RSUs and PSUs, both of which are considered restricted stock, pursuant to the 2010 Plan and satisfies such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of the Company's common stock. RSUs generally vest over a four-year period. Certain RSUs also have an accelerated vesting clause based on a specified market condition target and continued employment through the vesting period. PSUs for which the number of shares issuable at the end of performance period can reach up to 200% of the shares approved in the award based on the achievement of certain pre-defined Acadia-specific performance criteria and continued employment through the vesting period.

The following table summarizes the Company's restricted stock activity during the year ended December 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	4,187,107	$ 29.49	
Granted	1,960,482	$ 21.97	
Vested	(1,190,814)	$ 28.09	
Cancelled/forfeited	(571,030)	$ 28.23	
Outstanding at December 31, 2023	4,385,745	$ 26.67	$ 134,440

There were 1,734,828, 2,055,574 and 1,276,936 PSUs outstanding at December 31, 2023, 2022 and 2021, respectively, of which 484,757, 1,057,741 and 639,700 were related to the RSUs with an accelerated vesting clause based on a specified market condition target and continued employment through the vesting period. During the years ended 2023, 2022 and 2021, 517,290, 986,739, and 918,434 PSUs were granted, respectively, of which 459,420 were vested during the year ended December 31, 2023. There was no vesting during the years ended December 31, 2022 and 2021. During the years ended December 31, 2023, 2022 and 2021, total intrinsic value of PSUs outstanding was $50.0 million, $32.7 million and $29.8 million, respectively. Total unrecognized compensation cost related to RSUs was approximately $46.7 million, $44.6 million and $39.8 million for the years ended December 31, 2023, 2022 and 2021, respectively, and the weighted average period over which the cost is expected to be recognized is approximately 2.9 years, 2.7 years and 2.3 years, respectively. Total unrecognized compensation cost related to PSUs was approximately $5.7 million, $12.7 million and $11.5 million for the years ended December 31, 2023, 2022 and 2021, respectively, and the weighted average remaining contractual term related to outstanding PSUs was 3.2 years, 3.0 years and 3.3 years, respectively.

Employee Stock Purchase Plan

The Company's 2004 Employee Stock Purchase Plan (the Purchase Plan) became effective upon the closing of the Company's initial public offering in June 2004. In June 2016, June 2019 and June 2020, the Company's stockholders approved an amendment to the Purchase Plan to, among other things, increase the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 400,000 shares, 600,000 shares and 3,000,000 shares, respectively. At December 31, 2023, a total of 5,525,000 shares of common stock had been reserved for issuance under the Purchase Plan. At December 31, 2023, 2,131,122 shares of common stock remained available for issuance pursuant to the Purchase Plan. Eligible employees who elect to participate in an offering under the Purchase Plan may have up to 15 percent of their earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the Purchase Plan. The price of common stock purchased under the Purchase Plan is equal to 85 percent of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant purchase date.

During the years ended December 31, 2023, 2022, and 2021, a total of 348,498, 330,525 and 296,850 shares of common stock were issued under the Purchase Plan at average per share prices of $13.83, $13.60, and $17.89, respectively. The weighted average per share fair value of purchase rights granted during the years ended December 31, 2023, 2022, and 2021 was $22.25, $13.91, and $23.97, respectively. During the years ended December 31, 2023, 2022, and 2021, the Company recorded cash received from the exercise of purchase rights of $4.8 million, $4.5 million, and $5.3 million, respectively.

Contingent Cash Awards

In November 2021, the Company established a plan whereby substantially all full-time employees excluding executive management are eligible to receive a series of cash bonuses over certain periods based on continued employment and the Company's stock price reaching a pre-specified target. The maximum potential payout of the cash awards at the grant date was $15.1 million. The Company has determined that the cash awards were classified as liabilities pursuant to ASC Topic 718, *Compensation – Stock Compensation*. The Company estimates the fair value of the awards at each reporting period using the Monte Carlo simulation, which is recognized as compensation cost over the derived service period. Total fair value of the awards at the grant date was $4.4 million. The maximum potential payout at December 31, 2023 after adjusting for forfeitures was $10.1 million. The total fair value of the awards at December 31, 2023 was approximately $5.2 million, compared to $1.8 million at December 31, 2022. The estimated liability included on the December 31, 2023 and 2022 consolidated balance sheets was $4.5 million and $0.9 million. During years ended December 31, 2023 and 2022, the Company recorded a total of $3.6 million and $0.3 million compensation cost related to the awards.

2023 Inducement Plan

The Board adopted the Company's 2023 Inducement Plan (the Inducement Plan) on February 1, 2023. The Inducement Plan permits the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards and other stock-related awards. Stock awards granted under the Inducement Plan may only be made to individuals who did not previously serve as employees or non-employee directors of the Company or an affiliate of the Company. In addition, stock awards must be approved by either a majority of the Company's independent directors or the Compensation Committee. The terms of the Inducement Plan are otherwise substantially similar to the Company's 2010 Equity Incentive Plan. The maximum number of shares of Company common stock that may be issued under the Inducement Plan is 1,750,000 shares. At December 31, 2023, there were 599,864 shares available for new grants.

7. 401(k) Plan

Effective January 1997, the Company established a deferred compensation plan (the 401(k) Plan) pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended (the Code), whereby substantially all employees are eligible to contribute up to 60 percent of their pretax earnings, not to exceed amounts allowed under the Code. The Company makes discretionary contributions to the 401(k) Plan equal to 100 percent of each employee's pretax contributions up to 5 percent of his or her eligible compensation, subject to limitations under the Code. The Company's total contributions to the 401(k) Plan were $6.1 million, $5.1 million, and $5.8 million for the years ended December 31, 2023, 2022, and 2021, respectively.

8. Income Taxes

Domestic and foreign pre-tax income (loss) is as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Domestic	$ (100,215)	$ (233,216)	$ (138,913)
Foreign	49,179	19,772	(28,606)
	$ (51,036)	$ (213,444)	$ (167,519)

The income tax provision consists of the following (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Current provision:			
Federal	$ 5,440	$ —	$ —
State	4,805	2,531	351
Foreign	5	—	—
Total deferred tax assets	10,250	2,531	351
Total income tax provision	$ 10,250	$ 2,531	$ 351

At December 31, 2023, the Company had federal, state, and foreign net operating loss (NOL) carryforwards of approximately $196.8 million, $456.3 million, and $845.1 million, respectively. Utilization of the domestic NOL and research and development (R&D) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

The Company previously completed a study to assess whether an ownership change, as defined by Section 382 of the Code, had occurred from the Company's formation through December 31, 2013. Based upon this study, the Company determined that several ownership changes had occurred. Accordingly, the Company reduced its deferred tax assets related to the federal NOL carryforwards and the federal R&D credit carryforwards that are anticipated to expire unused as a result of these ownership changes. These tax attributes were excluded from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate. The Company completed a study through December 31, 2022 and concluded no additional ownership changes occurred. Future ownership changes may further limit the Company's ability to utilize its remaining tax attributes.

The Company had federal and state carryforwards of $29.4 million and $454.4 million that will begin to expire in 2031 and 2024 respectively unless utilized. The remaining federal and state NOL carryforwards of $167.4 million and $1.9 million will carry forward indefinitely. At December 31, 2023, the Company had federal and state charitable contribution carryforwards of $174.8 million which will begin to expire in 2024. At December 31, 2023, the Company had $75.6 million of federal R&D credit carryforwards, of which $0.5 million will expire in 2024 unless utilized, and the remaining federal R&D credit carryforwards will begin to expire beginning in 2025. At December 31, 2023, the Company had state R&D credit carryforwards of approximately $2.3 million that will begin to expire in 2025 and $20.3 million that have no expiration date. At December 31, 2023, the Company had foreign NOL carryforwards of $231.6 million that will expire in 2024 unless utilized and $6.5 million that have no expiration date. The Company continues to record the deferred tax assets related to these attributes, subject to valuation allowance, until expiration occurs.

The components of the deferred tax assets are as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets		
NOL carryforwards	$ 149,049	$ 225,993
R&D credit carryforwards	70,906	83,074
Capitalized R&D	90,164	38,507
Stock-based compensation	51,028	51,661
Charitable contributions	40,956	42,677
Lease liabilities	13,671	14,730
Intangibles	43,220	24,030
Property and equipment	51	—
Accrued rebates	19,401	5,748
Other	16,036	8,022
Total deferred tax assets	494,482	494,442
Valuation allowance	(482,089)	(481,210)
Deferred tax liabilities		
Property and equipment	—	(29)
Right-of-use assets	(12,393)	(13,203)
Total deferred tax liabilities	(12,393)	(13,232)
Total net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $0.9 million in 2023 primarily due to an increase in deferred tax assets generated by capitalization of research and development expenses, acquired intangibles and accrued rebates, offset in part by the utilization of US and state net operating losses and research credits, the expiration of Switzerland NOLs, and the remeasurement of the Company's deferred tax balance for future state tax rates.

An accounting policy may be selected to either (i) treat taxes due on future U.S. inclusions in taxable income related to global intangible low-taxed income (GILTI) as a current-period expense when incurred or (ii) factor such amounts into a company's measurement of its deferred taxes. The Company has elected to account for GILTI as a period cost.

A reconciliation of income taxes to the amount computed by applying the statutory federal income tax rate to the pretax loss is summarized as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Amounts computed at statutory federal rate	$ (10,718)	$ (44,823)	$ (35,179)
Stock-based compensation and other permanent differences	8,458	7,596	6,083
Branded pharmaceutical drug fee	1,848	1,454	613
Write-off of IP R&D	—	2,449	1,277
R&D credits	(5,827)	(9,974)	(11,727)
Change in valuation allowance	1,100	11,227	36,099
State taxes	(977)	(2,232)	(2,617)
Contingencies	(2,071)	6,993	3,879
Foreign rate differential	(5,076)	(1,971)	2,857
Deferred adjustments for limits on executive compensation	2,112	3,918	1,808
Deferred rate adjustment	(192)	922	(2,424)
Switzerland tax reform	(246)	—	(923)
Expiration of attributes	17,225	16,142	726
GILTI	7,665	10,804	—
Other	(3,051)	26	(121)
Income tax expense	$ 10,250	$ 2,531	$ 351

The tax years 2003-2022 remain open to examination by the major taxing jurisdictions to which the Company is subject.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination. The Company recorded an uncertain tax position reserve of $18.0 million, $5.1 million and $4.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. Due to the valuation allowance recorded against the Company's deferred tax assets, approximately $6.8 million and $1.2 million of the total unrecognized tax benefits as of December 31, 2023 and December 31, 2022, respectively, would reduce the annual effective tax rate if recognized. The Company does not anticipate that the amount of unrecognized tax benefits as of December 31, 2023 will significantly change within the next twelve months. The Company's practice is to recognize interest and/or penalties related to uncertain income tax positions in income tax expense. The Company had immaterial interest and/or penalties accrued on the Company's consolidated balance sheets at December 31, 2023 or 2022, respectively. Further, the Company recognized an insignificant amount of interest and/or penalties in the statement of operations for the years ended December 31, 2023, 2022 and 2021, respectively, related to uncertain tax positions.

The following table provides a reconciliation of changes in unrecognized tax benefits (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Balance at beginning of period	$ 19,064	$ 13,923	$ 9,843
Additions related to current period tax positions	5,304	5,140	3,973
Additions related to prior period tax positions	12,956	38	140
Reductions related to prior period tax positions	(212)	(37)	(33)
Balance at end of period	$ 37,112	$ 19,064	$ 13,923

9. Commitments and Contingencies

License and Merger Agreements

The Company has entered into various collaboration, licensing and merger agreements which provide the Company with rights to certain know-how, technology and patent rights. The agreements generally include upfront license fees, development and commercial milestone payments upon achievement of certain clinical and commercial development and annual net sales milestones, as well as royalties calculated as a percentage of product revenues, with rates that vary by agreement. The Company incurred $102.5 million, $88.7 million and $11.0 million in upfront and license payments in the years ended December 31, 2023, 2022 and 2021, respectively. These upfront and license payments were included in the research and development expenses in the consolidated statements of operations as there was no alternative future use associated with the payments. As of December 31, 2023, the Company may be required to make milestone payments up to $3.4 billion in the aggregate for candidates in its pipeline.

In May 2018, the Company signed an Exclusivity Deed (the Deed) with Neuren that provided for exclusive negotiations for a period of three months from the date of the Deed. Under the terms of the Deed, the Company invested $3.1 million to subscribe for 1,330,000 shares of Neuren and paid $0.9 million for the exclusive right to negotiate a deal with Neuren, which was recorded in selling, general and administrative expenses in the consolidated statements of operations in the second quarter of 2018. In 2023, the Company sold the 1,330,000 shares of Neuren for total proceeds of $12.3 million. Net gain on the strategic investments recognized in other income in the consolidated statements of operations for the year ended December 31, 2023, 2022 and 2021 was $5.1 million, $3.5 million and $2.3 million, respectively.

In August 2018, the Company entered into a license agreement with Neuren and obtained exclusive North American rights to develop and commercialize trofinetide for Rett syndrome and other indications. Under the terms of the agreement, the Company paid Neuren an upfront license fee of $10.0 million and it may be required to pay up to an additional $455.0 million in milestone payments based on the achievement of certain development and annual net sales milestones. In addition, the Company will be required to pay Neuren tiered, escalating, double-digit percentage royalties based on net sales. The license agreement was accounted for as an asset acquisition and the upfront cash payment of $10.0 million was expensed to research and development in the third quarter of 2018 as there is no alternative use for the asset. In connection with the FDA approval of DAYBUE, the Company paid a milestone payment of $40.0 million to Neuren following the first commercial sale of DAYBUE pursuant to the license agreement. The Company capitalized the $40.0 million milestone payment as an intangible asset as it was deemed probable of occurring as of March 31, 2023. In addition, the Company was granted a Rare Pediatric Disease PRV following the FDA approval of DAYBUE. Pursuant to the license agreement, the Company is required to pay Neuren one third of the value of the PRV at the time of sale or use of the PRV. The Company capitalized the $29.6 million for the estimated PRV value owed to Neuren as an intangible asset.

In July 2023, the Company expanded its licensing agreement for trofinetide with Neuren to acquire rights to the drug outside of North America as well as global rights in Rett syndrome and Fragile X syndrome to Neuren's development candidate NNZ-2591. Under the terms of the expanded agreement, Neuren received an upfront payment of $100.0 million and is eligible to receive up to an additional $426.3 million in milestone payments based on the achievement of certain commercial and sales milestones for trofinetide outside of North America and up to $831.3 million in milestone payments based on the achievement of certain development and sales milestones for NNZ-2591. In addition, the Company will be required to pay Neuren tiered royalties from the mid-teens to low-twenties percent of trofinetide net sales outside of North America. Percentage royalties related to NNZ-2591 net sales are identical to the trofinetide in each of North America and outside North America. The expanded license agreement was accounted for as an asset acquisition and the upfront cash payment of $100.0 million was expensed to research and development in the third quarter of 2023 as there is no alternative use for the asset.

In January 2022, the Company entered into a license and collaboration agreement with Stoke to discover, develop and commercialize novel RNA-based medicines for the potential treatment of severe and rare genetic neurodevelopmental diseases of the CNS. The collaboration includes SYNGAP1 syndrome, Rett syndrome (MECP2), and an undisclosed neurodevelopmental target. For the SYNGAP1 program, the two companies will jointly share global research, development and commercialization responsibilities and share 50/50 in all worldwide costs and future profits. In addition, Stoke is eligible to receive potential development, regulatory, first commercial sales and sales milestones. For the MECP2 program and the undisclosed neurodevelopmental program, the Company acquired an exclusive worldwide license to develop and commercialize MECP2 program and the undisclosed neurodevelopmental program. Stoke will lead research and pre-clinical

development activities, while the Company will lead clinical development and commercialization activities. The Company will fund research and pre-clinical development activities related to these two targets and Stoke is eligible to receive potential development, regulatory, first commercial sales and sales milestones as well as tiered royalty payments on worldwide sales starting in the mid-single digit range and escalating to the mid-teens based on revenue levels. Under the terms of the agreement, the Company paid Stoke a $60.0 million upfront payment which was accounted for as an asset acquisition and was expensed to research and development in the first quarter of 2022 as there is no alternative use for the asset. The Company may be required to pay up to an additional $907.5 million in milestones as well as royalties on future sales.

Corporate Credit Card Program

In connection with the Company's credit card program, the Company established a letter of credit in 2016 for $2.0 million, which has automatic annual extensions and is fully secured by restricted cash.

Fleet Program

In connection with the Company's fleet program, the Company established a letter of credit for $0.4 million, which has automatic annual extensions and is fully secured by restricted cash.

Legal Proceedings

Patent Infringement

On July 24, 2020, the Company filed complaints against (i) Aurobindo Pharma Limited and its affiliate Aurobindo Pharma USA, Inc. and (ii) Teva Pharmaceuticals USA, Inc. and its affiliate Teva Pharmaceutical Industries Ltd., and on July 30, 2020, the Company filed complaints against (i) Hetero Labs Limited and its affiliates Hetero Labs Limited Unit-V and Hetero USA Inc., (ii) MSN Laboratories Private Ltd. and its affiliate MSN Pharmaceuticals, Inc., and (iii) Zydus Pharmaceuticals (USA) Inc. and its affiliate Cadila Healthcare Limited. These complaints, which were filed in the United States District Court for the District of Delaware, allege infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID (Pimavanserin I Cases). The cases have been assigned to the Honorable Richard G. Andrews. On September 1, 2020, Aurobindo filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 22, 2020, the Company filed its answer to Aurobindo's counterclaims. On August 31, 2020, Teva filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On September 21, 2020, the Company filed its answer to Teva's counterclaims. On October 5, 2020, Hetero filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On October 26, 2020, the Company filed its answer to Hetero's counterclaims. On September 30, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On November 5, 2020, the Company filed its first amended complaint against MSN in the United States District Court for the District of Delaware, alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID. On November 19, 2020, MSN filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On December 10, 2020, the Company filed its answer to MSN's counterclaims. On November 2, 2020, Zydus filed its answer and counterclaims seeking declaratory judgments of noninfringement and invalidity. On November 23, 2020, the Company filed its answer to Zydus's counterclaims. On December 8, 2020, the parties' joint proposed scheduling order was entered by Judge Andrews. On April 7, 2021, the Company filed its first amended complaints against Hetero and Teva and its second amended complaint against MSN, to include an additional Orange Book-listed patent covering NUPLAZID. On April 8, 2021, the Company filed its first amended complaint against Zydus and on April 9, 2021, the Company filed its first amended complaint against Aurobindo. On April 20, 2021, MSN filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On April 21, 2021, Teva filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On April 22, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity.

On April 22, 2021, Aurobindo filed its answer, affirmative defenses, and counterclaims to the Company's first amended complaint, seeking declaratory judgments of noninfringement and invalidity. On May 11, 2021, the Company filed its answer to MSN's counterclaims. On May 12, the Company filed its answer to Teva's counterclaims. On May 13, the Company filed its answer to Zydus's counterclaims and its answer to Aurobindo's counterclaims. The Company entered into an agreement effective April 22, 2021 with Hetero settling all claims and counterclaims in the litigation. The agreement allows Hetero to launch its generic pimavanserin product on February 27, 2038, subject to certain triggers for earlier launch. The Hetero case was dismissed by joint agreement on May 3, 2021.

On August 27, 2021, the Company filed its second amended complaint against Zydus to include an additional Orange Book-listed patent covering NUPLAZID. On September 10, 2021, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity. Also on September 10, 2021, the parties filed their Joint Claim Construction Chart. On October 1, 2021, the Company filed its answer to Zydus's counterclaims. On November 30, 2021, the Company filed a stipulation and proposed order to dismiss two of its Orange Book-listed patents covering NUPLAZID against Teva, which was ordered by the Court on December 1, 2021. On January 28, 2022, the parties filed their Joint Claim Construction Brief and Appendix. On February 23, 2022, the Court heard oral argument on claim construction. On April 6, 2022, the Court issued a Memorandum Opinion construing several terms at issue, adopting the Company's construction on two terms, Defendants' construction on two terms, and one agreed-upon construction. On February 28, 2022, the Company filed a stipulation and proposed order to dismiss one patent against MSN, which was ordered by the Court on March 1, 2022. On March 10, 2022, the Company filed a stipulation and proposed order to dismiss one patent against Teva, which was ordered by the Court on March 10, 2022. On March 22, 2022, the Company filed a stipulation and proposed order to dismiss seven patents against Aurobindo, which was ordered by the Court on March 22, 2022. On March 30, 2022, the Company filed a stipulation and proposed order to dismiss two patents against Zydus, which was ordered by the Court on March 31, 2022. On April 22, 2022, the Company filed a stipulation and proposed order of non-infringement against Aurobindo regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 22, 2022. On April 26, 2022, the Company filed a stipulation and proposed order of non-infringement against MSN regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 26, 2022. On April 26, 2022, the Company filed a stipulation and proposed order of non-infringement against Teva regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on April 27, 2022. On May 10, 2022, the Company filed its second amended complaint against Teva to include an additional Orange Book-listed patent covering NUPLAZID. On May 18, 2022, the Company filed a stipulation and proposed order of non-infringement against Zydus regarding certain of the Company's Orange Book-listed patents covering NUPLAZID, which was ordered by the Court on May 19, 2022. On May 24, 2022, Teva filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 1, 2022, the Company filed its second amended complaint against Aurobindo alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 2, 2022, the Company filed its third amended complaint against Zydus alleging infringement of certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 14, 2022, the Company filed its answer to Teva's counterclaims. June 15, 2022, Aurobindo filed its answer, affirmative defenses, and counterclaims to the Company's second amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On June 16, 2022, Zydus filed its answer, affirmative defenses, and counterclaims to the Company's third amended complaint, seeking declaratory judgments of noninfringement and invalidity regarding certain of the Company's Orange Book-listed patents covering NUPLAZID. On July 6, 2022, the Company filed its answer to Aurobindo's counterclaims.

On September 7, 2022, the consolidated cases were reassigned to the Honorable Judge Gregory B. Williams. On September 30, 2022, the Company filed a stipulation and proposed order to stay the claims currently asserted against Teva and for Teva to be bound by the result of the litigation rendered against the remaining Defendants, which was ordered by the Court on October 4, 2022. On October 21, 2022, the Company filed complaints against Aurobindo, MSN and Zydus in the United States District Court for the District of Delaware alleging infringement of an additional Orange Book-listed patent covering NUPLAZID (Pimavanserin II Cases).

On March 29, 2023, following Aurobindo's conversion of various patent certifications from Paragraph IV certifications to Paragraph III certifications in connection with the Pimavanserin I Case, the Company filed a stipulation and proposed order in the Pimavanserin I Case to dismiss the remaining asserted patents against Aurobindo. This stipulation was ordered by the Court on March 30, 2023.

The Company entered into an agreement, effective March 31, 2023, with Zydus settling all claims and counterclaims in the Pimavanserin I Cases and Pimavanserin II Cases. The agreement allows Zydus to launch its generic pimavanserin 10 mg products on September 23, 2036 and 34 mg products on February 27, 2038, subject to certain triggers for earlier launch. On April 4, 2023, the Company filed a stipulation and proposed order to dismiss all claims and counterclaims between the Company and Zydus in the Pimavanserin I Cases and Pimavanserin II Cases, which was ordered by the Court on April 5, 2023.

As a result of the above, only MSN remained as an active defendant in the Pimavanserin I Cases. On April 6, 2023, the Company and MSN filed a stipulation and proposed order requesting adjournment of the final pre-trial conference and trial, and requesting resolution of the remaining issue – MSN's validity challenge of the sole patent in suit – through summary judgment briefing by the parties, which was ordered by the Court on April 10, 2023. Briefing was completed on June 28, 2023 and oral argument took place on September 27, 2023. On December 13, 2023, the Court ruled in the Company's favor on the summary judgment motions – denying MSN's motion for summary judgment of invalidity and granting the Company's cross-motion for no invalidity. MSN had previously stipulated to infringement of the patent-in-suit. On January 11, 2024, the District Court entered final judgment in the Company's favor that MSN's submission of ANDA No. 214925 was an act of infringement in the Pimavanserin I Case. On January 18, 2024, MSN filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit from the December 13, 2023 Memorandum Order of the United States District Court for the District of Delaware, and final judgment entered on January 11, 2024. On February 12, 2024, the Company filed an Entry of Appearance for the appeal to the United States Court of Appeals for the Federal Circuit. MSN's Opening Appeal Brief is due on March 29, 2024.

In connection with the Pimavanserin II cases, MSN and Aurobindo are the remaining defendants. On December 13, 2023, the Court issued a claim construction order finding in favor of the Company on all disputed terms of the patent-in-suit. Fact discovery closes on March 21, 2024. Trial is scheduled in the matter for December 3, 2024 to December 5, 2024.

Securities Class Action

On April 19, 2021, a purported stockholder of the Company filed a putative securities class action complaint (captioned Marechal v. Acadia Pharmaceuticals, Inc., Case No. 21-cv-0762) in the U.S. District Court for the Southern District of California against the Company and certain of the Company's current executive officers. On September 29, 2021, the Court issued an order designating lead plaintiff and lead counsel. On December 10, 2021, lead plaintiff filed an amended complaint. The amended complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to disclose that the materials submitted in support of its sNDA seeking approval of pimavanserin for the treatment of hallucinations and delusions associated with dementia-related psychosis contained statistical and design deficiencies and that the FDA was unlikely to approve the sNDA in its current form. The amended complaint seeks unspecified monetary damages and other relief. Defendants filed a motion to dismiss the amended complaint on February 15, 2022. On September 27, 2022, the Court issued an order denying Defendants' motion to dismiss. Defendants filed their answer to the amended complaint on October 19, 2022, and filed a motion for reconsideration on October 25, 2022. On February 2, 2023, the Court issued an order denying the motion for reconsideration. On August 21, 2023, plaintiffs filed a motion for class certification. Briefing on that motion concluded on January 12, 2024, and the Court will hear oral argument on the motion on February 28, 2024. The parties are currently engaged in discovery. The cutoff for fact discovery is June 13, 2024.

Derivative Suit

On December 15, 2023, a purported stockholder of the Company filed a derivative action (captioned *Kanner et al v. Biggar et al.*, Case No. 23-cv-2293) in the U.S. District Court for the Southern District of California against certain of the Company's current directors. The Company is named as a nominal defendant. The complaint is based on the same alleged misconduct as the Securities Class Action, and asserts state law claims, on behalf of the Company, against the individual defendants for breach of fiduciary duty, unjust enrichment, abuse of control, waste of corporate assets, and insider trading. The complaint also asserts federal claims under sections 10(b), 21D, and 14(a) of the Securities Exchange Act of 1934, as amended. On December 27, 2023, the action was reassigned to District Judge William Q. Hayes and Magistrate Judge Michael S. Berg due to its relation to the Securities Class Action. On January 30, 2024, the parties jointly requested a stay of the action. The Court granted that request and the action was stayed on February 20, 2024, pending the outcome of our Demand Review Committee's investigation into the underlying claims.

Given the unpredictability inherent in litigation, the Company cannot predict the outcome of these matters. The Company is unable to estimate possible losses or ranges of losses that may result from these matters, and therefore it has not accrued any amounts in connection with these matters other than attorneys' fees incurred to date.

10. Leases

The Company leases facilities and certain equipment under noncancelable operating leases that expire at various dates through February 2031. Under the terms of the facilities leases, the Company is required to pay its proportionate share of property taxes, insurance and normal maintenance costs.

In 2015, the Company entered into a master lease agreement giving the Company the ability to lease vehicles under operating leases with initial terms of 36 months from the date of delivery. In 2018, the lease agreement was terminated and a new master lease agreement was entered into with a new vendor giving the Company the ability to lease vehicles under operating leases with initial terms ranging from 12 to 50 months from the date of delivery. In 2021, the Company entered into a new master lease agreement giving the Company the ability to lease vehicles under operating leases with initial terms of 60 months from the date of delivery.

The Company leases facilities and certain equipment under noncancelable operating leases with remaining lease terms of 0.9 year to 7.4 years, some of which include options to extend the lease for up to two five-year terms. These optional periods were not considered in the determination of the right-of-use asset or the lease liability as the Company did not consider it reasonably certain that it would exercise such options.

The operating lease costs were as follows (in thousands):

	Years Ended December 31,		
	2023	2022	2021
Operating lease cost	$ 10,343	$ 8,095	$ 8,874
Operating sublease income	(93)	—	—
Net operating lease costs	$ 10,250	$ 8,095	$ 8,874

Supplemental cash flow information related to the Company's leases were as follows (in thousands):

	Years Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 9,456	$ 9,083
Right-of-use assets obtained in exchange for operating lease obligations:	2,051	3,871

The balance sheet classification of the Company's lease liabilities was as follows (in thousands):

	December 31, 2023	December 31, 2022
Operating lease liabilities		
Current portion included in accrued liabilities	$ 9,405	$ 9,305
Operating lease liabilities	47,800	52,695
Total operating lease liabilities	$ 57,205	$ 62,000

Maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2024	$ 9,662
2025	9,744
2026	9,127
2027	8,831
2028	8,521
Thereafter	20,586
Total lease payments	66,471
Less:	
Imputed interest	(9,266)
Total operating lease liabilities	$ 57,205

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. As of December 31, 2023 and 2022, the weighted average remaining lease term was 7.0 years and 7.9 years, respectively, and the weighted average discount rate used to determine the operating lease liability was 4.5% and 4.4%, respectively.

In the fourth quarter of 2018, the Company entered into an agreement to lease the 4th and 5th floors of corporate office space in San Diego, California with total minimum lease payments of $50.4 million over an initial term of 10 years and 9 months. In February 2020, the Company entered into the first amendment to the lease agreement to lease the 2nd floor of corporate office space in San Diego, California with total minimum lease payments of $25.3 million over an initial term of approximately 10 years and 7 months. In March 2020, the Company entered into the second amendment to the lease agreement which increased the total minimum lease payments of the original corporate office space to $51.4 million. In the third quarter of 2020, the lease for the 4th and 5th floors of corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $40.3 million. In the first quarter of 2021, the lease for the 2nd floor of corporate office space commenced and the Company capitalized a right of use asset and related lease liability of $19.2 million. In connection with this lease and the amendment, the Company established a letter of credit for $3.1 million, which has automatic annual extensions and is fully secured by restricted cash.

In May 2023, the Company entered into an agreement to sublease its 2nd floor of corporate office space in San Diego to a sublessee with a total minimum sublease income of $18.4 million over a term of approximately 7 years and 6 months. The Company delivered the full possession of its 2nd floor of corporate office space to the sublessee in August 2023. Pursuant to the sublease agreement, the Company received the first sublease payment in December 2023.

11. Selected Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for the years ended December 31, 2023 and 2022 are as follows (in thousands, except per share data):

	Fiscal Year 2023 Quarters				
	1st	2nd	3rd	4th	Total
Revenues	$ 118,462	$ 165,235	$ 211,699	$ 231,041	$ 726,437
Gross profit[(1)]	$ 116,795	$ 157,776	$ 197,077	$ 213,151	$ 684,799
Net income (loss)	$ (43,021)	$ 1,114	$ (65,176)	$ 45,797	$ (61,286)
Basic net income (loss) per share[(2)]	$ (0.27)	$ 0.01	$ (0.40)	$ 0.28	$ (0.37)
Diluted net income (loss) per share[(2)]	$ (0.27)	$ 0.01	$ (0.40)	$ 0.28	$ (0.37)

	Fiscal Year 2022 Quarters				
	1st	2nd	3rd	4th	Total
Revenues	$ 115,468	$ 134,563	$ 130,714	$ 136,490	$ 517,235
Gross profit[(1)]	$ 112,518	$ 131,896	$ 128,578	$ 134,076	$ 507,068
Net loss	$ (113,056)	$ (34,011)	$ (27,183)	$ (41,725)	$ (215,975)
Basic and diluted net loss per share[(2)]	$ (0.70)	$ (0.21)	$ (0.17)	$ (0.26)	$ (1.34)

(1) Determined by subtracting cost of product sales from product sales, net.

(2) Basic and diluted net income (loss) per common share are computed independently for each quarter and the full year based upon respective average shares outstanding. Therefore, the sum of the quarterly net income (loss) per common share amounts may not equal the annual amounts reported.

SCHEDULE II – Valuation and Qualifying Accounts
(in thousands)

	Balance at Beginning of Period	Additions: Provision Related to Current Period Sales	Deductions: Actual Distribution Fees, Discounts and Chargebacks Related to Current Period Sales	Deductions: Actual Distribution Fees, Discounts and Chargebacks Related to Prior Period Sales	Balance at End of Period
Allowance for distribution fees, discounts and chargebacks:					
For the year ended December 31, 2021	$ 4,221	$ 72,011	$ (63,544)	$ (4,221)	$ 8,467
For the year ended December 31, 2022	$ 8,467	$ 80,836	$ (69,913)	$ (8,467)	$ 10,923
For the year ended December 31, 2023	$ 10,923	$ 97,797	$ (85,641)	$ (10,923)	$ 12,156

Exhibit 10.5

ACADIA Pharmaceuticals, Inc.
Restricted Stock Unit Award Grant Notice
2010 Equity Incentive Plan

ACADIA Pharmaceuticals, Inc. (the ***"Company"***) hereby awards to Participant the number of Restricted Stock Units specified and on the terms set forth below (the ***"Award"***). The Award is subject to all of the terms and conditions as set forth in this Restricted Stock Unit Award Grant Notice (the "***Grant Notice***"), in the Restricted Stock Unit Award Agreement (the "***Award Agreement***") and in the Company's 2010 Equity Incentive Plan (the ***"Plan"***), all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Award Agreement shall have the meanings set forth in the Plan or the Award Agreement, as applicable. In the event of any conflict between the terms of this Grant Notice, the Award Agreement or the Plan, the terms of the Plan shall control.

Participant:
Date of Grant:
Vesting Commencement Date:
Number of Restricted Stock Units:
Consideration: Participant's services

Vesting Schedule: [_____, subject to the Participant's Continuous Service through such dates]

Issuance Schedule: One share of Common Stock will be issued for each Restricted Stock Unit which vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: By their signatures below, the Company and the Participant agree that the Award is governed by this Grant Notice and by the provisions of the Plan and the Award Agreement, both of which are attached to and made a part of this document. The Participant acknowledges receipt of copies of the Plan, this Grant Notice, the Award Agreement and the stock plan prospectus for this Plan and represents that the Participant has read and is familiar with their provisions. As of the Date of Grant set forth above, this Grant Notice, the Plan and the Award Agreement set forth the entire understanding between Participant and the Company and any Affiliate regarding the Award and supersedes all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) restricted stock units or other stock awards previously granted and delivered to Participant, (ii) any compensation recovery policy maintained by the Company or is otherwise required by applicable law and (iii) any written employment or severance or change in control (or similar) arrangement between the Participant and the Company or an Affiliate that would provide for vesting acceleration of this Award upon the terms and conditions set forth therein.

By signing below, the Participant hereby accepts the Award subject to all of the terms and conditions of this Notice, the Award Agreement and the Plan. Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

ACADIA Pharmaceuticals, Inc. Participant:

By: _____ _____
Signature Signature

Title: _____ Date: _____

[1] For CEO, add "and the potential vesting acceleration set forth in the Executive Employment Agreement between the Participant and the Company dated XX/XX/XXXX".

Date:_____

ATTACHMENTS: 2010 Equity Incentive Plan; Restricted Stock Unit Award Agreement and Plan Prospectus

ACADIA Pharmaceuticals, Inc.
2010 Equity Incentive Plan

Restricted Stock Unit Award Agreement

Pursuant to the Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Award Agreement***") and in consideration of your services, ACADIA Pharmaceuticals, Inc. (the "***Company***") has awarded you a Restricted Stock Unit Award (the "***Award***") under its 2010 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units indicated in the Grant Notice (the "***Stock Units***"). Capitalized terms not explicitly defined in this Award Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan are as follows:

1. Grant of the Award. This Award represents your right to be issued on a future date one share of the Company's Common Stock for each Stock Unit indicated in the Grant Notice that vests. As of the Date of Grant specified in the Grant Notice, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Stock Units subject to the Award. This Award was granted in consideration of your services to the Company. Except as otherwise provided herein, you will not be required to make any payment to the Company or an Affiliate (other than services to the Company or an Affiliate) with respect to your receipt of the Award, the vesting of the Stock Units or the delivery of the Company's Common Stock to be issued in respect of the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Common Stock, in part or in full satisfaction of the delivery of Common Stock upon vesting of your Stock Units, and, to the extent applicable, references in this Award Agreement and the Grant Notice to Common Stock issuable in connection with your Stock Units will include the potential issuance of its cash equivalent pursuant to such right.

2. Vesting. Subject to the provisions in this Award Agreement and in the Grant Notice, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service for any reason. Upon such termination of your Continuous Service, any Stock Units credited to the Account that were not yet vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such Stock Units or the shares of Common Stock to be issued in respect of such portion of the Award.

3. Number of Stock Units and Shares of Common Stock.

(a) The Stock Units subject to your Award will be adjusted for Capitalization Adjustments, as provided in the Plan.

(b) Any additional Stock Units and any shares, cash or other property that become subject to the Award pursuant to this Section 3, if any, will be subject, in a manner

determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Stock Units and shares covered by your Award.

(c) No fractional shares or rights for fractional shares of Common Stock will be created pursuant to this Section 3. Except as provided in Section 7 or otherwise provided by the Company, any fraction of a share will be rounded down to the nearest whole share.

4. Securities Law Compliance. You will not be issued any Common Stock in respect of your Stock Units or other shares with respect to your Stock Units unless the shares are registered under the Securities Act, or, if such shares of Common Stock are not then so registered, the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with all other applicable laws and regulations governing the Award, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. Transferability. Your Award is not transferable, except by will or by the laws of descent and distribution or as otherwise permitted by the Board or a committee thereof. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in your Stock Units or the shares of Common Stock that may be issued under your Award until the shares of Common Stock are issued to you in accordance with Section 6 of this Award Agreement. After shares of Common Stock have been issued to you under your Award, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, any applicable Company policies (including, but not limited to, insider trading and window period policies) and applicable securities laws. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to receive any distribution of Common Stock to which you were entitled at the time of your death pursuant to this Award Agreement. In the absence of such a designation, your legal representative will be entitled to receive, on behalf of your estate, such Common Stock or other consideration.

6. Date of Issuance.

(a) To the extent that your Award is exempt from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law or similar effect (collectively, "***Section 409A***"), the issuance of shares of Common Stock in respect of the Stock Units is intended to comply with Treasury Regulation Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Taxes set forth in Section 10 of this Award Agreement, in the event one or more Stock Units vests, the Company will issue to you, on the vesting date, one share of Common Stock for each Stock Unit that vests and such issuance date is referred to as the "***Original Issuance Date***." If the Original Issuance Date falls on a date that is not a business day, delivery will instead occur on the next following business day.

However, if (i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the

Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Plan***")), *and* (ii) the Company elects (A) not to satisfy the Withholding Taxes described in Section 10 by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 10 of this Agreement (including but not limited to a commitment under a 10b5-1 Plan) and (C) not to permit you to pay the Withholding Taxes in cash or from other compensation otherwise payable to you by the Company, then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulation Section 1.409A-1(b)(4), no later than the date that is the later of (i) the 15th day of the third calendar month of the year following the end of the calendar year in which such shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulation Section 1.409A-1(d) or (ii) the 15th day of the third month following the end of the Company's fiscal year in which such shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulation Section 1.409A-1(d). The form of delivery of the shares of Common Stock in respect of your Award (e.g., a stock certificate or electronic entry evidencing such shares) will be determined by the Company.

(b) The provisions of Appendix A will apply to the extent your Award is subject to, and not exempt from, application of Section 409A (a ***"Non-Exempt Award"***).

7. Dividends. You will receive no benefit or adjustment to your Award or Stock Units with respect to any cash dividend, stock dividend or other distribution that does not constitute a Capitalization Adjustment as provided in the Plan; provided, however, that this sentence will not apply with respect to any shares of Common Stock that are delivered to you in connection with your Award after such shares have been delivered to you.

8. Restrictive Legends. The Common Stock issued with respect to your Stock Units will be endorsed with appropriate legends, if any, as determined by the Company.

9. Award not a Service Contract.

(a) Except as otherwise provided in a separate, written employment or other agreement between the Company and/or its Affiliates and you, your Continuous Service is not for any specified term and may be terminated by you or by the Company or an Affiliate at any time, for any reason, with or without cause and with or without notice. Nothing in this Award Agreement (including, but not limited to, the vesting of your Stock Units or the issuance of the shares in respect of your Stock Units), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Award Agreement or the Plan will: (i) confer upon you any right to

continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Award Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Award Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice is earned only by continuing as an employee, director or consultant at the will of the Company or an Affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and as further described in the Plan, and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Award Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Award Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Award Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company's right to terminate your Continuous Service at any time, with or without cause and with or without notice.

10. WITHHOLDING OBLIGATIONS.

(a) On each vesting date, and on or before the time you receive a distribution of the shares in respect of your Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholdings from the shares of Common Stock or from other consideration issuable to you and/or otherwise agree to make adequate provision, including in cash, for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Taxes***"). Specifically, the Company or an Affiliate may, in its sole discretion to the extent permitted by law, satisfy all or any portion of the Withholding Taxes relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or an Affiliate; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with your Stock Units with a Fair Market Value (measured as of the date shares of Common Stock are issued to you) equal to the amount of such Withholding Taxes; *provided,*

however, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and, if applicable, foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and provided further, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, such share withholding procedure shall be subject to the express prior approval of the Board or a duly authorized committee thereof.

(b) Unless the Withholding Taxes of the Company and/or any Affiliate are satisfied, the Company will have no obligation to deliver to you any Common Stock or other consideration pursuant to this Award.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

11. Unsecured Obligation. Your Award is unfunded, and as a holder of vested Stock Units, you will be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Award Agreement. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Award Agreement until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a shareholder of the Company. Nothing contained in this Award Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

12. Other Documents. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

13. Notices. Any notices provided for in this Award Agreement or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

14. Additional Acknowledgements. You hereby consent and acknowledge that:

(a) Participation in the Plan is voluntary and therefore you must accept the terms and conditions of the Plan and this Award Agreement and Grant Notice as a condition to participating in the Plan and receipt of this Award. This Award and any other awards under the Plan are voluntary and occasional and do not create any contractual or other right to receive future awards or other benefits in lieu of future awards, even if similar awards have been granted repeatedly in the past. All determinations with respect to any such future awards, including, but not limited to, the time or times when such awards are made, the size of such awards and performance and other conditions applied to the awards, will be at the sole discretion of the Company.

(b) The future value of your Award is unknown and cannot be predicted with certainty. You do not have, and will not assert, any claim or entitlement to compensation, indemnity or damages arising from the termination of this Award or diminution in value of this Award and you irrevocably release the Company, its Affiliates and, if applicable, your employer, if different from the Company, from any such claim that may arise.

(c) The rights and obligations of the Company under your Award will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(d) Upon request, you agree to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(e) You have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(f) This Award Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(g) All obligations of the Company under the Plan and this Award Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

15. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In addition, your Award will be subject to recoupment in accordance with any clawback policy that the Company has adopted or any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd–Frank Wall Street Reform and Consumer Protection Act or other applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to

resign for "good reason" or "constructive termination" (or similar term) under any plan of or agreement with the Company. Except as expressly provided in this Award Agreement or the Grant Notice, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan will control.

16. Severability. If all or any part of this Award Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Award Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Award Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

17. Effect on Other Employee Benefit Plans. The value of the Award subject to this Award Agreement will not be included as compensation, earnings, salaries, or other similar terms used when calculating the Employee's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

18. Amendment. Any amendment to this Award Agreement must be in writing, signed by a duly authorized representative of the Company. The Board reserves the right to amend this Award Agreement in any way it may deem necessary or advisable to carry out the purpose of the grant as a result of any change in applicable laws or regulations or any future law, regulation, interpretation, ruling, or judicial decision.

19. Compliance with Section 409A of the Code. To the maximum extent possible, this Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. However, if this Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and therefore deemed to be deferred compensation subject to, Section 409A of the Code, this Award shall comply with Section 409A of the Code to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. To the extent this Award is subject to Section 409A of the Code and if you are a "Specified Employee" (within the meaning set forth Section 409A(a)(2)(B)(i) of the Code) as of the date of your separation from service (within the meaning of Treasury Regulation Section 1.409A-1(h)), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six months thereafter will not be made on the originally scheduled dates and will instead be issued in a lump sum on the earlier of: (i) the fifth business day following your death, or (ii) the date that is six months and one day after the date of the separation from service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

20.No Obligation to Minimize Taxes. The Company has no duty or obligation to minimize the tax consequences to you of this Award and will not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.

* * *

This Restricted Stock Unit Award Agreement will be deemed to be accepted by you upon your acceptance of the Restricted Stock Unit Award Grant Notice to which it is attached.

Appendix A

The provisions of this Appendix are intended to apply to the extent your Award is a Non-Exempt Award because of the terms of a severance arrangement or other agreement between you and the Company, if any, that provide for acceleration of vesting of your Award and issuance of the shares in respect of the Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) ("***Separation from Service***") and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) ("***Non-Exempt Severance Arrangement***"). To the extent your Award is a Non-Exempt Award due to application of a Non-Exempt Severance Arrangement, the following provisions in this Appendix A shall supersede anything to the contrary in Section 6(a) (or any other Section) of the Award Agreement or in the Plan.

21.*Vesting in the Ordinary Course.* If your Award vests in the ordinary course during your Continuous Service in accordance with the vesting schedule set forth in the Grant Notice, without accelerating vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of your Award any later than the later of: (i) December 31st of the calendar year that includes the applicable vesting date and (ii) the 60th day that follows the applicable vesting date.

22.*Vesting Acceleration Under Pre-Existing Non-Exempt Severance Arrangement.* If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of your Award and, therefore, are part of the terms of your Award as of the date of grant, then the shares will be issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. However, if at the time the shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six month period.

23.*Vesting Acceleration Under Subsequent Non-Exempt Severance Arrangement.* If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Award and, therefore, are not a part of the terms of your Award on the date of grant, then, unless otherwise permitted under Section 409A without incurring adverse tax consequences, such acceleration of vesting of your Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during your Continuous Service, notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

24.*General Superseding Provisions*. The provisions in this Section 4 shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of the Award Agreement with respect to the permitted treatment of your Non-Exempt Award:

(a) Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award (including in connection with a Change in Control or Corporate Transaction) shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A. Upon a Change in Control or Corporate Transaction, the treatment of your Non-Exempt Award shall in all respects comply with the requirements of Section 409A, as determined in the sole discretion of the Company.

(b) The Company explicitly reserves the right to earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).

(c) To the extent the terms of your Non-Exempt Award provide that it will be settled upon a merger, Corporate Transaction, Change in Control or similar transaction, to the extent it is required for compliance with the requirements of Section 409A, the merger, Corporate Transaction, Change in Control or similar transaction triggering settlement must also constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as described in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a "***409A Change in Control***").

(d) To the extent the terms of your Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation from Service. However, if at the time the shares would otherwise be issued to you in connection with your "separation from service" you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six month period.

(e) The provisions in this Appendix for delivery of the shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to you in respect of your Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

Exhibit 10.13

January 12, 2024

Jennifer Rhodes jenniferrhodes@mac.com

Dear Jennifer:

We are delighted to offer you the position of EVP, Chief Legal Officer with Acadia Pharmaceuticals Inc. (the "Company" or "Acadia"). As discussed with you, this offer is contingent subject to your satisfactory completion of a background investigation, including contact with your professional references, and review of any applicable agreements with your former employers, as outlined below ("Contingencies"). The start date for your employment with Acadia will be mutually agreed to by you and your supervisor, Steve Davis. The following summarizes the terms of our offer effective upon removal of the Contingencies:

Base Salary: Your semi-monthly salary will be $21,458.34 ($515,000.16 annualized). Your position is full time and is exempt/salaried.

Performance Bonus: You will be eligible to receive an annual performance bonus currently targeted at 50% of your annual base salary but which will be granted in the sole discretion of the Board based upon its evaluation of the Company's and your achievement of such specific performance goals as established by the Board. Performance Bonuses will be prorated based on time spent on a Performance Improvement Plan or any other disciplinary related suspension or probationary period. As allowed by law, including if you are terminated or resign, you must be an employee of the Company on the date upon which bonuses are paid to receive a Performance Bonus. If eligible, your bonus for the period in which you are hired will be prorated based on your date of hire with the Company.

Equity Award:
a) Initial Grant. Within 45 days of the commencement of your employment, you will be granted a new hire equity award consisting of nonqualified stock options ("Options") and restricted stock units ("RSUs") having an aggregate fair market value of $3,000,000.00 at the date of grant. 75% of the equity award value will be granted in the form of Options and 25% in the form of RSUs. The Options and the RSUs are intended to be an inducement material to your entering into employment with the Company and will be subject to the terms of the Company's 2023 Inducement Plan approved by the Compensation Committee of the Company's Board of Directors pursuant to the "inducement exception" provided under Nasdaq Market Place Rule 5635(c)(4) and Nasdaq IM-5635-1.

b) Vesting. Both the Options and the RSUs will vest over four years, as follows: one-quarter (25%) of the Options will vest on the first anniversary of the grant, and 1/48th of the Options will vest each month thereafter for the following three years; and one-half (50%) of the RSUs will vest on the second anniversary of the grant, and one-fourth of the RSUs will vest on each of the third and fourth

anniversaries of the grant; provided that you remain employed by the Company at each such vesting date.

c) Other Terms. The Options and RSUs will be subject to the terms of the Company's Inducement Plan and the related award notices and agreements.

Severance Benefits: You will be entitled to participate in our Management Severance Benefit Plan ("Severance Plan") and Change in Control Severance Benefit Plan ("CIC Severance Plan"). A copy of each of these plans is available to you on request and each is also on file with the SEC.

Benefits: You will be eligible to participate in the Company's standard benefit plans. Note that these plans for new employees are effective on the employment start date and enrollment. Your eligibility and participation in these plans, is, of course, subject to the terms of the plans themselves.

Vacation and Holidays: You will receive 20 vacation days each year, accrued monthly and paid holidays in accordance with the Company's annual holiday schedule, with a vacation accrual cap of 1.75 times your annual vacation accrual.

401(k): You will have the opportunity to participate in the Company's 401(k) plan. The plan provides for enrollment on a monthly basis.

Employee Stock Purchase Plan: You will have the opportunity to enroll in the Company's Employee Stock Purchase Plan (ESPP), which provides for the purchase of shares of Acadia common stock through payroll deductions. The ESPP currently provides for twice-annual purchases in May and November.

Inventions and Non-Disclosure: You will be required to sign the Inventions and Non-Disclosure Agreement, attached to this letter, as a condition of your employment.

Restrictive Covenants, Trade Secrets and Confidential Information from Current or Prior Employers: You agree that you will not bring or use any confidential information or trade secrets from current or former employers during your employment with the Company. You agree and acknowledge that you have notified the Company of any and all non-compete, non-solicitation, confidentiality or other restrictive agreements with your current or former employers that could impact your employment with the Company. Prior to your start date, you will provide the Company with copies of such agreements. You agree that you have reviewed the duties and responsibilities of your new position and that no contractual or other restrictions will prevent you from performing those duties.

Loyal and Conscientious Performance: During the Employment Period, you shall devote full time business energies, interest, abilities, and productive time to the Company. You are not precluded from engaging in civic, charitable or religious activities and are allowed to serve on boards of directors of for

profit companies or organizations that do not present any conflict with the interests of the Company or otherwise adversely affect your performance of your duties.

You will not, during the employment with the Company, compete with the Company, either directly or indirectly, in any manner or capacity, as adviser, consultant, principal, agent, partner, officer, director, employee, member of any association or otherwise, in any phase of developing, manufacturing or marketing any product or service that is in the same field of use or that otherwise competes with a product or service that is offered, is actively under development, or is actively being considered for development by the Company.

You agree not to acquire, assume or participate in, directly or indirectly, any position, investment or interest that Employee knows or should know is adverse or antagonistic to the Company, its business, clients, strategic partners, investors or prospects.

No Solicitation: You agree that for a period of twelve (12) months immediately following the termination of your employment with the Company, whether you resign voluntarily or are terminated by the Company involuntarily, you will not directly or indirectly hire, solicit, or recruit, or attempt to hire, solicit, or recruit, any employee of the Company to leave their employment with the Company, nor will you contact any employee of the Company, or cause an employee of the Company to be contacted, for the purpose of leaving employment with the Company.

Authorization to Work: Federal law requires that you provide the Company with the legally required proof of your identity and authorization to work in the United States. We will furnish you with a list of acceptable documents. This documentation must be provided within three (3) business days of the date your employment begins, or our employment relationship with you may be terminated.

At-Will; Entire Agreement: Your employment is at-will and for no specified period, and either you or Acadia may terminate this employment relationship at any time and for any reason. At all times during your employment, you will be subject to the direction and policies from time to time established by Senior Management and the Company's Board of Directors. The agreement in this letter sets forth our entire understanding regarding your employment and supersedes any other negotiations, written or oral.

Severability: The unenforceability, invalidity, or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid, or illegal.

By signing this offer, you hereby certify that you have not knowingly withheld any information that might adversely affect your chances for employment and that the answers given by you are true and correct to the best of your knowledge. You understand that any omission or misstatement of material fact used to secure employment shall be grounds for rejection of this offer or for immediate discharge if you are employed, regardless of the time elapsed before discovery.

We look forward to your joining Acadia Pharmaceuticals Inc. and believe that it will be a mutually beneficial experience. This contingent offer will expire if not accepted by January 29, 2024.
Please indicate your agreement with the above terms by signing below. Sincerely,

/s/Rob Ackles
Rob Ackles
Senior Vice President, Chief People Officer Accepted and agreed:
/s/Jennifer Rhodes

1/18/2024
Date

Attachments & Enclosures: Inventions and Non-Disclosure Agreement

Exhibit 10.17

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [...*...], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

Master Manufacturing Services Agreement

August 3, 2015

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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the "Agreement") is made as of August 3**,** 2015 (the "**Effective Date**")

B E T W E E N:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

("**Patheon**"),

- and -

ACADIA PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

("**Client**").

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), and intending to be legally bound the Parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This "master" form of agreement is intended to allow the Parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon's global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the Parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the Parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the Parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.

1.3 Definitions.

The following terms will have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Active Materials**", **"Active Pharmaceutical Ingredients" or "API"** means the materials listed in a Product Agreement on Schedule D;

"**Active Materials Credit Value**" means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

"**Actual Annual Yield**" or "**AAY**" has the meaning specified in Section 2.2(a);

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a Party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a Party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the controlling interest of a Party to this Agreement;

For this definition, "control" means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation or other business entity (with corresponding meanings for "controlling interest" and "controlled by");

"Annual Minimum" will have the meaning specified in Section 2.1;

"Annual Product Review Report" means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

"**Annual Report"** means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

"**Annual Volume**" means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in a Product Agreement on Schedule B;

"**Applicable Laws**" means the applicable provisions of any and all national, supranational, regional, state, provincial, county and local laws, statutes, treaties, ordinances, regulations, rules, administrative codes, guidance, ordinances, by-laws, judgments, decrees, directives, injunctions, permits (including marketing approvals) or orders of or from any Authority having jurisdiction over or related to the subject item;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether national, supranational, regional, state, provincial, county or local;

"Batch" means a specific quantity of Product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of Manufacturing Services;

"Bill Back Items" means the reasonable documented actual expenses in accordance with Section 2.1(g) for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable), RFID tags and supporting equipment, and other Product-specific items, in each case, as necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

"**Breach Notice**" will have the meaning specified in Section 8.2(a);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in the jurisdiction where the Manufacturing Site is located or in the State of California;

"**Capital Equipment Agreement**" means a separate agreement that the Parties may enter into that will address responsibility for the purchase of capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Division 2 of Part C of the *Food and Drug Regulations* (Canada);

(b) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(c) EC Directive 2003/94/EC; and

(d) ICH guidelines;

together with the latest Health Canada, FDA, and EMA and any other jurisdiction agreed to by the Parties guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time, and any foreign equivalents to any such regulations which may apply to the Manufacturing Site or be applicable to Products sold outside of the United States, Canada or the European Union;

"Certificate of Analysis" means, with respect to a Batch, that document setting for the measured and observable characteristics of Product from the Batch, as required by the Specifications, as dated, executed and provided to Client by Patheon prior to delivery of the Product;

"Certificate of Compliance" means a statement signed by Patheon that certifies that all Manufacturing Services of a Batch of Product was performed or otherwise implemented, packaged, stored and tested in accordance with cGMP and all other regulatory requirements;

"**Claims**" has the meaning specified in Section 10.3;

"**Client Indemnitees**" has the meaning specified in Section 10.3;

"Client Intellectual Property" means Intellectual Property generated or derived by Client or any of its Affiliates before entering into this Agreement or independent of this Agreement, or by Patheon or any of its Affiliates while performing any Manufacturing Services or otherwise

generated or derived by Patheon or any of its Affiliates in its business, which Intellectual Property is directly related to, specific to, or dependent upon, Client's Active Materials or Product;

"**Client Property**" will have the meaning specified in Section 8.4(e);

"**Client-Supplied Components**" means those Components to be supplied by Client or that have been supplied by Client;

"**CMC**" has the meaning specified in Section 7.8(c);

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Confidential Information**" has the meaning specified in Section 11.1;

"DDP" has the meaning as set forth in the 2010 edition of the International Commercial terms published by the International Chamber of Commerce, as may be amended or modified from time to time (**Incoterms 2010**);

"**Deficiencies**" has the meaning specified in Section 7.8(d);

"**Deficiency Notice**" has the meaning specified in Section 6.1(a);

"Delivery Date" means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);

"Delivery Documentation" has the meaning specified in Section 2.1(b);

"Disclosing Party" has the meaning specified in Section 11.1;

"Deviation" means a departure from an established quality standard, including, but not limited to, that set forth in any Product Agreement, any Quality Agreement, cGMP standard operating procedure, manufacturing work order, packaging order, raw material or product specification, analytical control procedure, water monitoring procedure, equipment maintenance schedule, or any unusual occurrence that could affect the Product. Deviations may be either anticipated or unanticipated departures from established quality standards and may have the potential to affect the safety, identity, strength, quality or purity of a Product;

"**EMA**" means the European Medicines Agency or any successor agency thereto which may regulate pharmaceutical products;

"EXW" has the meaning as set forth in Incoterms 2010;

"**FDA**" means the United States Food and Drug Administration or any successor agency thereto which may regulate pharmaceutical products;

"**Firm Order**" has the meaning specified in Section 5.1(c);

"**First Firm Order**" has the meaning specified in Section 5.1(b);

"For Cause Audit" means an audit of manufacturing records of Patheon or its subcontractors and supplies by Client following: (a) an unfavorable observation during regulatory inspections that is material to the quality of Product; or (b) a major or repeated quality excursion that may result in a failed manufacture Batch or Non-Conforming Product;

"**Force Majeure Event**" has the meaning specified in Section 13.7;

"**Health Canada**" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate or any successor agency thereto which may regulate pharmaceutical products;

"**Initial Manufacturing Month**" has the meaning specified in Section 5.1(b);

"**Initial Manufacturing Period**" has the meaning specified in Section 5.1(b);

"**Initial Product Term**" has the meaning specified in Section 8.1;

"**Initial Set Exchange Rate**" means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency, calculated as the daily average interbank exchange rate for conversion of one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"**Initial Term**" has the meaning specified in Section 8.1;

"**Intellectual Property**" means any and all rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means any and all information, results, data, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"**Inventory**" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"**Late Delivery**" will have the meaning specified in Section 5.5(b);

"Latent Defect" means a defect in any Batch of Product, the API or Materials that was not, and could not reasonably be expected to have been, found by exercise of ordinary care, following the approved specifications or in inspection at Delivery;

"Late Product" means Product ordered under a Firm Order that is not delivered on the Delivery Date;

"**Losses**" has the meaning specified in Section 10.3;

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, labelling, storage and related services provided by Patheon to manufacture Product or Products using the Active Materials, Components, and Bill Back Items pursuant to this Agreement;

"**Manufacturing Site**" means the facility owned and operated by Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

"Materials" means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"**Maximum Credit Value**" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;

"**Minimum Order Quantity**" means the minimum number of Batches of a Product to be produced as set forth in a Product Agreement on Schedule B;

"**Non-Conforming Products**" will have the meaning specified in Section 6.1(a);

"Out of Specification" or **"OOS"** means a confirmed result that falls outside the Specifications.

"Party" or "Parties" means, as the context requires individually or collectively, Patheon and Client;

"**Patheon Competitor**" means a business that derives greater than 50% of its revenues from performing contract pharmaceutical development or commercial manufacturing services for Third Parties;

"**Patheon Indemnitees**" has the meaning specified in Section 10.4;

"Patheon Intellectual Property" means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, or developed by Patheon while performing the Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is not Client Intellectual Property;

"Price" means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing costs as set forth in a Product Agreement on Schedule C;

"**Product(s)**" means the product(s) listed in a Product Agreement on Schedule A;

"**Product Agreement**" means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site as updated, amended and revised from time to time by the Parties in accordance with the terms of this Agreement;

"**Product Warranties**" will have the meaning specified in Section 9.3(a);

"**Quality Agreement**" means the agreement between the Parties entering into a Product Agreement that sets out the quality assurance standards and responsibilities for the

Manufacturing Services to be performed by Patheon for Client, as such agreement may be amended from time to time in accordance with its terms; the Parties anticipate that the Quality Agreement will be executed within 30 days after the Effective Date of the Product Agreement;

"Quantity Converted" as the meaning specified in Section 2.2(a);

"Quantity Dispensed" has the meaning specified in Section 2.2(a);

"Quantity Received" has the meaning specified in Section 2.2(a);

"Quarter" means each successive period of three calendar months commencing on January 1, April 1, July 1 and October 1;

"Recall" means any action (i) by Client or its Affiliates or licensees to recover title to or possession, or stop distribution, prescription or consumption, of quantities of the Products sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any Regulatory Authorities to detain or destroy any of the Products. Recall will also include any action by Client or its Affiliates or licensees to refrain from selling or shipping quantities of the Products to Third Parties that would have been subject to a Recall if sold or shipped.

"**Recipient**" has the meaning specified in Section 11.1;

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

"RFID" means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

"**Remediation Period**" has the meaning specified in Section 8.2(a);

"Set Exchange Rate" means the exchange rate to convert one unit of the Patheon Manufacturing Site local currency into one unit of the billing currency for each Year, calculated as the average daily interbank exchange rate for conversion of the Patheon Manufacturing Site local currency into one unit of the billing currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com "The Currency Site" under the heading "FxHistory: historical currency exchange rates" at www.OANDA.com/convert/fxhistory;

"**Shortfall**" has the meaning specified in Section 2.2(b);

"Significant Quality Event" means any event occurring during the Manufacturing of the Product resulting in a Deviation that materially impacts the quality, performance, safety or reliability of the Product or intermediates thereof. A confirmed Out of Specification result is a Significant Quality Event;

"**Specifications**" means the requirements, for each Material, Component, Active Material or Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents or requirements relating to each Product, including, without limitation:

(a) specifications for Active Materials and Components;

(b) manufacturing specifications, directions, and processes;

(c) storage requirements;

(d) all environmental, health and safety information for each Product including material safety data sheets;

(e) the in-process specifications; and

(f) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"**Target Yield**" has the meaning specified in Section 2.2(a);

"**Target Yield Determination Batches**" has the meaning specified in Section 2.2(a);

"**Technical Dispute**" has the meaning specified in Section 12.2;

"**Technology Transfer**" means the transfer to Client or any Third Party designated by Client by Patheon of all information relating to the process of manufacturing Product, all documents, manufacturing instructions, specifications, and any other relevant documentation, all relevant manufacturing know-how, licenses and materials (including raw materials specifications) related to Product that Patheon or its Affiliates, as applicable, controls or has the right to license at any time during the Term and that is necessary to enable Client or its designee to manufacture Product in accordance with the Specifications, and to comply with applicable regulatory requirements (including obtaining any necessary regulatory approvals, conducting any required studies and developing any other regulatory documentation) and all Applicable Laws in connection with the transfer;

"**Territory**" means any geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

"Third Party" means any party other than Client, Patheon or their respective Affiliates;

"**Third Party Rights**" means any Intellectual Property of any party other than Client or Patheon or their respective Affiliates;

"**United States**" means the United States of America including its territories and possessions; and

"**Year**" means in the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.4

Currency.

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.5 Sections and Headings.

The division of this Agreement into Articles, Sections, Subsections, an Appendix, Schedules and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix, Schedule or Exhibit refers to the specified Section, Appendix, Schedule or Exhibit to this Agreement. In this Agreement, the terms "**this Agreement**", "**hereof**", "**herein**", "**hereunder**" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix, Schedule or Exhibit of this Agreement.

1.6 Singular Terms.

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa, and all references to “includes” or “including” will mean “includes without limitation” or “including without limitation.”

1.7 Appendix 1, Schedules and Exhibits.

Appendix 1 (including Schedules thereto) and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

Appendix 1 - Form of Product Agreement (Including Schedules A to D)

Exhibit A - Technical Dispute Resolution
Exhibit B - Monthly Active Materials Inventory Report
Exhibit C - Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
Exhibit D - Example of Price Adjustment Due to Currency Fluctuation

ARTICLE 2

PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C. Schedule B to a Product Agreement sets forth a list of cost items that are included or not included in the unit Price for Products; all cost items that are not included in the Price are subject to additional fees to be paid by the Client as agreed by the Parties. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth and in accordance with Article 4. Patheon will perform the Manufacturing Services in strict compliance with the established Specifications, cGMP and Applicable Laws. Patheon may not change the Specifications or the Manufacturing Site (including facility modifications) or any other aspect of the manufacturing process used to perform the Manufacturing Services with respect to the Products except with the prior written consent of Client, this consent not to be unreasonably withheld. Unless otherwise agreed in a Product

Agreement or in this Agreement, and for so long as Patheon remains in material compliance with its obligations under this Agreement and the applicable Product Agreement, Patheon will manufacture at least […***…] % (**"Annual Minimum"**) of Products manufactured by or on Client's behalf for sale by Client in the Territory in a particular Year. If Patheon does not remain in material compliance, the Annual Minimum will no longer apply in addition to any other remedies the Client may have under this Agreement. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Use of Active Materials and Components. Patheon will use the Active Materials and Components to manufacture Products in accordance with this Agreement. Patheon will not use the Active Materials, any Client-Supplied Components or any other Components paid for by Client for any other use or purpose. Patheon will use all Active Materials and Components on a first-to-expire, first-to-use basis in manufacturing Products under this Agreement.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon's quality assurance group, consistent with the Quality Agreement. Patheon will perform its Batch review and release responsibilities in accordance with Patheon's standard operating procedures copies of which have been made available to Client and will not change in a material way related to Product without Client consent (not to be unreasonably withheld), and the Quality Agreement. Each time Patheon ships Products to Client or Client's designee, it will give Client a Certificate of Analysis and Certificate of Compliance, and a list of all Deviations (**"Delivery Documentation"**). Client will have sole responsibility for the release of Products to the market. The Batch documents, including, but not limited to, Batch production records, lot packaging/labeling records, equipment set up control, operating parameters, investigation/non-conformances, and data printouts, raw material data, and laboratory notebooks will be the exclusive property of Client. But any intellectual property comprised of the form and style of those Batch documents are the exclusive property of Patheon and Patheon will not be obligated to disclose to Client confidential or proprietary information of Third Parties contained in any lab notebooks that is unrelated to the Manufacturing Services. Subject to the foregoing, Patheon will provide any information reasonably required by Client to perform, if required, a Technology Transfer or if requested by a Regulatory Authority in a redacted form at Client's expense. Except for Patheon Intellectual Property, all information contained in the Batch documents, including, but not limited to specific Product related information, is Client property.

(c) Components. Patheon will purchase (with the exception of Client-Supplied Components) and test all Components at Patheon's expense and as required by the Product Agreement in accordance with the Specifications and the Quality Agreement.

(d) Stability Testing. Patheon will conduct stability testing on the Products as part of the Manufacturing Services provided hereunder. Patheon will perform this testing in accordance with the protocols set out in the Quality Agreement and the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement, if applicable. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within one Business Day, after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure in accordance with the Quality Agreement, including which Party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs or Applicable Laws. Patheon will give Client all stability test data and results (including a final report) at Client's request within […***…] Business Days, upon completion of the testing.

(e) Packaging. Patheon will package the Products as set out in the Specifications and the applicable master packaging records approved by Client. Client will be responsible for the cost of artwork development, as applicable. Patheon will determine and imprint the Batch numbers and expiration dates for each Product shipped. The expiration dates must be determined in accordance with the Specifications. The Batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by the Quality Agreement, cGMPs and Applicable Laws. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable Regulatory Authorities. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon's name will not appear on the label or anywhere else on the Products unless: (i) required by any Applicable Laws; or (ii) Patheon consents in writing to the use of its name.

(f) Active Materials and Client-Supplied Components. At least […***…] before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site DDP, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. Upon receipt of the Active Materials, Patheon will test all Active Materials in accordance with the provisions of the Product Agreement and in accordance with the applicable Quality Agreement. If the Active Materials and/or Client-Supplied Components are not received […***…] before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior Third Party production commitments, Patheon may delay the shipment until a later date as agreed to by the Parties, but Patheon will make commercially reasonable efforts to make the shipment as soon as possible. All shipments of Active Material will be accompanied by Certificate(s) of Analysis provided by Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material Specifications set forth in the Product Agreement.

(g) Bill Back Items. Bill Back Items purchased by Patheon will be charged to Client at Patheon's actual and reasonable cost plus a […***…]% handling fee for Bill Back Items that cost less than $5,000 and a […***…]% handling fee for Bill Back Items that cost $5,000 or more, but Client must give prior written approval for the purchase of all Bill Back items. Patheon will use commercially reasonable efforts to order Bill Back Items in amounts to minimize the handling fee.

(h) Handling and Storage. Patheon will store at no cost to Client inventory to support […***…] months of production per the forecast of the Active Material and Client-Supplied Components in a controlled and monitored environment and at appropriate conditions in accordance with Specifications, the Quality Agreement, and Applicable Laws.

2.2 Active Material Yield.

(a) Reporting. Patheon will give Client a monthly inventory report of the Active Materials held by Patheon within five Business Days of the end of the most recent monthly using the inventory report form set out in Exhibit B, which will contain the following information for the month:

> **Quantity Received:** The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable month (**"Quantity Received"**).
>
> **Quantity Dispensed:** The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable month (**"Quantity Dispensed"**). The Quantity

Dispensed is calculated by adding the Quantity Received to the inventory of Active Materials that complies with the Specifications and is held by Patheon at the beginning of the applicable month, less the inventory of Active Materials that complies with the Specifications and is held by Patheon at the end of the month. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test Batches manufactured during the applicable period, in each case of clauses (i) through (iv) in accordance with this Agreement.

Quantity Converted: The total amount of Active Materials contained in the Product manufactured with the Quantity Dispensed (including any additional Product produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon's failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Client acknowledges that, if there is no change in this information from one month to the next month, the report will reflect that.

Within […***…] days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit C including the calculation of the "**Actual Annual Yield**" or "**AAY**" for the Product at each Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Product and is calculated as follows:

$$\frac{\text{Quantity Converted during the Year}}{\text{Quantity Dispensed during the Year}} \times 100\%$$

After Patheon has produced a minimum of […***…] successful commercial production Batches of Product and has produced commercial production Batches for at least […***…] months at the Manufacturing Site (collectively, the "**Target Yield Determination Batches**"), the Parties will agree on the target yield for the Product at the Manufacturing Site (each, a "**Target Yield**"). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the Parties.

Additionally, promptly following production of the validation Batches, but prior to production of the […***…] Target Yield Determination Batches described above, the Parties will agree to an interim Target Yield that will apply before determination of the Target Yield set out above, based on data from production of the validation Batches. Promptly following production of the first […***…] Target Yield Determination Batches described above, the Parties will agree to an updated interim Target Yield that will apply before determination of the Target Yield set out above, based on data from production of the first […***…] Target Yield Determination Batches.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than […***…]% below the respective Target Yield in a Year, then the shortfall for the Year (the "**Shortfall**") will be calculated as follows:

Shortfall = [(Target Yield – […***…]%) – AAY] * Active Materials Credit Value * Quantity Dispensed

(c) Credit for Shortfall. If there is a Shortfall for a Product in a Year, then Patheon will credit Client's account for the amount of the Shortfall not later than […***…] days after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit C. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2 will be paid to Client within […***…] days of the expiration or termination of the Product Agreement. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) Maximum Credit. Patheon's liability for Active Materials calculated in accordance with this Section 2.2 for any Product Agreement in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to the Product Agreement.

(e) No Material Breach. It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield unless the Actual Annual Yield is more than […***…]% below the Target Yield.

ARTICLE 3

CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon for performing the Manufacturing Services in accordance with this Agreement according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under Sections 4.2 and 4.3 of this Agreement. Client will also pay Patheon for any Bill Back Items as provided in Section 2.1(g).

3.2 Active Materials and Qualification of Additional Sources of Supply.

Client will at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)). If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client's obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client's designated broker will be the "Importer of Record" for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. The Active Materials will at all times remain the property of Client. Patheon will ensure that the Active Materials will not become subject to any encumbrances, liens or other third-party claims while in Patheon's possession. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services.

If Client asks Patheon to qualify an additional source for the Active Material or any Component, Patheon will evaluate the Active Material or Component to be supplied by the additional source to determine if it is suitable for use in the Product. The Parties will agree on the scope of work to be performed by Patheon at Client's cost. For an Active Material, this work at a minimum will include:

(a) laboratory testing to confirm the Active Material meets existing specifications;

(b) manufacture of an experimental Batch of Product that will be placed on three months accelerated stability; and

(c) manufacture of three full-scale validation Batches that will be placed on concurrent stability (one Batch may be the registration Batch if manufactured at full scale).

Section 6.3(c) will apply to all Product manufactured using the newly approved Active Material or Component because of the limited material characterization that is performed on additional sources of supply.

ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing.

The tiered Price and annual stability Price for the Products through December 31, 2015 are listed in Schedules B and C in a Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3.

4.2 Price Adjustments – Subsequent Years' Pricing.

Beginning January 1, 2016, Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States or Puerto Rico, Patheon may adjust the conversion component of Price for inflation, based upon the preliminary number for any increase or decrease in the Producer Price Index pcu325412325412 for Pharmaceutical Preparation Manufacturing published by the United States Department of Labor, Bureau of Labor Statistics ("**PPI**") in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the Parties otherwise agree in writing. On or before November 30th of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. But Client will have the right to dispute the calculation in good faith and the existing Prices will continue to apply until the dispute is resolved. If necessary, the Price will be retroactively adjusted for the applicable period after the dispute is resolved. For Products manufactured outside the United States or Puerto Rico, Patheon may similarly adjust the Price for inflation using an equivalent inflation index to be agreed by the Parties in a Product Agreement.

(b) Component Costs. Patheon may increase or, if the average price of the Component costs decreases, Patheon will decrease the Price for the next Year to pass through the actual additional or reduced Component costs. In November of each Year, Patheon will give Client reasonably detailed information about the increase or decrease in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase or decrease is justified. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. But, at Client's request, Patheon will allow an independent third party auditor to review the information supporting the increase or decrease in Component costs and confirm that the information reasonably demonstrates that the Price increase or decrease is justified and reasonable.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if the specified Minimum Order Quantity changes or if the Annual Volume is not ordered in a Year. For greater clarity, if Patheon and Client agree that the Minimum Order Quantity will be reduced or the Annual Volume in the lowest tier will not be ordered in a Year whether as a result of a decrease in estimated Annual Volume or otherwise and, as a result of the reduction, Patheon demonstrates to Client's reasonable satisfaction that its costs to perform the Manufacturing Services or to acquire the Components for the Product will increase or decrease on a per unit basis (including the amount of the increase), then Patheon may increase or decrease the Price by an amount sufficient to absorb the documented increased or reduced costs. On or before November 1st of each Year, Patheon will give Client a statement setting forth the information to be applied in calculating those cost increases or decreases for the next Year. But Patheon will not be required to give information to Client that is subject to obligations of confidentiality between Patheon and its suppliers. But, at Client's request, Patheon will allow an independent third party auditor to review the information supporting the increase in Component costs and confirm that the information reasonably demonstrates that the Price increase is justified.

(d) Adjustments Due to Currency Fluctuations. If the Parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations in accordance with this Section 4.2(d). If the Set Exchange Rate for a given Year has changed, the adjustment will be calculated after all other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for a Canadian Manufacturing Site invoiced in USD) is set forth in Exhibit D.

(e) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon the Client's volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the […***…] month forecast provided in September of the previous Year. Within 30 days of the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within 45 days of the end of the Year or will issue payment to the Client for the overpayment within 45 days of the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment within 45 days of the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the Parties will work in good faith to resolve the disagreement amicably. If the Parties are unable to resolve the disagreement within 30 days, the matter will be handled under Section 12.1.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or before November 30th of each Year a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year, which revised Schedule B must be approved in writing by Client before it becomes binding on the Parties. Client's approval must not be unreasonably withheld.

4.3 Price Adjustments – Current Year Pricing.

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases or Decreases in Component Costs. If, at any time, market conditions result in Patheon's cost of Components being materially greater or less than the cost on which the current Price is based, then the Parties will adjust the Price for any affected Product that reflects the increased or decreased Component costs. Changes materially greater than normal forecasted increases or decreases will have occurred if: (i) the cost of a Component increases or decreases by […***…]% of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases or decreases by […***…]% of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase or decrease in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified, to Client's reasonable satisfaction. Client will have the right to dispute any Price adjustment in good faith, and for the duration of the dispute, the existing Prices will continue to apply. If necessary, the Price will be retroactively adjusted for the applicable period after the dispute is resolved. At Client's request, Patheon will allow an independent Third Party auditor to review the information supporting the increase or decrease in Component costs and confirm that the information reasonably demonstrates that the Price increase or decrease is justified and reasonable. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. For an undisputed Price adjustment, the revised Price will be effective for any Product delivered on or after the first day of the month following Client's receipt of the revised Schedule B to the Product Agreement. If the Price is revised pursuant to this Section 4.3, it will not be revised subsequently pursuant to Section 4.2(b) with respect to the same increased Component costs.

4.4 Adjustments Due to Technical Changes.

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review that Patheon will perform at Client's cost, and are subject to Client and Patheon reaching agreement on any Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client. Upon receiving notice of a request by Client for any such amendments, Patheon will promptly advise Client in writing of any scheduling adjustments, any cost increases or decreases or other changes that may result from the change, and (a) will use its best efforts to make any change identified in the Client request that is in response to a regulatory or safety issue pertaining to the Product, and (b) will use commercially reasonable efforts to implement any other change identified in a Client request by the date requested by Client, or as soon thereafter as it is commercially reasonable. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon's actual cost (including all reasonable costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the "old" Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, but only to the

extent the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will, at Client's sole discretion, be assigned to and satisfied by Client or cancelled by Patheon and Client will reimburse Patheon for any penalty it incurs due to the cancellation.

4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each such country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the change over fees for the Product destined for each such country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5

ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts.

(a) Rolling […***…] Month Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding […***…] month forecast of the volume of Product that Client expects to order in the first […***…] months of commercial manufacture of the Product. This forecast will then be updated by Client on or before the […***…] day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than […***…]%. The most recent […***…] month forecast will prevail.

(b) Firm Orders for Initial Manufacturing Month. At least […***…] months before the start of commercial manufacture of the Product, Client will update the rolling forecast for the first […***…] months of manufacture of the Product (the "**Initial Manufacturing Period**"). Subject to the provisions of Section 5.1(c), the first month of this updated forecast ("**Initial Manufacturing Month**") will constitute a firm written order in the form of a purchase order or otherwise ("**First Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture the quantity of the Product. If manufacturing has not started, Client may cancel any Batches from the First Firm Order at a cost of $[…***…] per cancelled Batch per month until manufacturing starts, if notice of cancellation is received by Patheon […***…] days or more before the scheduled Delivery Date under the First Firm Order. If manufacturing has not started, Client may cancel any Batches from the First Firm Order if notice of cancellation is received by Patheon more than […***…] days but fewer than […***…] days before the scheduled Delivery Date under the First Firm Order, but Client will pay Patheon $[…***…] for each cancelled Batch. The Parties agree that this payment will be considered liquidated damages for Patheon's loss of manufacturing capacity due to the Client's cancellation of manufacturing and will not be considered a penalty. If the First Firm Order is changed or adjusted as described above, then the initial rolling […***…] month forecast will also be adjusted as necessary.

(c) Firm Orders Thereafter. Before and during the Initial Manufacturing Period, and on a rolling basis during the term of the Product Agreement, Client will issue an updated […***…] month forecast on

or before the […***…] day of each month. This forecast will start on the first day of the next month. The first […***…] months of this updated forecast will be considered binding firm orders. But the initial order related to the launch of each Product will not be binding until the Client receives approval from the FDA to market the applicable Product. Concurrent with the delivery of the applicable forecast, Client will issue a firm written order for the first […***…] months of the forecast in the form of a purchase order or otherwise ("**Firm Order**") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products as set forth in the Firm Order. The Delivery Date specified in the Firm Order will not be less than …***… days following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client's purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. Upon Patheon's acceptance of a Firm Order, the quantities of Products ordered in the Firm Order will be firm and binding on the Parties and may only be reduced by written agreement of the Parties.

(d) […***…] Year Forecast. On or before the […***…] day of May of each Year, Client will give Patheon a written non-binding […***…]-year forecast, broken down by Quarters […***…], of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the […***…]-year period.

(e) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within […***…] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by written agreement of the Parties or as set forth in Section 2.1(f) or 5.1(b). If Patheon fails to send an acknowledgement to Client within the applicable […***…] Business Day period, then the Firm Order will be deemed to have been accepted by Patheon. Patheon will accept Firm Orders submitted in accordance with this Agreement. If Patheon rejects a Firm Order submitted in accordance with this Agreement, without limiting Client's other rights and remedies hereunder, Client may obtain the Product from another supplier, and this Product will not be included for purposes of calculating the Annual Minimum under this Agreement, and the Annual Minimum will automatically be reduced by […***…]%. If Patheon rejects two or more Firm Orders in a […***…]-month period, the Annual Minimum will no longer apply.

5.2 Reliance by Patheon.

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a) and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in reasonable volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to in writing by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components in quantities reasonably needed to satisfy the Manufacturing Services requirements for Products for the first […***…] months contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the Parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2(a) are not included in finished Products manufactured for Client within […***…] months after the forecasted month for which the purchases have been made (or for a longer period as the Parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all reasonable costs incurred by Patheon for the purchase and handling of the Components). But if these

Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client or, at Client's election, a refund in an amount equal to these costs. On a Quarterly basis, Patheon will provide a report summarizing the Inventory held by Patheon.

(b) If Client fails to take possession or arrange for the destruction of Components purchased by Patheon in accordance with Section 5.2(a) within 12 months of purchase or, in the case of finished Product that is not the subject of a Deficiency Notice, within three months of manufacture, Client will pay Patheon $100.00 per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at $200.00 per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product that is not the subject of a Deficiency Notice held by it longer than three months to the Client at Client's expense on 14 days' prior written notice to the Client in accordance with the Specifications.

5.3 Minimum Orders.

Client may only order Manufacturing Services for amounts of Products in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 Shipments.

Shipments of Products will be made EXW Patheon's shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client's instructions and as agent for Client, at Client's risk, (i) arrange for shipping to be paid by Client and (ii) at Client's expense, obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon's shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.

5.5 Late Delivery.

(a) Patheon will deliver Products ordered under a Firm Order on the applicable Delivery Date. The Parties agree that they will work together closely to expedite deliveries of Product, including, without limitation, any samples of Products and Products for initial launch, and manage the scheduling of the initial Product launch.

(b) If, after the Initial Manufacturing Period, Patheon is unable to deliver […***…]% of the quantity of a particular Product ordered under a Firm Order within […***…] days of the Delivery Date due to an act or omission by Patheon (a "**Late Delivery**"), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be […***…]% of the Price of the quantities of Product not delivered by Patheon under the Firm Order (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] * Price *[…***…]%). Patheon will make commercially reasonable efforts to replace the late Product within […***…] days. If, after the Initial Manufacturing Period, Patheon makes two or more Late Deliveries for the same Product in the same calendar Quarter, Client will receive an additional credit of […***…]% from Patheon for the Late Deliveries that will be applied against the purchase price under the next Firm Order. The total credit will be […***…]% of the Price of the quantities of Product not delivered by Patheon under the Firm Order (i.e., Client Credit = [Quantity Ordered in the Firm Order – Actual Delivery Quantities of Product] * Price *[…***…]%. Without

limiting Client's other rights or remedies in this Agreement, if Patheon makes two or more Late Deliveries within a […***…]-month period, the Annual Minimum will be reduced to […***…]%. In such case, for the remainder of the term of this Agreement, the Parties agree that Patheon will manufacture at least […***…]% of the Products manufactured by or on Client's behalf for sale by Client in the Territory in a particular Year until Patheon has no Late Deliveries for a […***…] month period in which case the Annual Minimum will increase by […***…]% and by […***…]% in each sequential […***…] month period that there are no Late Deliveries up to a maximum of […***…]%. Notwithstanding the foregoing, if Patheon makes two or more Late Deliveries within a […***…]-month period, the Parties will meet and agree on and implement a delivery improvement action plan within five Business Days. If, after the delivery improvement plan is in place, two additional Late Deliveries occur within a […***…]-month period, these Late Deliveries may be considered a material breach of this Agreement by Patheon under Section 8.2(a) and Patheon will not be allowed any further opportunity to remedy the material breach.

(c) A Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon's reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials, a delay in Product release approval from Client, inaccurate Client forecasts, or receipt of non-conforming API or Client-Supplied Components.

5.6 Invoices and Payment.

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment and the associated Delivery Documentation. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. All payments made that are associated with Inventory or Components will be credited against the Price of any Batch of Product that incorporates the Components and/or Inventory. Each invoice will also reflect any credit to Client under Section 5.2. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, Delivery Documentation and the total amount to be paid by Client. Client will pay all invoices within […***…] days of the date thereof. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the Parties will use good faith efforts to reconcile the disputed amount as soon as practicable, but in no case more than […***…] days. Interest on undisputed past due accounts will accrue at […***…]% per month which is equal to an annual rate of […***…]%. The Late Delivery credits set forth in Section 5.5(b) are only available to Client if all outstanding undisputed invoices have been paid in full or are within […***…] days outstanding from the invoice date when the Late Delivery arose. In the case of a Deficiency Notice, payments will be due within […***…] days following receipt of a replacement Batch or Batches that are not subject to a Deficiency Notice. Batches that are determined to have a Latent Defect due to Patheon will be either credited against future Batches or refunded at the sole discretion of Client. No payments will be due for Non-Conforming Product and Patheon will use commercially reasonable efforts to replace the Non-Conforming Product within […***…] days.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) Product Claims. Client has the right to reject any shipment of Products or any portion thereof that does not conform to the Product Warranties set forth in Section 9.3(a) ("**Non-Conforming Products**"), without invalidating any portion of the shipment of Products that conforms to the Product Warranties. Client will inspect the Products manufactured by Patheon upon receipt at the third-party site agreed to by Patheon and Client and will give Patheon written notice (a "**Deficiency Notice**") of all claims for Non-Conforming Products within […***…] days after Client's receipt of the Product and the Delivery Documentation thereof (or, in the case of Latent Defect, within […***…] days after confirmation by Client, its Affiliate or any licensee, distributor or other Third Party but not after the expiration date of the Product). If Client fails to give Patheon the Deficiency Notice within the applicable […***…]- or […***…]-day period, then the delivery will be deemed to have been accepted by Client on the […***…] or […***…] day after delivery or confirmation, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any Deviations for which it has not received notice within the applicable […***…]-day period except for a Latent Defect.

(b) Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon will have […***…] days to advise Client by notice in writing that it disagrees with the contents of the Deficiency Notice. Should Patheon fail to provide such notice to Client within the […***…] day period, then Patheon will be deemed to agree with the contents of the Deficiency Notice. If Client and Patheon fail to agree within […***…] days after Patheon's notice to Client as to whether any Products identified in the Deficiency Notice are Non-Conforming Products, then the Parties will mutually select an independent laboratory or expert to evaluate if the Products are Non-Conforming Products. This evaluation will be binding on the Parties. If the independent laboratory or expert determines that any Products are Non-Conforming Products, Client may reject those Products in the manner contemplated in this Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the independent laboratory determines that the Products conform to the Product Warranties, then Client will be deemed to have accepted delivery of the Products on the […***…] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, on the […***…] day after confirmation thereof by Client, but not after the expiration date of the Product) and Client will be responsible for the cost of the evaluation.

(c) Shortages. Claims for shortages in the amount of Products shipped by Patheon will be dealt with by reasonable agreement of the Parties.

6.2 Product Recalls and Returns.

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each Party will promptly notify the other by telephone to the contacts designated in the Quality Agreement (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products within one Business Day. Upon receiving this notice or upon this discovery, each Party will stop making any further shipments of any Products in either Party's possession or control until Client has made a decision as to whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client.

(b) Recalls. If (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns including, if requested by Client, appropriate investigations.

6.3 Patheon's Responsibility for Non-Conforming and Recalled Products.

(a) Non-Conforming Product. If Client rejects Products under Section 6.1, Client will not be required to pay for the Product under Section 3.1. Patheon will promptly, at Client's election, either: (i) refund the amount paid for the Non-Conforming Products if Client previously paid for the Products, and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products; (ii) offset the amount paid for the Non-Conforming Products, if Client previously paid for the Products, and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products, against other amounts due to Patheon hereunder; or (iii) at Patheon's sole expense (excluding expense to incur replacement Active Materials, but including the replacement of Client-Supplied Components and Bill Back Items), replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Non-Conforming Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall or return of Products results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the terms of this Agreement, including the warranties set forth in Sections 9.3 and 9.4 or other negligence or willful misconduct of Patheon, Patheon will be responsible for the documented costs and out-of-pocket expenses of the Recall or return and will promptly, at the election of Client, either: (i) refund the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products; (ii) offset the amount paid for the Recalled or returned Products and the cost incurred by Client for the Bill Back Items and Client-Supplied Components used in the Products, against other amounts due to Patheon hereunder; or (iii) replace the Recalled or returned Products with conforming Products, at Patheon's sole expense (excluding expense to incur replacement Active Materials, but including the expense to obtain replacement Bill Back Items and Client-Supplied Components), as promptly as practical without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon's responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client's cost and expense. For clarification, any refund of the amount paid by Client for the Recall or return of Products that is paid by Patheon subject to this Section 6.3(b) will not be considered a liability under, and therefore will not be subject to, Section 10.2(a).

(c) Product Rejection for Finished Product Specification Failure. Internal process specifications will be defined and agreed upon. If a Batch or portion of a Batch of Product does not meet a finished Product Specification despite Patheon's assertion that it manufactured the Product in accordance with the agreed upon process specifications, the Batch production record, and Patheon's standard operating procedures for manufacturing, the Parties agree that they will mutually select an

independent laboratory or expert to evaluate if such laboratory or expert can determine why the Products do not meet a finished Product Specification. The evaluation will be binding on the Parties. If the independent laboratory or expert determines that the Product is Non-Conforming due to an act or omission by Patheon or does not otherwise comply with the Terms of the Agreement, Client may reject those Products in the manner contemplated by Section 6.1 and Patheon will be responsible for the cost of the evaluation. If the independent laboratory determines that the Patheon complied with the agreed upon process specifications, the Batch production record, and Patheon's standard operating procedures and that the Product does not meet a finished Product specification, Client will be responsible for the cost of the evaluation and will pay Patheon the applicable fee per unit for the Non-Conforming Product. In which case, the API in the Non-Conforming Product will be included in the "Quantity Converted" for purposes of calculating the "Actual Annual Yield" under Section 2.2(a).

(d) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it (collectively, "**Product Claims**"). For greater clarity, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products manufactured in accordance with this Agreement and conforming to the Specifications or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the methods set forth in the Specifications or as otherwise provided in this Agreement, (iii) results from a defect in the Active Materials or Client-Supplied Components that is not reasonably discoverable by Patheon using the methods set forth in the Specifications or as otherwise provided in this Agreement, (iv) is caused by actions of Third Parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which neither Patheon nor any of its Affiliates or its or their employees, agents or subcontractors has any responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs, Applicable Laws, and the other terms of this Agreement, as determined by an independent laboratory or expert as set forth in Section 6.3(c) above; or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, Non-Conforming or Recalled Products for which it intends to assert a claim against Patheon without Patheon's prior written authorization to do so, which will not be unreasonably withheld or delayed. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition (including any applicable storage fees or the cost of destruction) for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.1 or 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client's and its Affiliates' and licensees' customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing and any other assistance reasonably requested by Client. In addition, Patheon promptly (and in any event within the timelines specified in the Quality Agreement) will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as set forth in the Quality Agreement.

Client will bear all costs incurred under this Section 6.5, except to the extent the complaint resulted from a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, Applicable Laws, and the other terms of this Agreement, in which case those costs incurred under this Section 6.5 will be borne by Patheon.

6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client's sole remedy for any failure by Patheon to supply Products that conform to the Product Warranties.

ARTICLE 7

CO-OPERATION

7.1 Quarterly Review.

Each Party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the Parties. The relationship managers will meet not less than Quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.8, Patheon may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products only if, in the opinion of Patheon's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law and a representative of Client is present for a verbal communication or has reviewed and approved a written communication. Patheon will notify Client immediately upon and in any event within 24 hours after receiving any request from a Regulatory Authority for communication related to a Product.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products (including evidence on the testing of raw materials, packaging and labeling materials as required by the Quality Agreement), and retain samples of the Products as are necessary to comply with applicable manufacturing regulatory requirements, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for five years or one year following the date of Product expiry (whichever is longer), or longer if required by Applicable Laws, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products at least 45 days prior to the destruction of the documents or samples. Patheon will not store these documents and/or samples beyond the time period set forth above.

7.4 Inspection of Financial Records.

Client or its designee may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice of at least […***…] Business Days, but a Patheon representative must be present during the inspection. In addition, as more fully set forth in Section 4.2, Client will have the right to allow an independent third party auditor to review the information supporting the price adjustments made under Sections 4.2, 4.3 and 4.4.

7.5 Access.

Patheon will give Client reasonable access at agreed times to procedures and documentation relevant to the Product, and to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped, to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, Applicable Laws and the Quality Agreement. But, with the exception of "For-Cause" Audits, Client will be limited each Year to one cGMP-type audit, lasting no more than […***…] days, and involving no more than […***…] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of $5,000 for each additional audit day and $1,000 per audit day for each additional auditor. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon's financial records. In addition, upon the request of any Regulatory Authority having jurisdiction over the manufacture of Products hereunder, the Regulatory Authority will have access to observe, audit and inspect any Manufacturing Site and Patheon's procedures used for the manufacture, release and stability testing, and/or warehousing of Products and to audit those facilities and procedures for compliance with cGMP and/or other regulatory requirements. Patheon specifically agrees to cooperate with any inspection by a Regulatory Authority, whether prior to or after Regulatory Approval of a Product, and to provide Client a copy of any inspection or audit report resulting from the inspection within three Business Days from receiving the report. Client may be present at the Facility for consultation during any such inspection.

7.6 Notification of Regulatory Inspections.

Patheon will notify Client within one Business Day of any inspection, receipt of notice of any inspection and/or any request for samples by any governmental agency specifically involving the Products. Patheon will also notify Client within three Business Days of receipt of any form 483's or warning letters or any other significant regulatory action or finding which could directly or indirectly impact the regulatory status of the Products or Patheon's ability to perform the Manufacturing Services. Within three Business Days of receipt, Patheon will provide Client with a reasonable description of the notifications and inspections and all supporting documentation, including, as applicable, all form 483's and warning letters or similar warning or objection, responses and all other correspondence and discussions of the applicable Regulatory Authority, which should be redacted to protect the confidential information of Third Parties. Patheon will discuss with Client and consider in good faith any comments provided by Client on the proposed response. Additionally, Patheon will obtain Client's prior approval of any such responses related to Product. Patheon will use commercially reasonable efforts to address and rectify any issues or problems in its manufacturing facility or procedures and any objections or warnings raised by the Regulatory Authority as soon as practicable and to continue to manufacture and supply to Client, in compliance with all Applicable Laws and the terms of this Agreement, the Products ordered by Client. After the filing of a response with the FDA or other Regulatory Authority, Patheon will notify Client of any further contacts with the Regulatory Authority relating to the subject matter of the response.

7.7 Reports.

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA or any other Regulatory Authority or other information related to the performance of the Manufacturing Services mandated by a Regulatory Authority. Patheon will promptly provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary

FDA or other Regulatory Authority requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 Regulatory Filings.

(a) Regulatory Authority. Client will have the sole right and responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the manufacture, import, export, distribution, marketing, sale, pricing and/or reimbursement of the Products. Patheon will assist Client, to the extent consistent with Patheon's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible. Client will provide copies of relevant sections of regulatory filings to Patheon that are necessary for Patheon to ensure compliance of the manufacturing processes to those submitted to Regulatory Authorities.

(b) Verification of Data. Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon requires […***…] days to perform this review but the Parties may agree to a shorter time for the review as needed, including as mandated by a Regulatory Authority. These documents will be Confidential Information of Client.

(c) Verification of CMC. Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA's Chemistry and Manufacturing Controls (all such documentation herein referred to as "**CMC**") related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC that directly relate to the Manufacturing Services provided by Patheon. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires […***…] days to perform this review but the Parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all FDA filings at the time of submission to the extent containing CMC information that directly relate to the Manufacturing Services provided by Patheon and may redact this information to protect the Confidential Information of any Third Party.

(d) Deficiencies. If, in Patheon's sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any material respect (the "**Deficiencies**"), Patheon will notify Client in writing of the Deficiencies as promptly as practical and in any case within the time frame set forth in clause (b) or (c), as applicable. The Parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) Client Responsibility. For clarity, the Parties agree that in reviewing the documents referred to in clause (b) above, Patheon's role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client.

(f) Inspection by Regulatory Authorities. If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested

documents that directly relate to the Manufacturing Services provided by Patheon and is satisfied with their contents.

7.9 Quality Agreement.

For clarification, if there is any conflict between the terms and conditions of this Agreement, including this Article 7, and the terms and conditions of the Quality Agreement, the terms and conditions of the Quality Agreement will control with regard to topics directly related to quality and compliance only.

ARTICLE 8

TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until **December 31, 2020** (the "**Initial Term**"), unless terminated earlier by one of the Parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of two Years each if there is a Product Agreement in effect, unless either Party gives written notice to the other Party of its intention to terminate this Agreement at least 24 months prior to the end of the then current term, subject to earlier termination in accordance with the terms of this Agreement. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of five Years from the start of commercial manufacture at the Manufacturing Site for the Product unless the Parties agree to a different number of Years in the applicable Product Agreement (each, an "**Initial Product Term**"), subject to earlier termination in accordance with the terms of this Agreement. Product Agreements will automatically renew after the Initial Product Term for successive terms of two Years each unless either Party gives written notice to the other Party of its intention to terminate the Product Agreement at least 24 months prior to the end of the then current term, subject to earlier termination in accordance with the terms of this Agreement.

8.2 Termination for Cause.

(a) Either Party at its sole option may terminate this Agreement or any Product Agreement upon written notice where the other Party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement or any Product Agreement within 60 days following receipt of a written notice (the "**Remediation Period**") of the breach that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**"). The aggrieved Party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved Party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either Party at its sole option may immediately terminate this Agreement or any Product Agreement upon written notice, but without prior advance notice, to the other Party if: (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other Party; or (iii) this Agreement or any Product Agreement is assigned by the other Party for the benefit of creditors.

(c) Client may terminate this Agreement as to any Product and the related Product Agreement upon at least 30 days' prior written notice, if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product, or Client (or its Affiliate or licensee) determines that for safety or efficacy reasons Client is not going to continue to develop or commercialize the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Client may terminate this Agreement or a Product Agreement at any time upon written notice to Patheon, without limiting Client's other rights or remedies under this Agreement, if any Authority takes any enforcement action regarding the Manufacturing Site that relates to the Product or could reasonably be expected to adversely affect the ability of Patheon to supply the Product.

(e) Patheon may terminate this Agreement or a Product Agreement upon 18 months' prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the opinion of Patheon acting reasonably is a Patheon Competitor. But this time period will automatically be extended by an additional three months if, at 18 months after the notice, Client is working in good-faith to secure, and/or obtain required approvals for, another supplier.

8.3 Product Discontinuation; Other Causes for Termination by Client.

(a) Client will give at least six months' advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product's discontinuance in the market. Upon expiration of the applicable six-month notice period, this Agreement will terminate with respect to the Product or, if the Product is the only Product subject to this Agreement, this Agreement will terminate in its entirety.

(b) Except for terminations under the other termination provisions of this Agreement (including Sections 8.2, 8.3(a), 9.4 and 13.7), Client will give at least 36 months' advance notice if it intends to no longer order Manufacturing Services for a Product for any other reason. In such case, the Annual Minimum will be reduced by […***…]% beginning one year from the date of notice and each year thereafter. Upon expiration of the applicable 36 month period, at Client's option, this Agreement will terminate with respect to the Product or, if the Product is the only Product subject to this Agreement, the Agreement will terminate in its entirety. Upon receipt of notice, Patheon will provide assistance to Client in a Technology Transfer. Except for a material breach of this Agreement by Patheon, Client will be responsible for all costs associated with the Technology Transfer. If the Technology Transfer is a result of a material breach of the Agreement by Patheon, each Party will be responsible for its own costs associated with the Technology Transfer. In all circumstances, Patheon will use at least commercially reasonable efforts to meet the timeline requested by Client.

8.4 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order and in compliance with the terms of this Agreement, at the price in effect at the time the Firm Order was placed;

(b) Client will purchase, at Patheon's actual cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced and maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2;

(c) Client will reimburse Patheon for the purchase price payable under Patheon's orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;

(d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within 30 days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon's care and control ("**Client Property**"). If Client fails to remove the Client Property within 30 days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon $100.00 per pallet, per month, one pallet minimum (except that Client will pay $200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.5 of this Agreement.

Any termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the termination or expiration, nor will it prejudice any other remedies that the Parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, expiration or termination of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the Parties under Articles 10, 11 and 12 and Sections 5.4, 5.6, 6.3, 6.4, 6.5, 6.6, 7.3, 7.4, 8.4, 13.1, 13.2, 13.3, 13.11, 13.15 and 13.16, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each Party covenants, represents, and warrants to the other Party, as of the Effective Date, that (a) it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder and has taken all necessary action on its part to authorize the performance of the obligations; (b) the execution and delivery of this Agreement and the performance of the Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Laws or regulations and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of the Party; (c) it is duly organized, validly existing and in good standing under the laws of the state or country in which it is organized; and (d) this Agreement has been duly executed and delivered on behalf of the Party, and constitutes a legal, valid, binding obligation, enforceable against the Party in accordance with its terms.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

(a) Non-Infringement.

(i) the Specifications for each of the Products are its or its Affiliate's property and Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property provided by Client for use by Patheon in performing the Manufacturing Services according to the Specifications and the other terms of this Agreement (i) is owned or controlled by Client or its Affiliate, (ii) may be lawfully used by Patheon as directed by Client, and (iii) when used by Patheon according to the Specifications and the other terms of this Agreement does not infringe any Third Party Rights known to Client;

(iii) subject to […***…], the […***…] or the […***…];

(iv) as of the Effective Date, there are no actions or other legal proceedings to which the Client is a party or of which Client is aware, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Client-Supplied Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) once Client has received approval from the FDA to market the Products, the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products and (iii) will be safe for human consumption;

(iii) on the date of shipment to the Manufacturing Site, the API will conform to the specifications for the API that Client has given to Patheon, subject to Patheon's obligation to test the API in accordance with the Quality Agreement before beginning manufacture of the Products using the API, and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) (1) all Products delivered hereunder will (i) conform to the applicable Specifications; (ii) be free and clear of any and all encumbrances, liens, or other third party claims; (iii) be manufactured, packaged, labelled and delivered in compliance with the Quality Agreement and applicable cGMP, all regulatory approvals for the Product, and Applicable Laws and in accordance with manufacturing procedures described in the applicable master Batch records for the Product; (iv) not be adulterated or misbranded within the meaning of the

United States Food, Drug and Cosmetic Act, as amended, and any regulations promulgated thereunder or comparable provisions under the laws and regulations of any other applicable jurisdiction (the **"Act"**); and (v) not be articles that, under the provisions of the Act, may not be introduced into interstate commerce; and (2) Patheon's processes used to perform the Manufacturing Services will not infringe on any Third Party Rights (collectively, the **"Product Warranties"**);

(b) it will perform the Manufacturing Services in accordance with the Quality Agreement, Specifications, cGMPs, and Applicable Laws;

(c) the Components, Active Materials and the Bill Back Items will at all times be free and clear of any and all encumbrances, liens, or other third party claims; and

(d) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b) or comparable provisions under the laws and regulations of any other applicable jurisdiction. Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Act. If Patheon or any officer, employee or agent of Patheon: (a) becomes debarred; or (b) receives notice of action or threat of action with respect to its debarment, during the term of this Agreement, Patheon agrees to notify Client immediately. If Patheon or any of its officers, employees or agents becomes debarred as set forth in clause (a) above or receives notice of action or threat of action as set forth in clause (b) above, Client will have the right to terminate this Agreement upon written notice to Patheon.

9.5 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

NEITHER PARTY MAKES ANY WARRANTY OR REPRESENTATION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. WITHOUT LIMITING THE FOREGOING, NEITHER PARTY MAKES ANY WARRANTY OR REPRESENTATION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR REPRESENTATION OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Except for liability for breach by either Party of its obligations of Confidentiality under Article 11, under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other Party of an indirect or consequential nature, regardless of any notice of the possibility of these damages. This Section 10.1 will not be deemed to limit either Party's indemnification obligations under this Article 10.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2 and Section 6, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon's maximum responsibility per Year for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(b) Maximum Liability. Subject to Section 10.2(c) and excluding Patheon's indemnity obligations arising under Section 10.3, Patheon's maximum liability to Client per Year under this Agreement or the Product Agreement for a single Product for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement or the applicable Product Agreement will not exceed on a per Product basis […***…].

(c) Nothing contained in this Agreement will exclude or limit either Party's liability for personal injury, death or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its Affiliates and licensees, and their respective directors, officers, employees, and agents (**"Client Indemnitees"**) against all losses, damages, costs, judgments, liability, fees and expenses (including reasonable attorneys' fees) (collectively, **"Losses"**) incurred by any Client Indemnitee due to any suit, claim, demand, judgment or action brought by any Third Parties (other than Affiliates) (each, a **"Claim"**), including, without limitation any Claim of personal injury or property damage, to the extent that the injury or damage is the result of (a) a failure by Patheon or any of its Affiliates to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws, (b) Patheon's breach of any of its obligations, representations or warranties under this Agreement, or (c) the negligence or willful misconduct of any Patheon Indemnitee except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or willful misconduct of any Client Indemnitee.

(b) If a Claim occurs, Client will: (a) promptly notify Patheon of the Claim; (b) use commercially reasonable efforts to mitigate the effects of the Claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense. Notwithstanding the foregoing, Patheon will not compromise or

settle any Claim for which a Client Indemnitee is requesting indemnification for any damages other than monetary damages without Client's prior written consent, which will not be unreasonably withheld.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon and its Affiliates and their respective directors, officers, employees, and agents ("**Patheon Indemnitees**") against all Losses, incurred by any Patheon Indemnitee due to any Claim of infringement or alleged infringement of any Third Party Rights in the Products, or any Claim of personal injury or property damage, in each case, to the extent that the Losses are the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, or the negligence or wilful misconduct of any Client Indemnitee, except to the extent that the Losses are due to the negligence or willful misconduct of any Patheon Indemnitee.

(b) If a Claim occurs, Patheon will: (a) promptly notify Client of the Claim; (b) use commercially reasonable efforts to mitigate the effects of the Claim; (c) reasonably cooperate with Client in the defense of the Claim; and (d) permit Client to control the defense and settlement of the Claim, all at Client's cost and expense. Notwithstanding the foregoing, Client will not compromise or settle any Claim for which a Patheon Indemnitee is requesting indemnification for any damages other than monetary damages without Patheon's prior written consent, which will not be unreasonably withheld.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients or client confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any Party's Representatives containing the Confidential Information will be considered Confidential Information. Samples or materials provided hereunder as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. For the purposes of this ARTICLE 11, a Party or its Representative receiving Confidential Information under this Agreement is a "**Recipient**," and a Party or its Representative disclosing Confidential Information under this Agreement is the **"Disclosing Party**."

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Additionally, Client will have the right to disclose Confidential Information

to sublicensees and/or other strategic partners or in connection with financings or similar transactions provided that the parties to whom Client discloses this information are bound by obligations of confidentiality and non-use no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using all reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will in no event be less than those exercised by Recipient with respect to its own confidential or proprietary Confidential Information of a similar nature. The obligations of confidentiality and non-use set forth in this Article 11 will remain in effect for a period of seven years following the termination of this Agreement.

11.3 Exclusions.

The obligations of confidentiality will not apply to the extent that the information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, provided that the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party with respect to the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information are not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information were publicly known, in the Recipient's possession, or received by the Recipient, unless the combination itself was publicly known, in the Recipient's possession, or received by the Recipient.

11.4 Photographs and Recordings.

Neither Party will take any photographs or videos of the other Party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other Party's facilities, without that Party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out

herein. If any public disclosure is required by law, the Parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party agrees to use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies thereof and any summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement.

11.8 Remedies.

The Parties acknowledge that monetary damages may not be sufficient to remedy a breach by either Party of this Agreement and agree that the non-breaching Party will be entitled to seek specific performance, injunctive and/or other equitable relief to prevent breaches of this Agreement and to specifically enforce the provisions hereof in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Agreement but will be in addition to any and all other remedies available at law or in equity.

ARTICLE 12

DISPUTE RESOLUTION

12.1 Commercial Disputes.

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the Parties will first try to resolve it amicably. In that regard, any Party may send a notice of dispute to the other, and each Party will appoint, within […***…] Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within […***…] from their appointment, or if a Party fails to appoint a representative within the […***…] Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of Patheon and the Chief Executive Officer of Client each Party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the Parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

12.2 Technical Dispute Resolution.

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the Parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a "**Technical Dispute**"), the Parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each Party will, as soon as possible and in any event no later than […***…] Business Days after a written request from either Party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the Parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within […***…] Business Days of the written request, the Technical Dispute will, at the request of either Party, be referred for determination to an expert in accordance with Exhibit A. If the Parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater clarity, the Parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13

MISCELLANEOUS

13.1 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license under Client's Intellectual Property solely to the extent necessary for Patheon to perform the Manufacturing Services in accordance with this Agreement, and not for any other purpose.

(b) All Inventions generated or derived by Patheon while performing the Manufacturing Services, to the extent relating specifically to the development, manufacture, use or sale of any Product that is the subject of the Manufacturing Services, and all Client Intellectual Property, will be the exclusive property of Client. Patheon hereby assigns, and agrees to assign, all of its right, title and interest in and to all such Inventions and Client Intellectual Property to Client and agrees to take all further acts reasonably required to evidence and/or perfect such assignment to Client, at Client's expense. Patheon will notify Client in writing, as promptly as practicable, of all Inventions and Client Intellectual Property made, created, discovered, generated or derived by Patheon in the course of performing the Manufacturing Services. Patheon may retain one copy of records relating to Client Intellectual Property to the extent required under Applicable Laws.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive, paid-up, royalty-free, transferable license, with the right to sublicense through multiple tiers, to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to manufacture the Product(s).

(d) Each Party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

13.2 Intellectual Property.

All Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon. Neither Party has, nor will it acquire, any interest in any of the other Party's Intellectual Property unless otherwise expressly agreed to in writing or expressly set forth in this Agreement. Neither Party will use any Intellectual Property of the other Party, except as specifically authorized by the other Party or as required for the performance of its obligations under this Agreement.

13.3 Insurance.

Each Party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that Party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less than (i) $[…***…] for each occurrence for personal injury or property damage liability; and (ii) $[…***…] in the aggregate per annum for product and completed operations liability. If requested each Party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. Each Party will further provide the other Party a minimum of 30 days' written notice of a cancellation of, or material change in, the insurance. If a Party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the Party will forthwith notify the other Party in writing and the Parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.4 Independent Contractors.

The Parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the Parties.

13.5 No Waiver.

Either Party's failure to require the other Party to comply with any provision of this Agreement or any Product Agreement will not be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement.

13.6 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations, or subcontract any of its rights or obligations, hereunder without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement without the consent of Client to the extent the subcontractors are specifically named and agreed in the Quality Agreement, provided that Patheon remains primarily liable to the Client for performance by Patheon's subcontractors. Further it is specifically agreed that Patheon may subcontract any part of the Services under a Product Agreement to any of its Affiliates to the extent the Affiliates are specifically named and agreed in the applicable Product Agreement and in the Quality Agreement, provided that Patheon remains primarily liable to the Client for performance by Patheon's Affiliates.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. Client will give Patheon prior

written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement and Client will remain liable hereunder. If Client only assigns a portion of this Agreement or a Product Agreement to a Third Party, the partial assignment will be subject to Patheon's cost review of the assigned Products and Patheon may terminate this Agreement or the Product Agreement or any assigned part thereof, on 18 months' prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time. But this time period will automatically be extended by an additional three months if, at 18 months after the notice, Client is working in good-faith to secure, and/or obtain required approvals for, another supplier.

(c) Despite the foregoing provisions of this Section 13.6, either Party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business to which this Agreement relates, but the assignee must execute an agreement with the non-assigning Party whereby it agrees to be bound hereunder.

13.7 Force Majeure.

Neither Party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that Party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A Party claiming a right to excused performance under this Section 13.7 will immediately notify the other Party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither Party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement. If the performance of any obligation under this Agreement is delayed due to a Force Majeure Event for a continuous period of more than 60 days, the other Party may terminate this Agreement without penalty upon written notice to the other Party under such event. All Annual Minimums will be suspended for the period of a Force Majeure Event but will be re-instated if the Force Majeure Event is cured. If this Agreement or any Product Agreement is terminated due to a Force Majeure Event lasting longer than 60 days as set forth above, Client may request Patheon to reasonably assist in the transfer of the technology required to manufacture the Product to a third party supplier designated by Client. If so requested, Patheon will promptly initiate and complete the technology transfer at Client's cost.

13.8 Additional Product.

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, and D as applicable.

13.9 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other Party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attention: […***…]
Telecopier No.: […***…]
Email address: […***…]

With a copy to:

ACADIA Pharmaceuticals Inc.
3611 Valley Centre Drive, Suite 300
San Diego, CA 92130
Attention: […***…]
Telecopier No.: […***…]
Email address: […***…]

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: […***…]
Telecopier No.: […***…]
Email address: […***…]

With a copy to:

Patheon Inc.
Canterbury Place
4815 Emperor Boulevard
Research Triangle Park,
NC 27703
Attention: […***…]
Telecopier No.: […***…]

or to any other addresses, telecopy or facsimile numbers or electronic mail addresses given to the other Party in accordance with the terms of this Section 13.9. Notices or written communications made or given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner, or one Business Day after being sent by overnight courier.

13.10 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.11 Entire Agreement.

This Agreement, and all Schedules hereto, together with the applicable Product Agreement and Quality Agreement, constitutes the full, complete, final and integrated agreement between the Parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of the Parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, and the Quality Agreement.

13.12 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the Parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by the Parties.

13.13 No Third Party Benefit or Right.

For greater clarity, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.14 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or facsimile signature, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.15 Use of Client Name.

Patheon will not make any use of Client's name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client's name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon's Manufacturing Services.

13.16 Governing Law.

This Agreement and any Product Agreement will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement or any Product Agreement.

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement as of the date first written above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Francis P. McCune

Name: Francis P. McCune

Title: Secretary

ACADIA PHARMACEUTICALS INC.

By: /s/ Steve Davis

Name: Steve Davis

Title: Interim CEO

APPENDIX 1

FORM OF PRODUCT AGREEMENT

(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated August 3, 2015 between **Patheon Pharmaceuticals Inc.**, and **ACADIA Pharmaceuticals Inc.** (the "**Master Agreement**"), and is entered into **[insert effective date]** (the "**Effective Date**"), between Patheon Pharmaceuticals Inc., **[or applicable Patheon Affiliate]**, a corporation existing under the laws of the State of Delaware **[or applicable founding jurisdiction for Patheon Affiliate]**, having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237-1625 **[or Patheon Affiliate address]** ("**Patheon**") and **[insert Client name, legal entity, founding jurisdiction and address]** ("**Client**").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. **Product List and Specifications** (See Schedule A attached hereto)

2. **Minimum Order Quantity, Annual Volume, and Price** (See Schedule B attached hereto)

3. **Annual Stability Testing and Validation Activities (if applicable)** (See Schedule C attached hereto)

4. **Active Materials, Active Materials Credit Value, and Maximum Credit Value** (See Schedule D attached hereto)

5. **Yearly Forecasted Volume:** (insert for sterile products if applicable under Section 4.2.1 of the Master Agreement)

6. **Territory**: (insert the description of the Territory here)

7. **Manufacturing Site**: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)

8. **Governing Law**: (if applicable under Section 13.16 of the Master Agreement)

9. **Inflation Index:** (if applicable under Section 4.2(a) of the Master Agreement for Products manufactured outside of the Unites States or Puerto Rico)

10. **Currency**: (if applicable under Section 1.4 of the Master Agreement)

11. **Initial Set Exchange Rate**: (if applicable under Section 4.2(d) of the Master Agreement)

12. **Initial Product Term:** (if applicable under Section 8.1 of the Master Agreement)

13. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

14. Other Modifications to the Master Agreement: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]

By: _____

Name: _____

Title: _____

ACADIA PHARMACEUTICALS INC. [or applicable Client Affiliate]

By: _____

Name: _____

Title: _____

SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

Product List

[insert product list]

Specifications

Prior to the start of commercial manufacturing of Product under this Agreement Client will give Patheon the originally executed copies of the Specifications as approved by the applicable Regulatory Authority or as most recently filed with such Regulatory Authority. If the Specifications received are subsequently amended, then Client will give Patheon the revised and originally executed copies of the revised Specifications. Upon acceptance of the revised Specifications, Patheon will give Client a signed and dated receipt indicating Patheon's receipt of the revised Specifications.

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[Insert Price Table]

Manufacturing Assumptions:

Packaging Assumptions:

Testing Assumptions:

Costs Included in Unit Pricing

[…***…]

Costs Not Included in Unit Pricing

[…***…]

[…***…]

SCHEDULE C

ANNUAL STABILITY TESTING

Patheon and Client will agree in writing on any stability testing to be performed by Patheon on the Products. This agreement will specify the commercial and Product stability protocols applicable to the stability testing and the fees payable by Client for this testing.

[NTD: Schedule C should clearly indicate when and/or under what conditions Patheon's responsibility to perform stability testing will end]

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
●	●
●	●

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
		Client's actual cost for Active Materials not to exceed $_____per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement **[for any Product]** in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
	[…***…]

[End of Product Agreement]

EXHIBIT A

TECHNICAL DISPUTE RESOLUTION

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert**. Within […***…] Business Days after a Party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the Parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the Parties are unable to so agree within the […***…] Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the Parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest**. Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the Parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator**. No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert's determination or the procedure by which the expert reaches his determination under this Exhibit A.

4. **Procedure**. Where an expert is appointed:

   (a) Timing. The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the Parties and that he issues the authorizations to the Parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within […***…] Business Days (or another other date as the Parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

   (b) Disclosure of Evidence. The Parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within […***…] Business Days of a written request from the relevant expert to do so.

   (c) Advisors. Each Party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the Parties will co-operate and seek to narrow and limit the issues to be determined.

   (d) Appointment of New Expert. If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either Party) be appointed and the appointment of the existing expert will thereupon cease for the purposes of determining the matter at issue between the Parties save this if the existing expert renders his decision with full reasons

prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(e) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the Parties.

(f) Costs. Each Party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the Parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

-

EXHIBIT B

MONTHLY ACTIVE MATERIALS INVENTORY REPORT

TO: ACADIA PHARMACEUTICALS INC.

FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]

RE: Active Materials monthly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated August 3, 2015 (the "**Agreement**")

Reporting month: _____

Active Materials on hand at beginning of month: _____kg (A)

Active Materials on hand at end of month: _____ kg (B)

Quantity Received during month: _____ kg (C)

Quantity Dispensed during month: _____ kg
(A + C – B)

Quantity Converted during month: _____ kg
(total Active Materials in Products produced and not rejected, recalled or returned)

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate] DATE:_____

Per: _____
Name:
Title:

EXHIBIT C

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: ACADIA PHARMACEUTICALS INC.

FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]

RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Mas Manufacturing Services Agreement dated August 3, 2015 (the "**Agreement**")

Reporting Year ending: _____

Active Materials on hand at beginning of Year: _____ kg (A)

Active Materials on hand at end of Year: _____ kg (B)

Quantity Received during Year: _____ kg (C)

Quantity Dispensed during Year: _____ kg (D)
(A + C - B)

Quantity Converted during Year: _____ kg (E)
(total Active Materials in Products produced and not rejected, recalled or returned)

Active Materials Credit Value: $_____ / kg (F)

Target Yield: _____ % (G)

Actual Annual Yield: _____ % (H)

((E／D) * 100)

Shortfall: $_____ (I)
(((G – […***…]) - H)／100) * F * D (if a negative number, insert zero)

Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $_____.

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: _____

PATHEON PHARMACEUTICALS INC.
[or applicable Patheon Affiliate]

Per: _____
Name:
Title:

-

EXHIBIT D

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(d)

Time period: 10/01/11 to 09/30/12.

Time period: 10/01/11 to 09/30/12.

Average (365 days):

0.998

-- "Set Exchange Rate"

SAMPLE EXCHANGE CALCULATION

Initial Exchange Rate:

1.000

CAD/USD

Set Exchange Rate:

0.998

CAD/USD

Initial Price:

3.59

Revised Price (FX):

3.70

(Material price and PPI adjustments)

Calculation:

[Revised Price (After FX)] = [Revised Price (Before FX)] X [Initial Exchange Rate] / [Set Exchange Rate]

= 3.70 X [1.000 / 0.998]

= 3.71

-

Exhibit 10.18

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [...*...], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

First Amendment to Product Agreement between Patheon Pharmaceuticals Inc. and ACADIA Pharmaceuticals Inc.

This First Amendment to Product Agreement (the "**Amendment**"), dated April 25, 2016 (the "**Amendment Date**"), is made by and between Patheon Pharmaceuticals Inc. ("**Patheon**") and ACADIA Pharmaceuticals Inc. ("**ACADIA**").

WHEREAS, Patheon and ACADIA have entered into that certain Master Manufacturing Services Agreement, dated August 3, 2015 (the "**MSA**") and that certain Product Agreement under the MSA, dated August 3, 2015 (the "**Product Agreement**"); and

WHEREAS, Patheon and ACADIA now wish to amend the Product Agreement as set forth in this Amendment. All capitalized terms used but not defined in this Amendment shall have the respective meanings set forth in the MSA or Product Agreement, as applicable.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree as follows:

1. Amendment to Schedule B. The Product pricing tables on Schedule B of the Product Agreement are hereby amended and replaced with the pricing tables set forth on Exhibit 1 of this Amendment. For clarity, the pricing set forth in the updated pricing tables applies with respect to Product purchases beginning retroactively as of January 1, 2016.

2. Amendment to Schedule C. The stability pricing table on Schedule C of the Product Agreement is hereby amended and replaced with the stability pricing tables set forth on Exhibit 2 of this Amendment.

3. No Other Modifications. Except as specifically modified by this Amendment, the terms and conditions of the Product Agreement including, without limitation, all other terms and conditions included in each of the amended Schedules, and the MSA, shall remain unchanged.

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of the Amendment Date.

Patheon Pharmaceuticals Inc.	**ACADIA Pharmaceuticals Inc.**
By: /s/ Francis P. McCune	By: /s/ James Nash
Name: Francis P. McCune	Name: James Nash
Title: Secretary	Title: SVP, Technology Development & Operations

Exhibit 1

Updated Pricing Tables

[…*…]**

Exhibit 2

Updated Stability Pricing

[…***…]

[…***…]

Exhibit 10.19

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [...*...], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

Second Amendment to Product Agreement between Patheon Pharmaceuticals Inc. and ACADIA Pharmaceuticals Inc.

This Second Amendment to Product Agreement (the "**Amendment**"), dated October 6, 2016 (the "**Amendment Date**"), is made by and between Patheon Pharmaceuticals Inc. ("**Patheon**") and ACADIA Pharmaceuticals Inc. ("**ACADIA**").

WHEREAS, Patheon and ACADIA have entered into that certain Master Manufacturing Services Agreement, dated August 3, 2015 (the "**MSA**") and that certain Product Agreement under the MSA, dated August 3, 2015, as amended on April 25, 2016 (the "**Product Agreement**"); and

WHEREAS, Patheon and ACADIA now wish to amend the Product Agreement as set forth in this Amendment. All capitalized terms used but not defined in this Amendment shall have the respective meanings set forth in the MSA or Product Agreement, as applicable.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree as follows:

1. **Amendment to Schedule C.** The stability pricing table on Schedule C of the Product Agreement is hereby amended and replaced with the stability pricing tables set forth on Exhibit 1 of this Amendment.

2. Side Letter Agreements. The parties hereby agree that any future changes to stability testing set forth in Schedule C of the Product Agreement, and any annual adjustments to Product pricing set forth in Schedule B of the Product Agreement pursuant to Section 4.2 of the MSA, may be documented via separate side letter agreement between Patheon and ACADIA.

3. No Other Modifications. Except as specifically modified by this Amendment, the terms and conditions of the Product Agreement including, without limitation, all other terms and conditions included in each of the amended Schedules, and the MSA, shall remain unchanged.

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of the Amendment Date.

Patheon Pharmaceuticals Inc.	**ACADIA Pharmaceuticals Inc.**
By: /s/ Nicholas M. Buschur	By: /s/ James Nash
Name: Nicholas M. Buschur	Name: James Nash
Title: Executive Director & GM	Title: SVP, Technology Development & Operations

Exhibit 1

Updated Stability Pricing

[…*…]**

[...***...]

[…***…]

[…***…]
[…***…]

Exhibit 10.20

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [...*...], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

Third Amendment to Product Agreement between Patheon Pharmaceuticals Inc. and ACADIA Pharmaceuticals Inc.

This Third Amendment to Product Agreement (this "**Amendment**"), dated December 11, 2017 (the "**Amendment Date**"), is made by and between Patheon Pharmaceuticals Inc. ("**Patheon**") and ACADIA Pharmaceuticals Inc. ("**ACADIA**").

WHEREAS, Patheon and ACADIA have entered into that certain Master Manufacturing Services Agreement, dated August 3, 2015 (the "**MSA**") and that certain Product Agreement under the MSA, dated August 3, 2015, as amended on April 25, 2016 and October 6, 2016 (the "**Product Agreement**"); and

WHEREAS, Patheon and ACADIA now wish to amend Schedules A, B, C, and D to the Product Agreement to add Nuplazid 10 mg tablets as a Product as set forth in this Amendment. All capitalized terms used but not defined in this Amendment will have the respective meanings set forth in the MSA or Product Agreement, as applicable.

NOW THEREFORE in consideration of the premises hereof and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, the parties agree as follows:

1. **Amendment to Schedules A, B, C, and D.**

   (a) Schedule A is revised to add to the Product List an additional and separate Product as follows: "**Pimavanserin Tablets 10mg Strength**." The language regarding Specifications shall remain as currently drafted, and is applicable to both Products.

   (b) Schedule B is revised to add information for Pimavanserin Tablets 10mg Strength as set forth in **Exhibit 1**.

   (c) Schedule C is revised to add information for Pimavanserin Tablets 10mg Strength as set forth in **Exhibit 2**.

   (d) Schedule D, Active Materials Credit Value, and Maximum Credit Value, Product, are revised to add "**Pimavanserin Tablets 10mg Strength**" in the Product column of each table.

   (e) For clarity, the term of the Product Agreement as set forth on the cover page of the Product Agreement shall remain unchanged.

2. Side Letter Agreements. For clarity, the language in Section 2 of the Second Amendment to the Product Agreement, dated April 25, 2016, regarding side letter agreements to document future changes to stability testing and annual adjustments to pricing pursuant to Section 4.2 of the MSA, shall continue to apply to both Products covered by the Product Agreement.

3. No Other Modifications. Except as specifically modified by this Amendment, the terms and conditions of the Product Agreement including, without limitation, all other terms and conditions included in each of the amended Schedules, and the MSA, remain unchanged.

[signature page to follow]

IN WITNESS WHEREOF, the parties have caused this Amendment to be duly executed by their authorized representatives, effective as of the Amendment Date.

Patheon Pharmaceuticals Inc.	**ACADIA Pharmaceuticals Inc.**
By: /s/ Amanda Bosse	By: /s/ James Nash
Name: Amanda Bosse	Name: James Nash
Title: VP and GM Cincinnati Regional Ops	Title: SVP, Technology Development & Operations

Exhibit 1

SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME AND PRICE
(Pimavanserin Tablets 10mg Strength)

Annual Volume Forecast

[…***…]

Pricing Tables

Pricing includes the cost of labor, overhead, raw materials, packaging components and QC testing and such additional items noted as being included in the price as described below. For clarity, both commercial and validation batches of Pimavanserin Tablets 10mg Strength are subject to this Product Agreement as described below.

[…***…]

Costs Included in Unit Price

[…***…]

Costs Not Included in Unit Price

[…***…]

Key Technical Assumptions

The following technical parameters apply to the production of Pimavanserin Tablets 10mg Strength and the materials used therein. […***…]

Manufacturing Assumptions

[…***…]

Packaging Assumptions

- **Packaging Components:**

[…***…]

Testing Assumptions

[…***…]

Supply Chain Assumptions

[…***…]

For clarity, the foregoing shall not amend the Pricing provisions of the MSA that are applicable to all Products and Product Agreements as set forth in the MSA.

Exhibit 2

SCHEDULE C

ANNUAL STABLITY TESTING
(Pimavanserin Tablets 10mg Strength)

ACTIVITY	*PRICE*
[…***…]	

Exhibit 10.35

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

MASTER COMMERCIAL SUPPLY AGREEMENT

THIS COMMERCIAL SUPPLY AGREEMENT (the "Agreement" or this "CSA") is made and entered into the 16th day of November , 2022 (the "**Effective Date**"), by and between **Corden Pharma Bergamo S.p.A.,** having a place of business at Via Bergamo 121, 24047 Treviglio (BG), Italy ("Corden"), and **Acadia Pharmaceuticals, Inc.**, a Delaware corporation with offices at 3611 Valley Centre Drive, Ste. 300, San Diego, CA 92130 ("**Customer**"). Corden and Customer, as used herein, may be referred to, collectively, as the "Parties" and individually as a "Party".

Recitals

WHEREAS, Customer is the licensor of proprietary Product;

WHEREAS, Customer is engaged in the registration, manufacturing, marketing, promotion and distribution of pharmaceuticals Product (as defined below) and has obtained all necessary permits and approvals from all relevant authorities for the completion of certain Phase III clinical studies and/or for the marketing and sale of the Product in the Territory;

WHEREAS, in order to ensure a continuous manufacturing and a reliable supply of the Product and to secure enough manufacturing capacity after the potential launch of Product, Customer is interested in entering in this CSA with Corden for commercial manufacturing services;

WHEREAS, Corden has the requisite infrastructure, licenses, permits ,and capabilities, including trained and experienced personnel and technical skills, to manufacture and supply the Product to Acadia for the purposes herein pursuant to the terms and conditions of this Agreement;

WHEREAS, the Parties previously entered into a Master Services Agreement ("MSA"), effective November 17, 2018, for Corden to perform certain non-commercial development, analysis, and manufacturing Product services for Acadia under the MSA;

WHEREAS, the Parties desire to maintain the MSA and now enter into this CSA to delineate, the terms and conditions for Corden to provide commercial supply manufacturing, related testing and ancillary services for Acadia as agreed by the Parties;

NOW, THEREFORE, for and in consideration of the foregoing premises and of the mutual covenants of the Parties hereinafter set forth, the Parties hereto agree as follows:

TABLE OF CONTENTS

1. DEFINITIONS

Definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms. The following words, terms and phrases, when used herein, shall have the following respective meanings:

1.1 "Acadia" shall have the meaning set forth on the front page of this Agreement.

1.2 "Affiliate" shall mean, with respect to a Party, any corporation or other entity that controls, is controlled by, or is under common control with such Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or controls, directly or indirectly, fifty percent (50%) or more of the share capital or voting rights of such entity or the power to direct or cause the direction of the management or policies of such other corporation or entity, whether through the ownership of voting securities, by contract or otherwise.

1.3 "Agreement" or **"CSA"** shall mean this Commercial Supply Agreement including its Annexes and Product Addenda (and appendices, if applicable), as amended from time to time by mutual written agreement signed by both Parties.

1.4 "API" shall mean any pharmaceutical or biopharmaceutical agent (whether chemical or biologic) identified as a Product in any CSA Product Addendum.

1.5 "Applicable Law(s)" means the applicable provisions of all ordinances, rules, regulations, constitutions, laws, statutes, treaties, orders, decrees guidelines, guidance, or other requirements of any Governmental and/or Regulatory Authority that may be in effect and that are applicable to a Party and its activities performed pursuant to this Agreement in the country where such activity is performed, including, but not limited to compliance with cGMP and any environmental or biohazard laws in the country where the manufacture takes place.

1.6 "Background IP" shall have the meaning as set out in Section 3.1.

1.7 "Batch" means a specific quantity of Product Manufactured by Corden under cGMP in accordance with the Manufacturer's Release Specifications and Service related requirement(s) stated herein or in any applicable Product Addendum, the Parties' Quality Agreement, and using the Manufacturing Process.

1.8 Batch Documentation means all documentation relating to a Batch, including the executed Batch record (EBRs) and additional documents relating to the Batch such as the analytical testing records, the release for the Materials, deviations, and all documents relating directly to a Batch that Corden is required to maintain according to cGMP, the Specifications, service requirements , the Quality Agreement, the relevant Purchase Order or Work Order, and all Applicable Laws. These records are generated by Corden's Quality Control and reviewed and approved by Quality Assurance.

1.9 "Business Day" means any day other than a Saturday or Sunday or a day that is a statutory holiday in Delaware, USA or Treviglio, Italy.

1.10 "Certificate of Analysis" means a document signed by an authorized representative of Corden describing the testing methods applied to the Product, the corresponding acceptance criteria, and the results of such testing.

1.11 "Certificate of Compliance" means a document signed by an authorized representative of Corden certifying that a particular batch of the Product was manufactured in accordance with cGMP, Applicable Law, and the Manufacturer's Release Specifications.

1.12 "cGMP" , **"GMP" or "Current Good Manufacturing Practices"** means the regulatory requirements for the current good manufacturing practices in the United States Code of Federal Regulations 21 CFR Part 210 & Part 211, the standards, rules, principles, and guidelines set out in the provisions of Chapter II of the EC Commission Directive 2003/94/EC, together with European Union ("EU") Volume 4 Good Manufacturing Guidelines, the MHLW GMP/GQP ordinances and applicable regulations in Japan and/or Canada, as applicable to the manufacture of the Product, and all rules,

regulations, promulgations, policies, and guidelines of other Regulatory Authorities applicable to the manufacture of the Product in the Territory in effect at any given time during the applicable Term.

1.13 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by either Party with respect to any objective, [***].

1.14 "Customer Release" means the release of cGMP Product by Customer used in humans in accordance with Customer's standard operating procedures, the Quality Agreement and cGMP. Such Customer Release shall be conducted by Customer through review of all appropriate documentation which signifies that the Product has been produced using approved processes, in compliance with appropriate regulations, including but not limited to, cGMP, and meets the established specifications including the Manufacturer's Release Specifications.

1.15 "CMC" means the chemistry, manufacturing, and controls section(s) and data in the Health Registrations that cover the chemical composition of the Product and its components and the control and Manufacturing Process for the Product, as amended from time to time.

1.16 "Corden" shall have the meaning set forth in the preamble on page 1.

1.17 "Confidential Information" shall have the meaning set forth in Section 12.1.

1.18 "Control" means the direct or indirect ownership of more than fifty percent (50%) of the equity interest in such corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity.

1.19 "Customer Material" mean Raw Materials provided by or on behalf of Customer to Corden. All Customer Material, including qualified suppliers, shall be listed in the respective Product Addendum.

1.20 "**Defect**" means, in respect of a Product, a failure to comply with the applicable Specification and/or to have been manufactured in accordance with cGMP, and "**Defective**" shall be construed accordingly.

1.21 "**Defective Product**" means a Product with a Defect.

1.22 "**Delivery Date**" means the date agreed by the Parties for the delivery of Products in a Product Addendum or Purchase Order or as otherwise agreed in writing by the Parties pursuant to Section 5.2.

1.23 "Delivery Term" shall have the meaning as described in Section 5.3 (a).

1.24 "Develop" or **"Development"** means studies and other activities conducted by Corden under this Agreement to develop a process(es) manufacture and supply of Product and/or to validate all or part of a Manufacturing process including without limitation analytical tests and methods, formulations and dosage forms and stability. Development activities shall be described in the applicable Product Addendum.

1.25 "Facility" or "Manufacturing Site" means Corden's facility where the Product is being manufactured as also defined in the Product Addendum.

1.26 "FDA" means the U.S. Food and Drug Administration.

1.27 "Force Majeure" is an event described in Section 14.

1.28 "Governmental Authority" means any supra-national, federal, national, regional, state, provincial or local entity responsible for granting approvals for the performance of services under this Agreement or for issuing or enforcing any Applicable Law, or for exercising authority with respect to the manufacture of the Product or the conduct of manufacturing services at any Production Facility, including without limitation the FDA and EMA.

1.29 "Health Registration" means, with respect to a pharmaceutical product containing Product, all registrations with and approvals from the relevant Governmental Authority necessary to market and sell such pharmaceutical product in a given country or group of countries, including the technical, medical and scientific licenses, registrations, authorizations and/or approvals of such medicinal product (including any marketing authorizations, pricing approvals, reimbursement approvals, and labeling approvals, as applicable). For the United States, the term Health Registration shall include a New Drug Application (NDA), for such pharmaceutical product and any amendments thereto.. For a Product in this Agreement, "Health Registration" shall also refer to the Health Registration for the Product's final finished form, as applicable. For clarity, Health Registrations shall exclude any permits specific to the Facility.

1.30 "Initial Term" shall have the meaning set forth in Section 13.1.

1.31 "Intellectual Property" means collectively, patents, patent applications, trademarks, copyright, trade secrets, inventions, service marks, design rights, including applications for any of the foregoing, all rights in the know-how, trade or business secrets, and/or trade or business names and other rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the Territory whether registerable or not.

1.32 "Latent Defect" means a Defect existing at the time of delivery of the Product to Customer or its designee(s) but which could not reasonably be discovered by a visual inspection of its outer packaging or any accompanying documentation.

1.33 "Losses" means all losses, claims, liabilities, costs, awards, fines, penalties, expenses (including reasonable attorney's fees, court fees and other reasonable professional expenses) and damages of any nature whatsoever reasonably foreseeable and unavoidable, however, always excluding any loss of profit or anticipated profit, loss of production, losses caused by business interruptions, loss of revenue and loss of goodwill or reputation.

1.34 "Manufacture" or "Manufacturing" means, as applicable, any and all operations, including without limitation, receipt of materials, Processing, testing, handling, labeling, quality control, releasing, storing, sample retention, serialization, and packaging for shipment and/or delivery according to the agreed Delivery Terms, carried out by or on behalf of Corden in the preparation and supply of the Product in accordance with the terms of this Agreement, the Quality Agreement, and subject to any applicable Product Addendum executed pursuant hereto.

1.35 "Manufacturing License" means any consent, permit, authorization or approval required by any Regulatory Authority for or in connection with Corden's Manufacture of the Product at the Manufacturing Site(s) and the export/import of the Product to Customer in the Territory in accordance with any stated Delivery Terms or as specified in the Product Addendum.

1.36 "Manufacturing Run" means a manufacturing campaign for the Product on under cGMP, in accordance with the Specifications, a Product Addendum, and Quality Agreement and using the Manufacturing Process.

1.37 "Manufacturing Process" means, with respect to the Product, the manufacturing process that is in effect on the effective date of a Product Addendum, which process shall not be changed by Corden or Customer during the Term except in accordance with the terms of this Agreement.

1.38 "Manufacturing Standards" has the meaning set forth in Section 2.5.

1.39 "**Marketing Application**" shall mean an application for marketing authorization, which has not yet been approved by the FDA or other Regulatory Authority, including without limitation, an FDA New Drug Application ("NDA"), and other similar marketing authorizations promulgated by Regulatory Authorities.

1.40 "Market Authorization" shall mean any approved Marketing Application promulgated by Regulatory Authorities.

1.41 "Master Batch Record" means a controlled document of Corden, approved by authorized representatives of both Parties, that documents the Manufacturing Process. It includes all relevant process parameters to be met and equipment and raw materials to be used.

1.42 "Manufacturer's Release" means Corden has: (i) Manufactured and/or packaged and/or labeled a Product according to the Master Batch Record; (ii) fulfilled its testing/analytical obligations as further set forth herein; (iii) had its quality department review and approve all Manufacturing and testing services performed by Corden; (iv) completed and made available to the Customer all documentation related to such Product pursuant to the Quality Agreement or any additional documentation reasonably requested from the Customer's quality department; and (v) provided Customer with notice that such Product is available to be picked up by Customer's carrier.

1.43 "Manufacturer's Release Specifications" means the defined list of analytical test methods performed by Corden or on behalf of Corden and the respective acceptance criteria thereto for the Product as set forth in the applicable Product Addendum for Corden Manufacturer's Release.

1.44 "**Materials**" means the active ingredients, raw materials, excipients, packaging materials and components used in the manufacture of the Products.

1.45 "Minimum Annual Volume Commitment" means the annual minimum volume of Product to be ordered by Customer per calendar year as specified in the Product Addendum.

1.46 "Minimum Order Quantity" means a minimum number of Batches or Product units to be ordered by Customer per Purchase Order as further specified in the Product Addendum.

1.47 "Product" means any pharmaceutical product, API, starting material, Intermediate, precursor to be manufactured by Corden pursuant to this Agreement as more specifically described in a Product Addendum.

1.48 "Product Addendum" means a written individual agreement, in a form similar to the Product Addendum template, Appendix 1, attached hereto and incorporated by reference, between the Parties for Corden to provide Services with respect to a specific Product and Manufacture such Product for Customer's commercial use according to the terms and conditions set forth in this Agreement.

1.49 "**Product Price**" means any fee for Services associated with the Manufacture of a Batch or agreed commercial price per Batch, vial or other units defined in the Product Addendum.

1.50 "Process" or **"Processing"** means, as applicable, manufacturing, handling, storing, analyzing, testing, filling, finishing, packaging, inspecting, labeling, and preparing for shipment of Product (as applicable) by Corden pursuant to this Agreement and/or Product Addendum, but excludes any optimization and/or improvement of the processes unrelated to the Product.

1.51 "Quality Agreement" refers to a separate agreement, which shall be incorporated by reference into this Agreement, that sets out the parties' respective quality related responsibilities and the Customer's quality assurance standards for Corden's Manufacture of Product and performance of Services.

1.52 "Raw Materials" means all raw materials, chemicals, components, excipients, packaging and labeling components, and other consumable items, which are useful or necessary for the Manufacture of the Product, as may be further specified in a bill of materials in the Product Addendum.

1.53 "**Regulatory Authority**" means any multinational, federal, state, local, municipal or other Governmental Authority in the Territory having jurisdiction over any aspect of the activities contemplated by this Agreement, including to the extent applicable, in the United States- the FDA, and in the EU,-the European Medicines Agency (EMA), as well as the respective authorities in Japan and Canada.

1.54 "Services" means certain pharmaceutical Development services in addition to the Processing and Manufacturing of Product, including without limitation, sourcing of certain Raw Materials,

analytical method development and analysis, stability services, clinical packaging, validation services, quality assurance, and regulatory consulting provided by Corden.

1.55 "Specifications" means numerical limits, ranges, required quality and characteristics of the Product, and/or other acceptance criteria to which the Raw Materials, intermediates, Product or in-process samples of making the Product, must conform to in order for the Product to be acceptable for its intended use under this Agreement and the Quality Agreement, including, but not limited, Manufacturer's Release Specifications.

1.56 "Testing Specification" means the specific master document that lists the testing parameters, references to analytical procedures and their Specifications. Types of Testing Specifications include but are not limited to the Raw Materials, in-process controls, intermediates and Product.

1.57 "Term" shall have the meaning set forth in Section 13.1.

1.58 "Territory" means the countries and/or jurisdictions, where Customer intends to market the Product: [***].

1.59 "Tech Transfer" means the transfer of all technology and information belonging to the Customer and relating to (a) the Product, including the Processing, testing, or Manufacturing of the Product; (b) all information belonging to or acquired by Customer under this Agreement; and (c) any relating documentation whether created individually or jointly by Corden or Customer.

2. MANUFACTURING OBLIGATIONS

2.1 Scope of the Agreement. Subject to the terms and conditions set forth herein, Corden agrees to Manufacture Product for Customer and perform additional services as defined below in accordance with Customer's requirements as defined and forecasted pursuant to Section 5 and as specified in a Product Addendum.

2.2 Additional Services. Corden shall provide such other Services in connection with Manufacturing of Product as may be agreed upon by the Parties in a Product Addendum, including but not limited to stability studies (including registration stability), analytical validation completion based on identified gaps, placebo manufacture (if required), services arising from the preparation of a response to a question from a Regulatory Authority (to the extent necessary), additional validation protocols / testing (if required for future commercial batches), redevelopment (if required), scale up Batch size, process improvements.

2.3 License. Commencing on the Effective Date and continuing only until the expiration or termination of this Agreement, in order to enable Corden to operate and perform its obligations set forth in this Agreement, Customer hereby grants to Corden a non-exclusive, non-transferable, sub-licensable (but only to Approved Subcontractors, listed in Product Addendum), royalty-free, limited license under the Product Intellectual Property for the limited purpose of manufacturing the Product for sale to Customer pursuant to the terms and conditions of this Agreement.

2.4 No General Terms and Conditions. All Product Addenda are governed by the terms and conditions of this Agreement. The general terms and conditions of each Party and each of the Party's Affiliates shall not apply under this Agreement and are hereby expressly excluded. Any reference in a Purchase Order to the general terms and conditions of any Party, Affiliates or Third Parties shall not become legally effective between the involved legal entities.

2.5 Product Manufacturing Standards. Corden shall manufacture the Product at the Manufacturing Site specified in a Product Addendum in accordance with cGMP, the Manufacturer's Release Specifications, the Manufacturing License, and the Parties' Quality Agreement, and all Applicable Laws relevant to the Manufacture of the Product at the Facility and with personnel that are knowledgeable, qualified and trained to perform the activities required to Manufacture the Product pursuant to the terms and conditions of this Agreement ("**Manufacturing Standards**"). For Services to be performed in accordance with cGMP Regulations, the Parties

agree to enter in a Quality Agreement between the Parties (or its Affiliates) that shall be incorporated herein by reference, as same may be amended from time to time by mutual written agreement between the Parties. The Quality Agreement shall supplement the terms of this Agreement. In the event of inconsistencies between this Quality Agreement and this Agreement, the terms of the Quality Agreement shall control with respect to quality requirements and this Agreement shall control with respect to all other matters.

2.6 Affiliates. Any Affiliate of Corden who enters into a Product Addendum hereunder shall be defined as "Corden" hereunder in lieu of Corden for the purposes of such Product Addendum and shall enjoy the rights and assume the obligations set forth in this Agreement with respect to such Product Addendum. For clarity, under no circumstances shall Corden Bergamo be jointly liable for acts or omissions of any of its Affiliates, or shall the amount limiting the liability of Corden Bergamo be increased by amounts paid by Customer for services or products to any of Corden's Affiliates.

2.7 Subcontracting. Corden may subcontract any part of the Services or the Manufacturing only after prior written consent of Customer to any of its Affiliates and/or to any approved subcontractor. Corden shall remain liable for acts or omissions of its approved subcontractors.

2.8 Timelines and Delivery Dates. Corden will provide Customer with the Manufacturing and related services and deliveries pursuant to any timelines indicated in a Product Addendum.

2.9 Grant of Exclusivity. To the extent and as defined in the Product Addendum, Corden shall not manufacture Product on its own or for any Third Party for marketing, sale, or distribution.

2.10 Minimum Annual Volume Commitment. During the Term of this Agreement, Customer agrees to purchase from Corden the Minimum Annual Volume Commitment as defined in the Product Addendum per each such calendar year. In the event that Customer fails to place Purchase Orders to satisfy the Product quantities relating to the Minimum Annual Volume Commitment in each calendar year, Customer shall compensate Corden with the Product Price for the Product corresponding the to the missing quantities from the Minimum Annual Volume Commitment.

3. INTELLECTUAL PROPERTY (IP)

3.1 **Background IP**. Each Party shall, at all times throughout and after the Term, remain the owner of any and all IP that it owned (or was licensed to use) by the effective date of the signed CDA, and which IP shall, for the purposes of this Agreement shall remain owned or licensed by the Party (collectively "**Background IP**"). Corden acknowledges that (a) IP relating to the Product shall be vested in and belong exclusively to Customer; (b) IP relating to Manufacturing Processes of Product, including testing and packaging that are developed and/or created pursuant to this Agreement shall belong to Customer; however, Corden IP, which is generally used at its Manufacturing Site (to the extent existing prior to the Effective Date, or developed independently of this Agreement without the use of Customer's Confidential Information), shall remain vested in and belong to Corden or its relevant Affiliate. For the purposes of this Section, Background IP vested in Corden (or its Affiliates) shall be defined as "Corden Background IP" and Background IP vested in Customer (or its Affiliates) shall be defined as "Customer Background IP."

3.2 **Customer Arising IP.** Neither Corden, its Affiliates, nor any of its respective subcontractors shall acquire any rights whatsoever to the Product by performing any services pursuant to this Agreement and/or a Product Addendum. All rights to any IP (whether or not patentable) conceived (whether or not reduced to practice) in the performance of Services or Processing pursuant to this Agreement by Corden or its Affiliates' employees, or independent contractors, either solely or jointly with employees, agents, consultants or other representatives of Corden exclusively or primarily relating to the Product, will be owned solely and exclusively by Customer ("**Customer Arising IP**"). Excluding Customer Arising IP, Corden shall own all Inventions and other Intellectual Property (including improvements to Corden's Background IP) made or conceived in connection with the Services or the Manufacturing (collectively, "**Corden IP**").

3.3 **Use of Intellectual Property**. Corden will not use, or allow others to use, any Customer Background or Customer Arising IP for any other purpose other than stated in this Agreement and Product Addenda. Customer hereby grants Corden and any Affiliates and subcontractors approved by Customer a non-exclusive and royalty free license for the term to use Customer Background IP and Customer Arising IP to the extent necessary to Manufacture the Product and perform services under this Agreement. Corden hereby grants to Customer and its Affiliates an irrevocable, worldwide, non-exclusive, and royalty free license to use Corden Background IP and Corden IP to the extent necessary for Customer or its Affiliates to further manufacture, commercialize, distribute, market, export, sell and otherwise use the Product.

3.4 **Assistance**. Corden shall fully cooperate in the preparation, filing, prosecution and maintenance of all trademarks, copyrights, patents or other Intellectual Property of any Customer Arising IP at Customer's sole cost. Such cooperation shall include without limitation execution of all papers and instruments appropriate so as to enable Customer to prepare, file, enforce, and maintain such rights in any country, provided that Customer shall compensate Corden for its reasonable out-of-pocket costs and expenses associated with such actions.

4. CUSTOMER MATERIAL AND RAW MATERIAL

4.1 **Sourcing of Customer Material:**

(a) Unless otherwise agreed between the Parties in a Product Addendum, Customer will at its sole cost and expense deliver the Customer Material to the Facility DDP (Incoterms 2020). Customer's obligation will include obtaining the release of the Customer Materials from the applicable customs agency and Government Authority. Unless otherwise agreed in writing, Customer or Customer's designated broker will be the "Importer" or "Importer of Record" (or equivalent, as understood under Applicable Laws) for Customer Materials imported to the Facility, and Customer is responsible for compliance with Applicable Laws (and the cost of compliance) relating to that role. For Customer Materials which may be subject to import or export to or from the United States, Customer agrees that its vendors and carriers will comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

(b) Unless otherwise agreed between the Parties in a Product Addendum, Customer or its designee shall use Commercially Reasonable Efforts to, except as provided in 4.1 (e) below, deliver to the Facility such quantities of Customer Material within the required timeframe, [***] days or as defined in the Product Addendum, as are reasonably forecasted by Corden pursuant to Section 5.1 (e) for Corden to manufacture the amount of Product ordered by Customer pursuant to Section 5.2, at no cost to Corden. Each delivery of Customer Material shall be accompanied by an appropriate certificate of analysis or equivalent documentation and a statement setting forth the amount of Customer Material being delivered (the "**Quantity Statement**"). Customer Materials shall be delivered in accordance with the provisions and standards set forth in the Quality Agreement or the approved Material specifications, as applicable.

(c) Upon receipt of Customer Material, Corden shall conduct or perform (i) visual inspections in accordance with the Quality Agreement, including identification testing, (ii) testing in accordance with the Testing Specifications, and (iii) a quantity check to confirm that the quantities delivered are as set forth in the applicable Quantity Statement.

(d) Within [***] calendar days or as defined in the Product Addendum after Corden's receipt of Customer Material (" **Inspection Period**"), Corden shall also provide Customer with written confirmation that such shipment conforms with and to the Customer Material Specifications to the extent required under the Quality Agreement, and the Quantity Statement. Corden QA will release and provide COA for the Customer Materials according to the terms of the Quality Agreement, if applicable. Corden shall maintain control samples of the Customer Material and records with respect to such testing and/or inspection, in accordance with Corden's internal

record retention policies and cGMP, and shall make such records available to Customer during normal business hours, upon Customer' prior written request.

(e) In the event that the required quantities of Customer Materials in accordance with Section 5.1.(e) are not received within [***] calendar days, or as defined in the Product Addendum, before the scheduled Manufacturing date not due to a reason within Corden's control, and no other released Customer Materials are stored as Safety Stock at Corden's Facility or its qualified warehouse, Corden is no longer bound by the shipment dates set forth in the Rolling Forecast, and the Parties shall agree in good faith on an appropriate modification of the Manufacturing schedule.

(f) In the event that Corden reasonably determines that any Customer Material does not conform with or to the Customer Material Specifications, Corden shall notify Customer thereof as soon as practicable but not later than [***] Business Days after the conclusion of the Inspection Period, and Corden shall not use such Customer Material for the manufacture of the Product until the conformity of such shipment is established or negated as set forth in this Section Notwithstanding the foregoing, non-conforming materials that are not reasonably discoverable are not subject to the above timelines and will be communicated in writing as soon as possible to Customer, but in no event more than [***] days after the date Corden first becomes aware of the non-conforming material.

(g) Notwithstanding the foregoing and in addition to any further rights of Corden hereunder, the timelines as agreed between the Parties for Purchase Orders concerning the supply of Customer Material either not timely delivered or not meeting the Customer Material Specifications shall be appropriately extended. For clarity, Corden shall not be responsible for any delays in delivery of Product or Non-Conforming Product caused by Customer Material being delivered late or not meeting Specifications. Corden shall use Commercially Reasonable Efforts to make use of the manufacturing slot initially reserved for the Manufacturing of Product for Customer for Third Parties in order to minimise any cost for lost capacity and to find a new manufacturing slot in order that Product that was not manufactured due to such non-conforming or late delivered (i.e. delivery more than [***] Business Days late) Customer Material may be manufactured as soon as practicable using conforming Customer Material. The same will apply with regard to additional time needed for testing of Customer Material. At Customer' discretion and upon request only, Corden shall deliver to Customer (or its designee), or destroy, any rejected Customer Material at Customer' sole cost and expense. Corden shall use Commercially Reasonable Efforts to mitigate loss including but not limited to partial execution of the Product campaign or use of idle capacity for third party projects. If Corden is unable to use such partial of full capacity despite its good faith efforts, Customer agrees to compensate Corden for such lost or idle capacity based on [***]% of Product Price of the respective Product which was planned to be manufactured during the time of idle capacity using the Customer Material which is not available according to a case of subsection 4.1 (e) or 4.1 (f) above.

(h) Customer shall at all times exclusively own and retain all right, title and interest in, to and under any Customer Material delivered to Corden pursuant to this Agreement, except that Corden shall be liable for loss or damage pursuant to Section 11.4.

4.2 All Raw Materials (other than the Customer Material) required for the manufacture of the Products shall be procured and/or purchased by Corden for its own account, at the sole cost and expense of Corden. Prior to use of any such other Raw Materials, Corden shall ensure that such Raw Materials conforms with or to the applicable Raw Materials specifications. Corden shall maintain adequate inventory of such qualified Raw Materials to meet its obligations at Corden's sole expense.

4.3 Safety Stock: no later than [***] months after a Product has obtained regulatory approval, the Parties will negotiate and mutually agree in writing on the quantity of safety stock of Materials, if any, to be carried by Corden to be utilized by Corden for fulfillment of Services for Customer at a later date to ensure that there is a continuity of Product supply in the marketplace ("Safety Stock"), at Customer's expense. Corden will maintain and continually replenish, at Customer's

expense (based on FIFO and FEFO methods to usage) a rolling Safety Stock of Materials, as the case may be, in the quantities agreed to in writing by the Parties, as well as the threshold levels of Safety Stock that must be maintained at all times, taking into account procurement lead time of all Product specific Materials and Product production cycle times. The safety stock will be in place at Customer's expense within [***] months after regulatory approval or within a timeframe mutually agreed upon by both Parties in writing taking into consideration reasonable time to build it. Once safety stock is in place, Corden will replace any defective Materials by utilizing safety stock. Corden will promptly notify Customer of any reduction in safety stock and the level of any safety stock until such time as Safety Stock is replenished to the original agreed upon level. Corden will: (i) store and handle all safety stock in accordance with the provisions of the Quality Agreement, and will take necessary care to prevent its damage, loss or theft; (ii) clearly identify all such safety stock in storage and in its books as goods belonging to Customer; and (iii) always use FIFO and FEFO methods of usage for safety stock.

4.4 Any Customer Material under the control or in the possession of Corden shall be used by Corden solely and exclusively to manufacture Product to be supplied to Customer pursuant to this Agreement. Corden shall supply Customer with all of the Product that Corden manufactures using the Customer Material during the Term.

4.5 Within [***] Business Days after the end of each month during the Term, Corden will provide Customer with an inventory report, which report will minimally include a description of Raw Materials, Customer Material and Product then in its possession or control, including the lot number(s), quantity and inventory status of same.

5. FORECASTS, ORDERS

5.1 Forecasts

(a) Prior to the first commercial launch of the Product using Corden as a registered commercial Manufacturer ("**Launch**"), the Parties shall agree on a binding reservation schedule for the manufacturing capacity required for commercial manufacturing of Product. This reservation schedule as well as the milestones for services for the validation batches may only be changed by mutual agreement of the Parties, ,as further detailed in the Product Addendum.

(b) Unless otherwise agreed in a Product Addendum, during the Term, but no later than the Quarter in which the Product is launched in the first market of the Territory, on a [***] basis, Customer shall provide Corden with a rolling [***]-month forecast ("Rolling Forecast") indicating Customer' expected delivery of Product for the next [***] (i.e., [***]), in full batch sizes. The first [***] months (i.e., the first [***]) of the Rolling Forecast (i.e., [***]) shall be considered binding for both Parties under this Section 5 ("**Binding Forecast**"), and the second [***] period (i.e., [***]) shall be considered non-binding for both Parties ("**Non-Binding Forecast**"). The initial Rolling Forecast is attached hereto as Schedule 1, and each subsequent update will be due on or before the [***] Business Day of each new [***] during the Term (covering such new [***] and the subsequent [***]).

(c) Corden shall review each update to the Rolling Forecast and assess if it is able to manufacture or otherwise supply Customer' requirements for Product in excess of the amount set forth in the previous Binding Forecast, if any, and assuming that the remainder of the Rolling Forecast will become binding in time as contemplated by this Agreement. In the event that, upon receipt of an updated Rolling Forecast, Corden anticipates that it shall not be able to manufacture or otherwise supply Customer' requirements for Product in excess of the amount set forth in the previous Binding Forecast, Corden shall inform Customer in writing within [***] Business Days after Corden's receipt of said updated Rolling Forecast, and Customer shall then be entitled to obtain from alternative suppliers any such excess amount of Product which Corden has indicated that it would not be able to manufacture or otherwise supply for Customer.

For the avoidance of doubt, Corden will not be obliged to manufacture any portion of the initial Binding Forecast that requires a capital investment in the Production Facility, unless otherwise agreed by Corden.

(d) Non-Binding Forecasts provided by Customer shall be made in good faith, using the degree of diligence that Customer would apply in the event that Customer was engaged to manufacture or otherwise supply the Product for itself or another Person. For clarity, as [***]of the Non-binding Forecast becomes [***]of the Binding Forecast, it will automatically become binding except to the extent Customer increase or decrease the amount forecast for such quarter by more than [***]percent ([***]%) over the previous Non-Binding Forecast. The Parties agree to discuss as soon as practicable any such overage request, provided Corden will use commercially reasonable efforts to fulfill such overage and any other additional Product requirement of Customer not contemplated by the updated Binding Forecast.

(e) Within [***] Business Days after receipt of each Rolling Forecast, Corden shall submit to Customer a corresponding good faith, non-binding, estimated rolling forecast of Corden's expected requirements of/for Customer Material based on such Rolling Forecast (taking into account any released quantities of Customer Material already on hand at the Production Facility). Each such forecast provided by Corden shall include a reasonable safety stock of Customer Material (sufficient to manufacture at least the next calendar quarter's Binding Forecast). For clarity, the delivery dates set forth in Corden's forecast for such Customer Materials shall allow [***] days or as specified in the Product Addendum for analytical testing and release of such Customer Materials by Corden.

5.2 Purchase Orders

(a) Customer shall place purchase orders covering the quantities of Product contained in each Binding Forecast (each, a "Purchase Order") and Corden shall accept such Purchase Orders in full (to the extent consistent with the Binding Forecast and meeting the Minimum Order Quantity) and deliver the quantities of Product covered by such Purchase Orders with such delivery dates as are consistent with the agreed lead times for production as specified between the Parties in writing. Customer or its designee shall issue Purchase Orders that include timelines for delivery and quantity of Product to be supplied by Corden and such other details as may be agreed to by the Parties in writing in accordance with such specified lead times. Together with the first Rolling Forecast delivered hereunder, Customer will issue Purchase Orders covering the first [***]-month period thereof (i.e., the initial Binding Forecast). Thereafter, Customer will issue Purchase Orders with each subsequent Rolling Forecast that covers the new calendar quarter added to the latest Binding Forecast. Each Purchase Order will be confirmatory of, and supplemental to, the latest Binding Forecast rather than creating a new legal obligation. For the sake of clarity, after the first [***]-months period thereof (i.e., the initial Binding Forecast) and according to the above-mentioned Order protocol, Customer will routinely place Purchase Orders [***]months prior the delivery date of the Product. If Customer fails to place a Purchase Order for the volumes covered by the Binding Forecast, Corden may invoice Customer the price of Product planned under the Binding Forecast at the end of the [***]-month period. Corden shall use Commercially Reasonable Efforts to mitigate any idle capacity associated with Customer's failure to timely place a Purchase Order. If Corden is able to use the idle Manufacturing slot, Customer shall only pay to Corden the difference between the value of the Binding Forecast and the value of the replacement project(s).

(b) Each Purchase Order placed by Customer must be accepted by Corden by way of a written Purchase Order confirmation within [***] Business Days after Corden's receipt of such Purchase Order to the extent that it is consistent with the Binding Forecast, subject only to the exception set forth in Section 5.1(c) above. Corden shall deliver the Product covered by any such Purchase Orders on or before the scheduled delivery date as specified in the applicable Purchase Order confirmation.

(c) Any material change in or to any Purchase Order shall require the prior written agreement of Corden and Customer. Any accepted Purchase Orders pursuant to Section 5.2 above shall be firm and binding on the Parties and may not be cancelled, either totally or partially, unless agreed to by the Parties in writing.

(d) Corden shall not be liable for any delay in manufacturing/supplying Product to the extent such delay is due to circumstances caused by or within the direct control of Customer, or is due to Force Majeure. Corden shall promptly inform Customer of any circumstance which may cause delays in manufacturing/supplying Product and both Parties will use commercially reasonable efforts to mitigate the effects of any such delay.

5.3 Delivery; Invoicing; Payment; Release

(a) **Delivery Terms**. The Product shall be packaged and labelled as instructed by Customer and all shipments of same shall be accompanied by the appropriate documentation as described below and as set forth in the Quality Agreement. All Product containers shall be appropriately labelled with the name and presentation of the Product, traceable batch number, container item number, date of manufacturing, SAP code, quantity of Product and storage conditions. All shipments shall be appropriately labelled with the name and presentation of the Product, traceable batch number, date of manufacturing, quantity of/in each Product containers and storage conditions. The packing slip for the Product shall also contain: [***]. Corden shall deliver each shipment of Product, [***] to Customer or Customer' authorized designee/carrier at the Production Facility or as otherwise reasonably instructed in a Product Addendum or in writing by Customer. Title to each Product, risk of loss, delay or damage in transit shall be with Corden until delivered by Corden to Customer or Customer designee in accordance with delivery terms as stated in a Product Addendum or once Product is stored by Corden in consignment stock in accordance with 5.3 (f) (ii).

(b) **Accompanying Documentation.** If, based upon the review performed by Corden, the Product conforms to the Manufacturer's Release Specifications, Testing Specifications and was otherwise manufactured according to Applicable Laws, then a Certificate of Compliance will be completed by Corden. Corden shall comply with all warranties as specified in Section 7 and confirm in writing to Customer that such Product has been cleared for delivery, and Corden shall issue the corresponding invoice. Together with such confirmation, Corden will deliver the applicable Manufacturer's Release Specifications and Testing Specifications results to Customer, CoA, CoC, and Lot Genealogy. Corden will also deliver to Customer all raw data and other records including Executed Batch Record in the possession or under the control of Corden relating to the manufacture of such Product, as well as summaries of all applicable analytical results in machine-readable format and any other required documentation as defined in the Product Addendum or Quality Agreement. Upon receipt of such Manufacturer's Release Specifications and Testing Specifications results, Customer will review as outlined in the Quality Agreement no later than forty [***] calendar days upon receipt of the requested documentation. During this period, Customer shall have the right to request reasonable additional clarifying information from Corden, which Corden shall provide promptly. Failure by Corden to provide such clarifying information available to Corden shall delay Customer' review period for [***] days. Prior to Customer' release of the Product, Corden will also deliver verified, machine-readable process data used for Customer' Continued Process Verification program. Corden will inform Customer of statistical outliers as part of the release process. When clearing any Product for delivery, Corden shall do so in accordance with the instructions for shipping and packaging specified in the applicable Purchase Order accepted by the Parties or as otherwise agreed to by the Parties in relevant shipping documents.

(c) **Shipment**. Customer shall authorize shipment of the Product within [***] calendar days after the date Corden communicates to Customer that the Product has been cleared for delivery, as outlined in this Agreement and the Quality Agreement. Corden shall provide Customer with reasonable assistance to obtain and maintain any necessary export

approvals, licenses and customs clearance applications, forms and other correspondence in connection with the delivery of Product. In any case, Corden will invoice the Product at the release date. In case Customer wants Corden to store the released Product according to Section 5.3. (f), Corden will not have the Product anymore in its books but in Customer Inventory.

(d) **Inspection.** Customer will review the provided documentation and evaluate the Product upon receipt, and may test it against the Manufacturer's Release Specifications, and will notify Corden in writing of its acceptance or rejection of such Batch as promptly as possible after its receipt. If Customer intends to reject a Batch on the grounds of non-conformity to the Specifications or damaged or incorrect packaging caused by Corden, Customer shall notify such rejection to Corden in writing, such notice to be given within [***] calendar days after receipt of the Product by Customer or its designee, to be accompanied, if applicable, by a sample of the Product analyzed by Customer together with all relevant documentation and Manufacturer's Release Specifications regarding such analysis, and a report indicating the methods used by Customer to evaluate same. If Customer does not report the failure to conform to the Manufacturer's Release Specifications that should have been reasonably detected by Customer when reviewing the Product supplied by Corden and, if applicable, testing it against the Manufacturer's Release Specifications or Purchase Order terms for packaging within the period of [***] calendar days after receipt of the Product, such Product shall be deemed to have been accepted by Customer as conforming to the applicable Manufacturer's Release Specifications. Notwithstanding the forgoing, for a maximum period up to the currently approved retest period of the relevant Product, Customer or its designee reserves the right to reject Product as Non-Conforming Product if the reason such Product (a) does not conform with the applicable Manufacturing Standards, (b) is adulterated within the meaning of Section 501 (a)(2)(B) of the FDCA, or (c) was not otherwise manufactured in accordance with Applicable Law, because such Product contained a Latent Defect that was not reasonably detectable, unless such Latent Defect was directly attributable solely to a nonconformity of the Customer Material used in the manufacture of such Product, or was due to the negligent transportation of such Product from the Production Facility to Customer or its designee and further provided that Customer shall notify any Latent Defect to Corden promptly after it becomes aware of the defect but in any event within [***] calendar days thereafter.

(e) **Late Delivery**. Without prejudice to the Customer's rights and Corden's obligations under this Agreement, in the event that the Corden makes a late delivery and/or is unable to deliver and fulfil the services and/or a PO, regardless of whether such Services are Manufacturing Services or related services, within the timelines defined under this Agreement Corden shall notify Customer as soon as possible and the Parties will work together to agree a mutually acceptable resolution. If conforming Product is not received by Customer within [***] from the Delivery Date, except where Corden can reasonably demonstrate that the delay is not due to its fault (e.g. unavailability of Materials), then Customer shall have the right to claim from Corden a late delivery payment penalty equal to [***]% ([***] percent) of the Price of such delayed Manufacturing Run per each calendar [***] beyond the above [***] grace period, up to a total amount of [***]% ([***] percent) of the Price of such delayed Manufacturing Run in total. Such amounts may be deducted by Customer or credited by Corden from any amounts invoiced to Customer. The rights and remedies contained in this Section 5.3 (e) are without prejudice to Customer's right to terminate this Agreement pursuant to Section 13 or any other remedy under this Agreement, however, the above late delivery penalty shall be deducted from any claim of Customer for damages arising from late delivery of a Batch by Corden.

(f) **Storage and Handling**

(i) Corden shall store and handle all Customer Materials and the Product in accordance with the relevant Specifications, the Quality Agreement, Applicable Laws, and under other appropriate conditions, including without limitation, appropriate temperature, humidity, light and cleanliness conditions in order to avoid any material adverse effect on the identity, strength, quality and/or purity of the Products. In addition to the foregoing, Corden shall store and handle all Customer Materials and the Product so as to prevent the commingling

of same with Corden's own inventories and supplies, or those held by Corden for Third Parties. Storage conditions and handling of the Product, a Customer Materials, and Product will be described in the Product Addendum.

(ii) Handling and storage of Customer Materials and Product are free of charge the quantities required for the Binding Forecast, in the case of Product, for up to [***] calendar days from the date the Product is cleared by Corden for delivery to Customer or its designee in accordance with Section 5.3. In the event that storage in excess of [***] calendar days is required, Corden shall offer Customer storage for such Product on consignment either at the Facility, or at a Third-Party facility, at mutually acceptable financial terms. If Corden is unable to store any Product due to capacity constraints, Corden may use an Affiliate or qualified third party to store outside the Facility any Product under this Agreement. Third party storage shall be qualified by Customer, if deemed necessary by the quality department of Customer. Customer acknowledges that such a consignment storage may lead to a delivery of Product which is subject to local VAT. The third party will be reported in the Quality Agreement.

(iii) In case any Product is returned to Corden after having been shipped by Corden, due to any cause which is not connected to Corden actions, then such reshipment and/or possible storage costs shall be Customer's responsibility.

5.4 Non-Conforming Product(s)

(a) A Product that does not conform to the applicable Manufacturing Standards as defined in Section 2.5 above or that is adulterated within the meaning of Section 501 (a)(2)(B) of the **FDCA** or similar provisions of any applicable laws in the country where the manufacture takes place for any reason or that was not otherwise manufactured in accordance with Applicable Law, shall be deemed to be a non-conforming Product ("**Non-Conforming Product**").

(b) In the event of any disagreement between the Parties regarding whether a Product is a Non-Conforming Product, the quality assurance representatives of the Parties will attempt to resolve any such disagreement in good faith. If the disagreement is not resolved in a reasonable time (which will not exceed [***] calendar days after a notice of dispute is provided by one Party to the other Party), a representative sample of the Product and/or relevant documentation will be submitted for tests and final determination as to whether or not such Product is Non-Conforming Product. The Parties shall designate an independent testing laboratory or consultant or both to determine whether the relevant Product is a Non-Conforming Product, the findings of which testing laboratory shall be binding on the Parties, absent manifest error, gross negligence or fraud on the part of the testing laboratory. The independent testing laboratory shall be instructed to complete its analysis within [***] Business Days after its appointment using the test methods contained in the Manufacturer's Release Specifications. The costs and expenses of such laboratory testing shall be borne solely by the Party whose position is determined to have been in error or, if the testing laboratory cannot place the fault noticed and complained about on one Party, then the Parties shall share equally the costs and expenses of the testing laboratory. If, after the later of (i) [***] days from the date of receipt by Corden of Customer' notice pursuant to subsection (a) hereof and (ii) completion by the independent testing laboratory of its analysis of the relevant Product, the Parties have not agreed as to the payment of any outstanding fees related to such Product, the Parties shall commence arbitration pursuant to Section 16.14.

(c) Notwithstanding any further right of Customer, as stipulated in this Agreement, in the event that any Product is ultimately agreed or found to be Non-Conforming-Product and provided that such failure has been notified in accordance with Section 5.3. (d) and further provided that such failure is directly attributable to Corden and not due to the acts or omissions of Customer or any Third Party after delivery of such Product but regardless of when it was discovered, then (save in respect of any claims by Third Parties, which shall be subject to the limitation set forth below in this Agreement), Corden's liability shall be limited (i) if possible according to Applicable Law, reworking or reprocessing the Non-Conforming Product, at Corden's sole cost and expense, so that such Non-Conforming Product

conforms to the applicable Manufacturer's Release Specifications; or (ii) if (i) is not possible, manufacturing and supplying for/to Customer new Product (in the same quantity as that which was deemed to be non-conforming) at [***]% of the Product Price in addition to the Product Price for the Non-Conforming Product and provided that Customer shall provide Customer Material required for the new Product free of charge, subject to Section 11.4 (b). Corden shall forward to Customer any insurance payments received by Corden as compensation for the cost of replacing the respective Customer Material that was used/lost in connection with the manufacture of such Non-Conforming Product or (iii) if neither (i) nor (ii) are possible, and provided the Non-Conforming Product has been paid in full by Customer, refunding in full the Product Price paid by Customer for such Non-Conforming Product. The Parties will negotiate in good faith the option that is deemed to be the most reasonable one in each particular case taking into account all relevant circumstances, and when so doing the Parties shall attempt to mitigate the inconveniences resulting from the situation for both Parties.

5.5 Inability to Supply

(a) Corden shall immediately notify Customer: (i) upon becoming aware of an event of Force Majeure or any other event that would render Corden unable to: (i) transfer the quantities that Corden is required to supply pursuant to any confirmed Purchase Order(s), or (ii) otherwise meet any of its supply obligations to Customer under this Agreement; and/or (iii) if Corden reasonably believes that it will not be able to meet any portion of the latest Binding Forecast provided by Customer following Corden's receipt thereof.

(b) In the event that Corden fails to: (i) transfer to Customer the quantities specified in the relevant confirmed Purchase Order; or (ii) otherwise meet any of its supply obligations to Customer hereunder, then in either such event the difference between the number of Batches transferred under a confirmed Purchase Order that meets the requirements under this Agreement and the number specified in such Purchase Order shall constitute a "**Supply Deficiency**" for purposes of this Agreement, provided, however, that such Supply Deficiency represents more than [***] percent ([***]%) of the amount specified in the confirmed Purchase Order.

5.6 Procedure to Cure Supply Deficiencies. If there is a Supply Deficiency, then, if requested by Customer and at Customer' election, Corden shall promptly take the selected following steps to remedy the Supply Deficiency, in the following order of preference whenever practicable (i.e., with highest preference given to the remedy in paragraph (a) and the lowest preference given to the remedy in paragraph (d)):

(a) use commercially reasonable efforts to increase the length of a manufacturing campaign at the Production Facility in order to manufacture and transfer to Customer additional Batches that meet the relevant requirements under this Agreement to fully remedy such Supply Deficiency ("**Deficiency Cure Batches**," and each such Batch, a "**Deficiency Cure Batch**");

(b) use commercially reasonable efforts to utilize any capacity at the Facility which is not then contractually committed to the performance of manufacturing services for Third Party customers during the applicable Contract Year to manufacture and transfer to Customer such Deficiency Cure Batches that meet the relevant requirements under this Agreement;

(c) coordinate and cooperate with Customer to re-schedule manufacture and transfer Batches of Product ordered hereunder that meet the relevant requirements under this Agreement in order to maximize Corden's ability to manufacture and transfer to Customer such Deficiency Cure Batches that meet the relevant requirements under this Agreement while minimizing the disruption of manufacture at the Production Facility then in force and any contractual commitments to Third Party customers; and

(d) use commercially reasonable efforts to remedy the Supply Deficiency in subsequent periods, if any, by utilizing and dedicating excess capacity not contractually committed to Third Party customers to manufacture and transfer Deficiency Cure Batches that meet the

relevant requirements under this Agreement and to reserve such capacity for Customer' requirements until all of the issues surrounding the Supply Deficiency have been remedied to Customer' complete satisfaction.

(e) Except for Customer Materials, Corden, shall, at its own costs and expense: (i) procure and obtain any necessary materials, raw materials, and/or supplies to remedy the Supply Deficiency; and (ii) pay for any additional costs related to cure the Supply Deficiency.

For clarity, these are the only remedies available due to a Supply Deficiency.

5.7 **Key Performance Indicators.** The Parties agree to measure Corden's performance of its Manufacturing Services through the establishment of Key Performance Indicators ("**KPIs**"). The KPIs will be mutually defined and discussed in good faith after the completion of the first [***] commercial batches after process validation or as otherwise agreed in a Product Addendum and will be incorporated into this Agreement by the Parties mutually agreed written amendment. The Parties may agree on additional KPIs by written amendment to this Agreement. The Parties shall agree in good faith after completion of the first [***] batches of production of commercial batches after process validation the performance level objectives of Corden The performance level objectives shall be established for individual KPIs and for overall performance and on the basis of actual, past performance, and shall be expressed in measurable values. In addition, minimum acceptance levels shall be agreed upon for all critical KPIs and for overall performance. Corden shall use all Commercially Reasonable Efforts to ensure that its performance does not fall below these minimum acceptance levels. Notwithstanding Corden's use of all Commercially Reasonable Efforts, if at any time Corden's overall performance or performance for critical KPIs falls below the established minimum acceptance levels, Corden shall promptly take corrective action to cure such under-performance. For any additional KPIs outside Corden's standards, Customer shall bear the costs.

5.8 **Process Improvements and Sharing of Costs Efficiencies.** Corden shall monitor potential cost and quality improvements, including by seeking productivity improvements, by minimizing waste and improving yields, by purchasing quality materials at lower cost, by improving manufacturing processes, by streamlining organizational processes and by reducing manufacturing production times. The Parties shall meet to discuss potential improvements identified by Corden. Customer shall decide whether or not to implement at Customer's costs necessary changes to achieve the potential improvements. The Parties shall equally share any cost savings so achieved.

5.9 **Average Yield.** Only for the Customer Material as identified in the Product Addendum: After the Manufacture of the first [***] commercial Batches of Product after process validation, the Parties shall calculate the average yield for a Customer Material for [***] Batches, deducting the Batches with the highest and the lowest yield. The ratio of kilogram Customer Material used per kilogram of Product of these Batches is the average yield ("**Initial Average Yield**"). For the following years Corden shall calculate the Average Yield based on all released commercial Batches manufactured ("**Average Yield**"). Corden shall recalculate the Initial Average Yield in case of changes to the Product or the Manufacturing Process. At the beginning of each subsequent calendar year, Corden shall calculate the Actual Yield of Customer Material achieved for all Batches Manufactured in the previous year ("**Actual Yield**"). In case the Actual Yield for a Customer Material is more than [***] percent lower than the Average Yield, for the difference between the Actual Yield and the Average Yield ("**Difference**") following shall apply: Subject to Section 11.4 and provided the Difference lies within the control of Corden, Customer shall receive a credit note on the next invoice in an amount equal to the Difference, [***]). In case the Actual Yield exceeds the Average Yield, the Parties shall share the financial benefits equally as mutually agreed in writing.

6. PAYMENTS, TAXES

6.1 Payments. Customer shall pay all invoices to be paid under this Agreement that are properly invoiced in accordance with Section 5.3 and the respective Product Addendum.

(a) Payments shall be made by Customer within [***] days after the date the applicable invoice is received by Customer. All invoices and payments required to be paid hereunder shall be in the currency agreed in each Product Addendum and all such payments shall be completed electronically and wired in immediately available funds to an account designated by Corden. Undisputed late payments shall bear interest at an annual rate equal to SONIA plus [***]percent ([***]%). Failure by Customer to pay undisputed invoices within [***] days after the date the applicable invoice is received by Customer shall be considered a breach of this Agreement by Customer.

(b) Customer shall have the right to withhold payment of any portion of an invoice that is subject to justified warranty claims or other claims hereunder. If the claim is later found to be unjustified, Corden shall have the right to reinvoice Customer with the applicable interest included as per Section 6.1(a).

(c) Corden reserves the right to adjust Product Prices [***] to cover material, resource, and energy cost increases based on the increase in the annual average monthly Italian index of producer prices of industrial products, non-durable goods during the preceding [***] period, as published by the Italian Statistic Office (“Italian IPPI”).

(d) Customer reserves the right to request Product Price reductions no more often than once per calendar year based on any decrease in the annual average monthly Italian-IPPI during the preceding [***] period. The Parties shall negotiate in good faith any such price reduction

(e) The Parties agree that in case payments will be effectuated in any other currency than Euros, the Parties will agree in the pertinent Product Addendum to a currency exchange variability clause.

6.2 Taxes. Except for value added tax, any and all federal, provincial or municipal taxes, levies, charges or fees imposed upon or with respect to or measured by the production, sale, or delivery by Corden to Customer of Product in accordance with Customer’ instructions, shall be borne by of Corden. If applicable, each invoice will show any applicable VAT required to be charged separately. In the event that Corden will be charged by local tax authority for importation VAT for Customer Materials supplied to Corden, Corden will invoice Customer for such paid importation VAT as a pass-through cost for the importation VAT paid by Corden. Corden shall cooperate with Customer in its efforts to recover the VAT incurred and shall provide the required import documentation to support Customer in such activities.

6.3 Withholding Tax. The amounts payable by one Party (the “Payer”) to another Party(the “Payee”) pursuant to this Agreement (“Payments”) shall not be reduced on account of any Taxes sunless required by law. The Payee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Payer) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Payer shall deduct or withhold from the Payments any Taxes that it is required by law to deduct or withhold. Notwithstanding the foregoing, if the Payee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it shall promptly deliver to the Payer or the appropriate Governmental Authority (with the assistance of the Payer to the extent that this is reasonably required and is expressly requested in writing) the forms necessary to reduce the applicable rate of withholding or to relieve the Payer of its obligation to withhold Tax, and the Payer shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be. If, in accordance with the foregoing, the Payer withholds any amount, it shall make timely payment to the proper Governmental Authority of the withheld amount, and send to the Payee reasonable proof of such payment within [***] days following that payment. If Taxes

are paid to a tax authority, each Party will provide the other such assistance as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

7. WARRANTIES

7.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that:

(a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation; and

(b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action; and

(c) it has full corporate authority to enter into this Agreement and the Agreement is binding upon it in accordance with its terms.

7.2 Customer Warranties. Customer hereby represents and warrants that:

(a) to the best of its knowledge, as of the Effective Date, the Product as well as the Customer Background IP and all Customer Confidential Information (including for the avoidance of doubt the Manufacturing Process) and their use by Corden or its Affiliates in accordance with this Agreement do not infringe the Intellectual Property Rights of any third party; and

(b) as of the Effective Date, Customer has the right to grant Corden the licenses stipulated under this Agreement, and will notify Corden if at any time during the term of this Agreement it no longer has the right to grant such licenses; and

(c) the Customer Materials provided by Customer (i) have been manufactured and tested in accordance with cGMP or ISO guidelines (as applicable), (ii) meet the required specifications and (iii) are neither adulterated nor contaminated;

(d) for avoidance of doubt, all Customer liability or indemnification obligations that might result from the representations and warranties under this Section 7.2 are always subject to the limitations set forth in Section 11 of this Agreement.

7.3 Corden Warranties. Corden hereby represents and warrants that:

(a) the Product, if and to the extent it is required to be manufactured under cGMP conditions and a validated Manufacturing Process, (i) will conform to the agreed Manufacturer's Release Specifications; (ii) has been manufactured, stored, transported, tested, labelled, and packaged in accordance with Applicable Laws including cGMP and any environmental or biohazard laws in the country where the Manufacture takes place; (iii) will not be adulterated within the meaning of Section 501 (a)(2)(B) of the U.S. Food, Drug and Cosmetic Act or similar provisions of any Applicable Laws in the country where the Manufacture takes place; and (iv) will be transfer to Customer and convey good title to the Product, free and clear of any security interests, lien or encumbrances;

(b) It has the title and/or right to any and all Manufacturer Background IP used to Manufacture the Products in accordance with this Agreement to the best of its knowledge at the Effective Date, there are no third party claims against Corden or its Affiliates asserting that the Corden Background IP and Corden Confidential Information to be used in the performance of the Services and/or Manufacturing infringe the Intellectual Property Rights of any third party, and Corden will promptly notify Customer in writing should it become aware of any claims asserting such infringement in the performance of any Product; and

(c) neither Corden nor any of its representatives has been debarred, nor is subject to a pending debarment, and that neither Corden nor any of its representatives will use in any capacity in connection with the Services and/or Manufacturing under this Agreement any person, who has been debarred pursuant to section 306 of the FDCA. 21 U.S.C. § 335a, or who is the subject of a conviction described in such Section. Corden agrees to notify Customer in writing immediately if it

comes to its knowledge that Corden or any person who is performing Services is debarred or is the subject of a conviction described in section 306 of the FDCA or if any action, suit, claim, investigation, or proceeding is pending, or to Corden' s knowledge, is threatened, relating to the debarment or conviction of Corden or any person performing Services under this Agreement.

(d) for avoidance of doubt, all Corden liability or indemnification obligations that might result from the representations and warranties under this Section 7.3 are always subject to the limitations set forth in Section 11 of this Agreement.

(e) **Compliance Obligations**. Corden intends to conduct its business in accordance with appropriate and applicable environmental and labor laws and industry standard as well as comply with any such standards of Customer. Corden shall also comply, and shall ensure that its subcontractors also comply, with appropriate and applicable environmental and labor laws and industry standards social standards and the principles of the *OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions*. Should Customer discover that Corden or its subcontractors are in breach of the foregoing, Customer may terminate this Agreement without notice.

(f) **Compliance with Responsible Sourcing Principles and Customs and Foreign Trade**. Corden will, and it will endeavor to ensure that its subcontractors follow responsible sourcing practices and principles and comply with appropriate and applicable Customs and Foreign Trade laws, regulations, guidelines and standards. Upon request of Customer, Corden shall provide Customer with a supplier declaration as requested by Customer.

(g) **Change in Control or Name of Business Entity**. Corden will provide prompt written notice to Customer in the event of any change in control and/or name of its business entity including without limitation, a change(s) resulting from a merger and/or acquisition.

7.4 Disclaimer of Warranties. THE WARRANTIES SET FORTH IN THIS SECTION ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY CORDEN TO CUSTOMER AND CORDEN MAKES NO OTHER WARRANTIES, REPRESENTATIONS OR GUARANTEES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, REGARDING THE PRODUCT, RAW MATERIALS OR SERVICES TO BE SUPPLIED UNDER THIS AGREEMENT OR ANY PRODUCT ADDENDUM, INCLUDING WITHOUT LIMITATION, ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

8. CHANGES TO PRODUCTS / CHANGE CONTROL

8.1 Changes to the Products (including the Raw Materials), the Manufacturing or the Facility may only be made in accordance with the Quality Agreement. For the purpose of clarity, changes to the Facility under this Section 8.1 and in the relevant sections included in the Quality Agreement only refers to changes directly relating to the Manufacturing of Product and/or impacting the Product.

8.2 Corden shall solely bear all of its actual and related costs resulting from:

(a) Changes to the Facility (including but not limited to changes related to Facility safety reasons) requested by Corden (on its own or on behalf of any approved subcontractor); and

(b) Non-Product specific changes (i) required under Applicable Laws applicable in the country where the Facility is located; (ii) requested or required by the Government Authorities relating to the Facility and to the manufacture of pharmaceutical products; and/or (iii) related to the establishment and/or maintenance of cGMP; and

(c) Changes in the materials or suppliers of the Raw Materials requested by Corden and to the extent within Corden's control.

8.3 Customer shall solely bear all actual and related costs resulting from:

(a) Changes requested by Customer (other than changes requested or required as set out in Section 8.18.1(b))**;**

(b) Changes requested or required by the Regulatory Authorities relating to the Product, Manufacturing of Product and marketing of the pharmaceutical products containing the Product (except as set forth in Section (8.2(b)); and

(c) Changes to the Product, Raw Materials and/or suppliers of Raw Materials for Product or the Manufacturing requested by Customer.

8.4 In the event that Applicable Laws change such that Corden's expense for the Manufacture of the Product increases by more than [***] percent, Corden shall be entitled to add the additional, reasonable and documented expenses to the Product Price apportioned to Customer on a pro-rata share of the increase based on Corden's apportioned utilization of the Facility.

8.5 In the event and solely to the extent that a change requested by Customer (or by Corden in accordance with Section 8.1(b)) may reasonably be expected to have an impact on the Manufacturing Process and/or the Manufacturer's Release Specifications, the warranty obligation of CORDEN pursuant to Section 7.3(a)(i) shall be waived, but solely to the extent relating to such change and solely until such time that real-time stability data is available to reasonably support that such change does not negatively impact the Manufacturing Process and/or the Manufacturer's Release Specifications. Under no circumstance shall such change relieve Corden of its general obligations to comply with the terms of this Agreement and the Quality Agreement.

9. HEALTH REGISTRATION APPROVAL SUPPORT; REGULATORY MATTERS

9.1 Filing and Maintenance of the Health Registrations. As between the Parties, Customer shall have the sole right to prepare and file for Market Authorization, the Health Registrations, including the NDA and the CMC, with the applicable Governmental Authorities, and, for clarity, Corden shall have no right to do so except in the case of an inspection of the Facility and/or other request for information made by an applicable Governmental Authority. Customer may at its own discretion include a designation of Corden and the Facility as a Manufacturer and Manufacturing site of Product in the applicable Health Registrations.

9.2 CMC Information. Customer shall provide Corden with CMC information applicable to Corden to the extent necessary for Corden to Manufacture the Product in accordance with this Agreement, and Corden shall comply with all such CMC information in performing its activities hereunder. In the event Customer subsequently modifies any relevant Health Registration (or the CMC) which will affect the Manufacture of the Product hereunder, it shall promptly notify Corden and provide it with necessary information about such Health Registration (or CMC) supplements or amendments to the extent necessary for Corden to Manufacture the Product in accordance with this Agreement, and the provisions of Section 8.3 shall apply.

9.3 Regulatory Support for Maintaining Filings. Corden shall perform the activities (including tests), which according to Customer are necessary for Marketing Applications and Market Authorizations, in accordance with cGMP, Applicable Laws, as reasonably requested by Customer from time to time, at Customer's cost and as mutually agreed between the Parties in writing. In all cases, Corden shall be prepared for any and all inspections, including pre-approval inspections, by Governmental Authorities. Without limitation of the foregoing, Corden shall provide Customer with information and assistance as Customer may reasonably request for purposes of applying for and maintaining all relevant Health Registrations for the Product including providing Customer with all reports, authorizations, certificates, methodologies, specifications and other documentation in the possession or under the control of Corden (or any

of its Affiliates) relating to the pharmaceutical/technical development and/or Manufacture of the Product or any component thereof. Corden hereby grants Customer a right of reference to any regulatory approvals and/or Corden's (and/or any of its Affiliates) site master file for use in connection with the Product.

9.4 Corden Approvals. Except as otherwise specifically set forth herein, Corden shall be responsible for obtaining and maintaining (and throughout the Term, Corden shall maintain in full force and effect) all permits and approvals from all Governmental Authorities or as otherwise may be required under Applicable Laws, in each case, to operate the Facility and shall ensure that its subcontractors operate in compliance with any applicable regulations.

9.5 Audit Reports and Other Information. Corden acknowledges that Governmental Authorities may, in conducting an inspection of Customer, request copies of reports of Customer audits of its suppliers. For clarity, in response to such a request, Customer shall have the right to provide to the Governmental Authority any report of any compliance audit conducted hereunder (including as may be conducted in accordance with the Quality Agreement) and any other information in connection with the activities hereunder, provided that such disclosure is made in compliance with the provisions set forth in Section 12 (Confidentiality).

9.6 Communication with Governmental Authorities. As between the Parties, Customer shall have the sole right to communicate with the appropriate Governmental Authorities relating to the Product, and Corden shall have no right to do so unless required to do so by Applicable Laws. Corden shall provide Customer or its Affiliate, in a timely manner, all information in Corden's (or its Affiliate's) possession or control concerning the Product which is reasonably requested by Customer (or its Affiliates) and which is reasonably necessary to meet Customer's (and its Affiliate's) regulatory obligations. Corden shall immediately notify Customer of any Governmental Authority request for samples of the Product, or Executed Batch Records or Master Batch Records or any other information related to the Product and will not provide such material, records or information until such notification is made to Customer.

10. QUALITY

10.1 Promptly after the Effective Date, the Parties shall enter into good faith discussions and use their respective good faith reasonable efforts to enter into a quality agreement ("Quality Agreement") within [***] days after the Effective Date. Such Quality Agreement shall be consistent with all Applicable Laws and regulations relating to the Manufacture of the Product and describe the respective quality assurance responsibilities and obligations of the Parties for the Manufacture of Product.

10.2 Quality Control. Corden shall maintain a quality assurance and quality control program in accordance with cGMP, Applicable Laws and the Quality Agreement.

10.3 Quality Audits and Regulatory Inspections. In accordance with the terms of the Quality Agreement, Corden shall (and shall reasonably cause its Affiliates and approved subcontractors to) permit (i) Customer or its designated representatives to annually audit the Facility and any facility where Products are being Manufactured, handled or stored, or Services are performed by approved subcontractors; and (ii) Government Authorities to inspect any such facilities. With the exception of Product-specific pre-approval audits which require an audit frequency of greater than one audit per calendar year, and Product-specific regulatory inspections, for which the Parties shall agree a Service Fee upfront, all audits and inspections performed in accordance with the Quality Agreement shall be free of charge for Customer. Customer's personnel shall comply with Corden's procedures concerning cGMP, training, safety, hygiene, confidentiality and controlled access to facilities and documents. For practical reasons and in order to ensure a smooth Manufacturing Process, a maximum of [***] Customer representatives or employees shall be permitted in the manufacturing area for no more than [***] business days per Quality audit.

10.4 Person in Plant. Customer shall have the right to have personnel at the Facility during regular business hours during a manufacturing campaign for the Product as set forth in the Quality Agreement. Such personnel may either be technical or quality personnel. Customer's personnel shall comply with Corden's procedures concerning cGMP, training, safety, hygiene, confidentiality and controlled access to facilities and documents as set forth under the Quality Agreement.

10.5 Data review: A biannual Acadia data review will be performed. This can be remote or onsite, a maximum of [***] Customer representatives or employees shall be permitted in the analytical lab, with possible third person for translation purposes for no more than [***] Business Days. Customer shall reimburse Corden for the costs for such data review.

11. RECALL, INDEMNIFICATION, INSURANCE, SECURITY MEASURES

11.1 Investigation, Recall, Voluntary Withdrawal. In the event that any Regulatory Authority in any country shall allege or prove that the Product does not comply with Applicable Law in such country where such Product is marketed, distributed and sold, the Party becoming aware of same shall notify the other Party in writing within [***], and thereafter both Parties shall cooperate fully regarding the investigation and disposition of any such matter. If (a) such Product is adulterated within the meaning of Section 501 (a)(2)(B) of the FDCA due to the acts or omissions of Corden and not due to the acts or omissions of Customer or any Third Party after delivery of such Product or (b) Customer is required or should deem it appropriate to voluntarily withdraw such Product, then to the extent that such recall or withdrawal is due to any negligence, fraud, recklessness or wrongful intentional acts or omissions by, or breach of any representation, warranty or covenant of or by Corden that could not have been reasonably detected by Customer during the Customer Release, then Corden shall bear the actual, documented and reasonable expenses of the Parties in carrying out the recall subject to the limitation of liability under Section 11.4 below, and Section 5.4 (c) shall apply, to the extent the recall concerned Non-Conforming Product.

11.2 Indemnification by Corden. Corden shall indemnify, defend and hold harmless Customer, its Affiliates, its sublicensees and distributors, and its and their respective directors, officers, representatives, shareholders, employees, and agents and their respective successors and permitted assigns, from and against any and all Losses from any Third Party claims, proceedings, actions or causes of action, ("**Third Party Claims**") which arise out of:

(a) any breach of Corden's warranties as set forth in Section 7 or the Quality Agreement or any other material breach by Corden or any of its representations, warranties, covenants, agreements or obligations under this Agreement, or the gross negligence, reckless, or wilful misconduct of Corden, or its Affiliates or subcontractors in the performance of the Services and Manufacturing of Product and any of its obligations hereunder;

(b) personal injury (including death) or property damage relating to or arising out of any Manufacture of Product by Corden or its Affiliates due to any negligence, fraud, recklessness or wrongful intentional acts or omissions by, or strict liability of, Corden or its Affiliates, and/or their respective directors, officers, employees or agents;

(c) the claimed infringement of any third party patent, trademark or other intellectual property right Corden was aware of and that is asserted due to any activities of Corden or any of its Affiliates relating to any of its Manufacturing processes or methods used in the Manufacture and/or production of the Product, except to the extent that such activities, processes or methods were specifically provided or required by Customer.

11.3 Indemnification by Customer. Customer shall indemnify, defend and hold harmless Corden and its Affiliates, and their respective directors, officers, employees and agents, from and against any and all Losses arising out of or resulting from Third Party Claims based upon:

(a) any claim that the use of the Customer Materials provided by Customer infringes the intellectual property right(s) of the third party;

(b) any breach of Customer' obligations, covenants, representations and warranties set forth in this Agreement or the Quality Agreement;

(c) personal injury (including death) or property damage or Product liability relating to or arising out of any use, distribution or sale of Product by Customer, its Affiliates or Partners, unless due to any negligence, fraud, recklessness or wrongful intentional acts or omissions by, or strict liability of, Corden, its Affiliates or its Partners, and/or their respective directors, officers, employees, subcontractors, representatives, or agents; or

(d) Customer or its Affiliates' negligence, fraud, recklessness or wrongful intentional acts or omissions in the manufacture or procurement of Customer Materials to the extent used by Corden in the manufacture and production of Product.

11.4 Limitation of Liability: Except for: (a) any unauthorized use of Customer's Intellectual Property or Confidential Information; (b) Corden's gross negligence, wilful misconduct, wrongful intentional acts or omissions, recklessness, or fraud; or (c) third party Losses, including for (i) personal injury or death, (ii) Product liability or (iii) liability resulting from a breach of the warranties given in Section 7, in no event shall Corden's maximum liability to Customer for:

(a) the cost for replacement of Customer Material exceed [***] ([***]%) percent of the amount payable for the Non-Conforming Product(s) that gave rise to the Claim, except in case of Section 5.4 (c) (iii) where such reimbursement shall be excluded, and/or

(b) any other claim relating to any breach of Corden's obligations, covenants, representations and warranties set forth in this Agreement or the applicable Quality Agreement exceed [***] ([***]%) percent of the amount payable under the Purchase Order that gave rise to the Claim.

11.5 No Consequential Damages. EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS IN SECTION 11.2 AND 11.3 ABOVE, AS APPLICABLE, AND/OR EXCEPT FOR: (A) ANY UNAUTHORIZED USE OF CUSTOMER'S INTELLECTUAL PROPERTY OR CONFIDENTIAL INFORMATION; OR (B) EITHER PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT, RECKLESSNESS, OR FRAUD; UNDER NO CIRCUMSTANCES WHATSOEVER (INCLUDING DUE TO NEGLIGENCE) SHALL EITHER PARTY OR ANY OF ITS AFFILIATES FOR BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (I) ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES,OR CLAIMS BROUGHT BY THE OTHER PARTY OR ANY THIRD PARTY, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE,STRICT LIABILITY OROTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE QUALITY AGREEMENT, OR ANY BREACH HEREOF. FOR THE PURPOSES OF THIS CLAUSE "**CONSEQUENTIAL DAMAGES**" SHALL BE DEFINED AS LOSSOF PROFIT OR ANTICIPATED PROFIT, LOSS OF PRODUCTION, LOSSES CAUSED BY BUSINESS INTERRUPTIONS, LOSS OF REVENUE AND LOSS OF GOODWILL OR REPUTATION AS WELL AS DAMAGES RESULTING FROM REMOTE EVENTS THAT ARE VERY UNLIKELY TO HAPPEN, "**PUNITIVE DAMAGES**" SHALL BE DEFINED AS COMPENSATION CLAIMS THAT EXCEED THE DAMAGE ACTUALLY INCURRED.

11.6 Notice of Indemnification. In the event that any Person entitled to indemnification ("Indemnitee") under Sections 11.2 or 11.3 is seeking such indemnification, such Indemnitee shall inform the indemnifying Party of the Claim as soon as reasonably practicable after such Indemnitee receives notice of such Claim; provided that failure to give such notification shall not affect the indemnification provided under this Agreement, except to the extent the indemnifying Party shall actually have been prejudiced by such failure in a material manner. Thereafter, the Indemnitee shall deliver to the indemnifying Party, promptly after the Indemnitee's receipt thereof, copies of all notices and documents (including court papers) received by the Indemnitee relating to the Claim. The indemnifying Party shall have the right to assume the direction and control of the defense of the Claim (including the sole right to settle it at the sole discretion of the indemnifying Party; provided that such settlement does not impose any obligation on, or otherwise adversely affect, the Indemnitee) and the Indemnitee shall cooperate as requested (at the expense of the indemnifying Party) in the defense of such Claim. In any such proceeding the defense of which the indemnifying Party shall have so assumed, the Indemnitee shall have the right to participate therein and retain its own counsel (without otherwise affecting the rights of the Parties under this Section 11.6) at its own expense unless (i) the Indemnitee and the indemnifying Party shall have mutually agreed on the retention of counsel, (ii) the Indemnitee shall have reasonably concluded that there may be one or more legal defenses available to it which are different from or additional to those available to the indemnifying Party, or (iii) the named Parties (including the impleaded Parties) include both the indemnifying Party and the Indemnitee, and representation of both Parties by the same counsel would be inappropriate in the opinion of the indemnifying Party's counsel due to actual or potential differing interests between them; in any such case, one firm of attorneys separate from the indemnifying Party's counsel may be retained to represent Indemnitee at the indemnifying Party's expense. The Indemnifying Party shall have no liability under this Section 11.6 with respect to claims or suits settled or compromised without its prior consent.

11.7 Insurance. During the Term and for [***] thereafter, Corden shall, at its sole cost and expense, obtain and maintain, with financially sound and reputable insurers, insurance coverage at or above the applicable statutory limits, comprehensive liability coverage with contractual liability, professional liability/errors and omissions coverage and such other coverage types and amounts as are reasonable and customary in the pharmaceutical and biotechnology industry for companies engaged in comparable activities in the jurisdiction and Territory where such activities are being performed covering its obligations and performance under this Agreement, including its storage and use of Customer Material, including, without limitation, endorsements for Product(s) liability. Without prejudice to the foregoing, Corden shall maintain the insurance described herein not less than the equivalent of ten million euro (EUR [***]) per occurrence and ten million euro (EUR [***]) per year in the aggregate per policy. The Parties understand and agree that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Upon Customer request, Corden shall provide a certificate demonstrating the insurance it is required to obtain and maintain under this Section 11.7.

11.8 Security Measures. Corden shall take reasonable measures to protect the Production Facility, the Customer Material, the other Raw Materials, the Product and all work-in-progress from and against events, including but not limited to, cyber security, theft, vandalism and terrorism. Corden agrees to notify Customer in writing as soon as practicable of any such events which threaten or negatively impact the Production Facility, the Customer Material, other Raw Materials, the Product, or any work-in-progress.

12. CONFIDENTIALITY

12.1 Generally. During the period from and after the Effective Date until the [***] anniversary of the expiration or termination of this Agreement, each Party shall keep confidential and shall not use for any purpose other than the performance of such Party's obligations under this Agreement, and shall cause its Affiliates and such Party's and its Affiliates' respective directors, officers, employees and advisers to keep confidential and not to use for any purpose other than the performance of such Party's obligations under this Agreement, all information acquired from the other Party or its Affiliates, in connection with this Agreement and the transactions contemplated hereby, including, without limitation, all information concerning the Process, Product Intellectual

Property, the contents and existence of this Agreement and all Customer Material Specifications, Manufacturer's Release Specifications and Testing Specifications and other quality standards hereunder ("**Confidential Information")**, other than any information that: (i) is or hereafter becomes generally available to the public other than by reason of any default with respect to a confidentiality obligation; (ii) was already known to the receiving Party (which, in the case of Corden, shall mean known prior to the effectiveness of the Previous Manufacturing Agreement) as evidenced by prior written documents in the receiving Party's possession; or (iii) is disclosed to the receiving Party by a Third Party who or which is not in default of any confidentiality obligation to the disclosing Party (such information to which none of the foregoing exceptions applies, "Confidential Information"). Each receiving Party shall transmit, and shall cause each of its Affiliates to transmit, Confidential Information only to those of its employees, agents or representatives who shall need same for the purpose of this Agreement and shall take all necessary measures to assure that such employees, agents or representatives do not reveal such Confidential Information to any Third Party without prior written authorization from the disclosing Party for as long as the receiving Party is obliged to hold such information in confidence hereunder, regardless of the respective terms of employment of such employees. Notwithstanding any other provision of this Agreement, Customer may disclose Confidential Information of Corden to a Partner; provided that such Partner is under confidentiality obligations at least as restrictive as those set forth herein.

12.2 Exceptions. The provisions of this Section 12 shall not apply to Confidential Information: (i) that is submitted by the receiving Party to Governmental Authorities to facilitate the issuance or maintenance of marketing approvals for the Product; provided that, to the extent permitted by Applicable Law, reasonable measures shall have been taken to ensure confidential treatment of such Confidential Information; (ii) that is required to be disclosed in compliance with Applicable Laws or order by any court, supervisory, regulatory, judicial or Governmental Authority having competent jurisdiction (including without limitation SEC reporting); provided that, to the extent permitted by Applicable Law, reasonable measures shall have been taken to ensure confidential treatment of such Confidential Information; or (iii) that is necessary to facilitate due diligence in connection with entering into a financing or similar arrangement with a bank or other credit institution. Each Third Party who receives Confidential Information pursuant to subclauses (i), (ii) and (iii) of this Section 12.2 shall be bound by the same confidentiality obligations set out in Section 12.1.

12.3 To the extent that the Confidential Information is in the form of reports or any tangibly recorded data, products or other property, the same shall be returned to the disclosing Party promptly at its request together with all copies thereof. The receiving Party assumes all liability for damage to, or loss of any such property while in the possession of the Receiving Party or subject to its control. Notwithstanding the foregoing, the Receiving Party may retain one (1) copy of the Confidential Information in its legal files, solely for the purposes of verifying compliance with the provisions of this Agreement or Applicable Law. In addition, the receiving Party will not be obliged to destroy copies of Confidential Information remaining on their standard back-up devices unless requested to do so by the disclosing Party and technically feasible. Any Confidential Information so retained will continue to be subject to the terms of this Agreement for the time period set forth in Section 12.5

12.4 Remedies. Each Party shall be entitled, in addition to any other right or remedy it may have, at law, in equity or under this Agreement, to obtain temporary, preliminary and permanent injunctions, without the posting of any bond or other security, enjoining or restraining the other Party and its Affiliates from any violation or threatened violation of this Section 12.

12.5 Survival. The obligations of confidentiality, non-disclosure and non-use shall survive termination or expiration of this Agreement for a period of [***] years.

13. TERM, TERMINATION

13.1 Term, Extension. This Agreement shall commence on the Effective Date and shall continue for an initial term of five (5) years ("Initial Term"). If not terminated with eighteen (18) months' written notice prior to the expiration of the Initial Term (or any subsequent renewal term), it shall be

renewed for consecutive terms of two (2) year(s) each (the Initial Term, together with any such renewal terms, the "Term"). In the event that this Agreement expires or is terminated under this Section 13.1 or 13.2 prior to completion of a Product Addendum, this Agreement will remain in effect with regard to each surviving Product Addendum until the Services and other work as described in the surviving Product Addendum(s) is fully completed or the Product Addendum expires or is terminated.

13.2 Termination for convenience. Either Party may terminate this Agreement for convenience upon twelve (12) months prior written notice.

13.3 Termination for Cause. A Party shall have the right to terminate this Agreement upon the occurrence of any of the following events:

(a) if the other Party commits a material breach of this Agreement, which (in the case of a breach capable of remedy) is not remedied within [***] Business Days after the receipt by the breaching Party of written notice from the non-breaching Party that identifies the breach and requires its remedy; provided that a breach of payment obligations shall be subject to a [***] Business Day cure period; or

(b) upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings by or against the other Party (and if such proceedings are by or against Corden, Corden shall provide written notice of such proceedings to Customer within [***] Business Days after such filing or institution, so that Customer may take possession of its property, including Product); provided, however, that in the event of any involuntary bankruptcy or receivership proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within [***] Business Days after the filing thereof; or

(c) if the other Party ceases for any reason to carry on its business, or makes an assignment for the benefit of its creditors, or is the subject of any proposal for a voluntary arrangement. In addition, Vendor shall promptly notify Customer in writing if Vendor receives notice of the debarment or threatened debarment of any individual or entity utilized by Corden in connection with this Agreement, and Customer shall have the right to immediately terminate this Agreement upon written notice to Corden without further cost or liability, except for payments of accrued and unpaid obligations accrued before the date of termination if Corden is not able to replace such individual or entity with another individual or entity reasonably acceptable to Customer within reasonable time.

13.4 Effects of Termination. Expiration or termination of this Agreement for any reason shall not relieve Customer of payment obligations under this Agreement for Services performed prior to expiration or termination and payment associated with any close-out costs of any Purchase Orders and (except if such termination is due to an uncured material breach by Corden) all reasonably incurred future obligations to third parties and out-of-pocket expenses pre-incurred by Corden in connection with the performance of the Services, that cannot be reasonably avoided, cancelled or mitigated. For the avoidance of doubt, it is hereby clarified that in case of termination of this Agreement immediately after acceptance of such termination notice from Customer, (i) Corden will wind down any respective ongoing activities; and (ii) Corden shall neither incur any additional future obligations nor start any new activities, without receipt of Customer's specific written consent, such as, but not limited to, Tech Transfer activities as set forth in Section 13.4.2.

13.4.1 Regulatory Assistance. After termination of this Agreement, Corden shall assist Customer with reasonable support in relation to any investigation required by any Regulatory Authority with respect to Manufacture of the Product carried out by Corden at

its Manufacturing Site during the Term, provided that Customer shall reimburse Corden for its reasonable costs in providing such assistance in the event it terminates for convenience.

13.4.2 Technical Transfer Assistance. Following termination of this Agreement for any reason, Corden will provide, upon Customer's request, reasonable support and cooperation in transferring the then-current manufacturing process of the Product to an alternative site, designated by Corden. Corden shall be entitled to charge for its reasonable costs in supporting the Tech Transfer of the Product at a mutually agreed upon hourly rate based on a written and accepted quotation, provided, however, if the Tech Transfer is requested by Customer following its termination of this Agreement under Sections 13.3 (a), (b), or (e), then Corden shall provide such Tech Transfer services free-of-charge. Additionally, in connection with the Tech Transfer assistance provided pursuant to this Section, Corden shall grant to Customer and its Affiliates and designees a perpetual, fully-paid, non-exclusive, royalty-free license, with the right to sublicense, under any Corden IP which is necessary for the Manufacture of Product. Corden's obligations to support a Tech Transfer shall continue until such time as Customer, or its designee, successfully manufactures a validated Batch of each Product.

13.5 Survival. The following Sections shall survive the termination or expiration of this Agreement for any reason: Sections 3, 12, 13, 14, 15 and 16 each for the period specified therein, or, if no period is specified therein, then perpetually. Expiration or termination of this Agreement shall not relieve the Parties of any rights, causes of action, or obligations accruing prior to such expiration or termination.

14. FORCE MAJEURE

Neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation of this Agreement when such failure or delay is due to Force Majeure, and without the fault or negligence of the Party so failing or delaying. For purposes of this Agreement, "Force Majeure" is defined as unforeseeable causes beyond the control of a Party, including without limitation, acts of God; war; civil commotion; epidemics, quarantines, and the destruction of production facilities or materials by fire, flood, earthquake, explosion or storm. In such event, Customer or Corden, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled and for [***] days thereafter. To the extent possible, each Party shall use commercially reasonable efforts to minimize the duration of any event of Force Majeure. If Corden is unable to perform its obligations under this provision, Customer shall be entitled to obtain immediately any Customer Material, and/or other Raw Materials dedicated exclusively to the Product or work-in process involving Customer Material then in the custody of Corden so that Customer may arrange for the production or completion of Product by other manufacturers, in its discretion. If such Force Majeure event is expected to delay production for more than [***] days, the Parties shall immediately consult with each other to consider how to best address such delay.

15. LEGAL COMPLIANCE

15.1 Anti-Corruption. Each Party will conduct itself and undertake the arrangements contemplated by this Agreement in a manner which is consistent with the applicable anti-corruption legislation (national and foreign), including but not limited to the German laws regarding corruption, the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act 2010, as amended. Failure of a Party to comply with the provisions of this Section will be deemed a material breach of this Agreement.

15.2 Export Control

(a) Customer agrees and understands that the Product and other Corden deliverable may be subject to trade restrictions (e.g. export/import license requirements, sanctions programs in terms of embargoes or sanctioned party lists) by the Export Control Regulations imposing restrictions on trade including export, re-export, import, transfer, disclosure, supply or comparable transaction, regardless of the way of provision to other countries or parties. Customer agrees and accepts liability to always comply with all such Export Control Regulations and to instruct its agents, brokers, vendors and carriers (hereinafter each a "Customer Agent") to comply. In particular, Customer and Customer Agent shall not, without first obtaining permission to do so from the appropriate authorities, (i) provide any such Product or Corden deliverable to any country, person or other party that is ineligible to receive such Product or Corden deliverable under the Export Control Regulations (hereinafter "Embargoed Country or Embargoed Party"); or (ii) provide any Product or Corden deliverable to a person or other party if Customer or Customer Agent knows or has reason to assume that such person or other party intends to provide the Product or Corden deliverable to any such Embargoed Country or Embargoed Party, or intends to use or allow others to use the Product or Corden deliverable for activities related to military or otherwise restricted use. Customer and each Customer Agent shall cooperate fully with (i) Corden in any official or unofficial audit or inspection related to this Agreement in connection with any Export Control Regulations and (ii) Corden's reasonable requests for information and/or documentary evidence to support and/or verify compliance with any Export Control Regulations.

(b) Neither Party shall disclose Confidential Information to the other Party in violation of the Export Control Regulations. In the event that either Party knows, or has reason to believe that any Confidential Information to be disclosed hereunder is subject to the Export Control Regulations, such Party shall notify the other Party in advance of planned disclosure and before disclosure the Parties will reasonably cooperate to ensure compliance therewith. In no case shall such Confidential Information be disclosed to the other Party without its prior written agreement.

15.3 Data Protection. Each Party shall comply with applicable data protection laws, to the extent that such Party receives and/or processes and uses personal data in the performance of its obligations under this Agreement. Upon a Party's request, the other Party agrees to enter into any additional agreements required by Applicable Law, and specifically the European General Data Protection Regulation 2016/679 (GDPR), relating to data use and protection. In case of transfer of personal data to recipients seated outside the European Union/European Economic Area, which do not provide for an adequate data protection level, such contractual arrangements may include (i) the European Union's Standard Contractual Clauses/Standard Data Protection Clauses for the transfer of personal data to processors and/or (ii) any other agreement that competent data protection authorities have declared to be compulsory or acceptable to comply with data protection law obligations.

16. MISCELLANEOUS

16.1 Relationship of Parties. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. The Parties' obligations and rights in connection with the subject matter hereof are solely as specifically set forth in this Agreement, and they agree and acknowledge that they owe no fiduciary or other duties or obligations to each other by virtue of any relationship created by this Agreement. Without limiting the foregoing, the Parties also acknowledge and agree that if it should be determined by a court of competent jurisdiction that, notwithstanding the foregoing, such duties or obligations exist, the Parties hereby waive same and agree not to assert or rely on same in any proceeding. Neither Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein. Customer shall sell the Product without participation of Corden in the negotiation or consummation of such sales, and, as between the Parties, Customer shall derive the entire income and incur the entire loss, as

the case may be, from such sales. Corden shall only be entitled to the applicable properly invoiced Fees as set forth in this Agreement.

16.2 Books and Records. Any non-technical or Product related books and records to be maintained under this Agreement by a Party or its Affiliates shall be maintained in accordance with generally accepted accounting principles, consistently applied. Any right to examine records under this Agreement shall be deemed to include the right to make copies thereof, subject to the Parties' respective obligations under Section 11.

16.3 Assignment. Neither Party shall be entitled to assign its rights or delegate its obligations hereunder without the express prior written consent of the other Party, except that: (i) Customer may assign its rights and delegate its obligations hereunder, in whole or in part, to an Affiliate of Customer; (ii) Customer may assign its rights and delegate its obligations hereunder with respect to the Product to a Person who acquires all or substantially all of Customer' business, rights or obligations with respect to the Product or the applicable Product line; and (iii) Customer may assign its rights and delegate all of its obligations hereunder in the event of Customer' or its Affiliates' merger or consolidation, sale of all or substantially all its assets or business or similar transaction. Any assignment not in accordance with this Section 13.3 shall be null and void.

16.4 Sub-contracting. Corden shall not sub-contract any of the work to be performed by Corden hereunder without the prior written consent of Customer. No such sub-contracting, even if approved by Customer, shall relieve Corden of any of its obligations hereunder.

16.5 Binding Effect; No Third Party Beneficiaries. Except as otherwise provided in this Agreement, this Agreement shall be binding on the successors and permitted assigns of the Parties, each of such permitted universal successors or assigns being deemed to be a Party hereunder in substitution of its respective predecessor. This Agreement is for the sole benefit of the Parties and their respective successors, Affiliates and permitted assigns, and in the case of Customer, as applicable, its Partners, and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such assigns or Partners, any legal or equitable rights hereunder.

16.6 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

16.7 Notices. Any notice, request or other communication required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given solely if in writing and personally delivered or sent by registered or certified mail (return receipt requested), email transmission (receipt verified) or express courier service (signature required) to the Party for which such notice is intended, at the address set forth below for such Party:

(a) In the case of Corden, to:

Corden Pharma Bergamo S.p.A.

Attn.:

E-mail:

Copy to:

Corden Pharma International GmbH

Attention:

E-mail:

(b) In the case of Customer, to:

Acadia Pharmaceuticals Inc.
Telephone:
Attn.:
Email:

or to such other address for such Party as it shall have specified by like notice to the other Party; provided that notices of a change of address shall be effective only upon receipt thereof. If delivered personally, the date of delivery shall be the date on which such notice or request has been given. If sent by mail or express courier, the date of actual receipt shall be the date on which such notice or request has been given (unless such mailed or couriered notice or request merely confirms a notice or request previously delivered in accordance with this Section 16.7). If sent by facsimile transmission or email, the date of transmission shall be deemed to be the date on which such notice or request has been given, unless the date of transmission is not a Business Day in the location to which such notice or request is transmitted, in which event the next Business Day in such location shall be deemed to be the date on which such notice or request has been given. All notices, requests or other communications required by this Agreement shall be in the English language.

16.8 Use of Name. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name or trademark of the other Party for any purpose in connection with the performance of this Agreement.

16.9 Public Announcements. Neither Party shall make any public announcement regarding this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld, conditioned or delayed. In the event of permitted public announcement, or of an announcement required by Applicable Law, regulation or a Governmental Authority, the Party making such announcement shall provide the other Party with a copy of the proposed text prior to such announcement sufficiently in advance of the scheduled release of such announcement to afford such other Party a reasonable opportunity to review and comment upon the proposed text, except where such prior disclosure is not permitted by Applicable Law or regulation or would otherwise jeopardize the timely delivery by the other Party of any required public announcement. Following approval of the proposed text, such text may be used in subsequent public announcements without further approval, to the extent it remains accurate, complete and not misleading.

16.10 Waiver. Any waiver by a Party of a breach of any provision of this Agreement shall not operate as, or be construed to be, a waiver of any other breach of such provision or of any breach of any other provision of this Agreement. The failure of a Party to insist upon strict adherence to any term of this Agreement on one or more occasions shall not be considered a waiver or deprive that Party of the right thereafter to insist upon strict adherence to that term or any other term of this Agreement. Any waiver must be in writing by the waiving Party.

16.11 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, then (i) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and the same shall be legal, valid and enforceable, and (ii) the legality, validity and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

16.12 Amendment. This Agreement may only be amended with the written consent of both Parties.

16.13 Governing Law; English Original Controlling. This Agreement and all matters relating thereto and arising therefrom shall be governed by, administered under and construed in accordance with the laws of [***], and the patent laws of [***], without reference to provisions of conflicts of laws. The application of the *United Nations* Convention on Contracts for the International Sale of Goods (CISG) shall be excluded. The English original of this Agreement shall prevail over any translation hereof.

16.14 Dispute Resolution

(a) Any dispute, controversy or claim arising out of, or in relation to, this Agreement, including the validity, invalidity, breach, or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers' Arbitration Institution in force on the date on which the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators shall be one or three. The seat of the arbitration shall be [***]. The arbitral proceedings shall be conducted in English.

(b) The arbitration award will be final and binding upon the Parties. Both Parties consent to the exclusive jurisdiction of such arbitration procedure and waive any objection to the propriety or convenience of such venues. Nothing in this section shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief, if such Party thinks this is necessary to protect its interests.

(c) The Parties agree (i) that any such award or order shall be a reasoned award, shall be in writing and in English, shall specify the factual and legal basis for the award and shall be final and binding; and (ii) that judgment or any arbitral award or order resulting from an arbitration conducted under this Section 16.14 may be entered in any court, in any country of competent jurisdiction, having jurisdiction thereof or having jurisdiction over the Parties or any of their respective assets.

(d) Customer and Corden hereby irrevocably waive and exclude all rights of appeal, challenge or recourse to any court from any arbitral award or order resulting from any arbitration conducted under this Section 16.14 (except for initiating actions or proceedings to obtain a judgment recognizing or enforcing an arbitral award or order and except for actions or proceedings seeking interim, interlocutory or other provisional relief in any court having jurisdiction, but only on the ground that the award to which the applicant may be entitled may be rendered ineffectual without such provisional relief).

(e) The arbitrator, in his or her discretion, may consolidate two or more arbitrations or claims between the Parties into one arbitration, or terminate any such consolidation and/or establish other arbitration proceedings for different claims that may arise in any one arbitration. Notwithstanding the foregoing, the arbitrator shall consolidate arbitrations and/or claims, if they determine that it would be more efficient to consolidate such arbitrations and/or claims than to continue them separately and (i) there are matters of fact or law that are common to the arbitrations and/or claims to be consolidated, (ii) there are related payment and performance obligations considered in the arbitrations and/or claims to be consolidated, or (iii) there is a danger of inconsistent awards.

(f) The costs of the arbitration (including reasonable attorney’s fees and associated costs and expenses) shall be borne by the parties in proportion to the outcome of the arbitration (taking into account the relative success of the claims and defenses of the parties), as ordered by the arbitrators.

16.15 Interpretation. Except as the context otherwise requires, (i) any reference in this Agreement to a Section, subsection, paragraph, clause or Exhibit will be deemed to be a reference to a

Section, subsection, paragraph, clause or Exhibit of or to this Agreement, (ii) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein); (iii) the words “herein,” “hereof” and “hereunder,” and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof; (iv) the word “include” (and variants thereof) shall be deemed to be followed by the phrase “without limitation” or words of similar import, and (v) except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

16.16 Entire Agreement / Priority of Documents. This Agreement together with the appendices and schedules attached hereto and thereto, contain the entire understanding and agreement among the Parties with respect to the subject matter hereof and supersede all prior oral and written understandings and agreements relating thereto. In the event of a conflict or ambiguity between any term of this Agreement, its appendices, the Quality Agreement and any Purchase Order, the following order of precedence shall apply, whereas 1 equals to the highest priority. The document with the higher priority shall prevail over the document with the lower priority.

1. This Agreement and any Appendices;

2. Product Addendum;

3. Quality Agreement (except to the extent such conflict relates to quality matters, in which case the QA shall be of highest priority and shall prevail over the Agreement and its appendices, Product Addendum, and any Purchase Order);

4. Any Purchase Order (except to the extent that such Purchase Orders expressly and conspicuously contain terms intended to supersede the terms and conditions of this Agreement and its Appendices, Product Addendum, or, in which case the Purchase Order supersedes the Agreement only with regards to these specific terms).

16.17 Descriptive Headings. The headings contained in this Agreement, in the table of contents to this Agreement and in any exhibits or schedules to this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

16.18 Counterparts. This Agreement is executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The Parties agree that execution of this Agreement by industry standard electronic signature software or by exchanging executed signatures by facsimile, email, portable document format (.pdf) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same legal force and effect as the physical delivery of the paper document bearing original signature.

[signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed, as of the date first above written, by their duly authorized representatives.

CORDEN PHARMA BERGAMO S.p.A.	**ACADIA PHARMACEUTICALS, INC.**
By:	By:
Name: Luca Porcu	Name: Benir Ruano
Title: Managing Director	Title: SVP, Strategy and Tech Operations
Date:	Date:
By:	By:
Name: Vito Caroli	Name: Mark Schneyer
Title: CFO	Title: EVP, Chief Financial Officer
Date:	Date:

APPENDIX 1- TEMPLATE - Product Addendum

This Product Addendum # 1 (**Product Addendum**), effective as of Mo / Day / Year (**CSA Effective Date**) is entered into between **Corden Pharma Bergamo S.p.A**. ("Corden") and **Acadia Pharmaceuticals, Inc.** ("Customer") under the Commercial Supply Agreement dated Mo/Day/Year, between the parties (the **Agreement**). Pursuant to the Agreement, Corden has agreed to perform certain Services in accordance with written Product Addenda, such as this one, entered into from time to time. Capitalized terms used in this Product Addendum and not otherwise defined have the meanings given to them in the Agreement.

The Parties hereby agree as follows:

1. Product Addendum

This document constitutes a **Product Addendum** under the Agreement, and this Product Addendum and the Services contemplated herein are subject to the terms and provisions of the Agreement. Except if expressly modified in this Product Addendum, the terms of the Agreement are hereby incorporated by reference herein.

2. Services, Product, and Materials

A.	Services:	[xxxxxx]
B.	Corden Facility:	[xxxxxx]
C.	Product:	[xxxxxx]
D.	Raw Materials	[xxxxxx]

3. Commercial Terms

A.	Purchase Requirements:	[xxxxxx]
B.	Territory:	[xxxxxx]
C.	Product Price:	[xxxxxx]
D.	Shipping Terms:	[xxxxxx]
E.	Minimum Order Quantity:	[xxxxxx]
F.	Minimum Annual Volume Commitment:	[xxxxxx]
G.	Storage Fee:	[xxxxxx]
H.	Price Adjustment:	[xxxxxx]
I.	Rolling Forecast:	[xxxxxx]
J.	Cancellation:	[xxxxxx]
K.		[xxxxxx]
L.	Miscellaneous:	[xxxxxx]

IN WITNESS WHEREOF, the Parties hereto have caused this Product Addendum to be executed, as of the date first above written, by their duly authorized representatives.

CORDEN PHARMA [….]	**ACADIA PHARMACEUTICALS, INC.**
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:
By:	By:
Name:	Name:
Title:	Title:
Date:	Date:

Exhibit 10.36

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement is entered into as of December 15, 2021 (the **Effective Date**) between

F.I.S. Fabbrica Italiana Sintetici S.p.A.,
an Italian corporation, with offices at Viale Milano 26, 36075 Montecchio Maggiore (VI), Italy,
(**FIS**)

and

Acadia Pharmaceuticals Inc.
a Delaware corporation, with offices at 12830 El Camino Real, Suite 4300, San Diego, California USA 92130,

(**Acadia**)

Preamble

A. Acadia (and its Affiliates) engages in the business of research, development and commercialization of pharmaceutical compounds and products;

B. FIS (and its Affiliates) has substantial expertise in process development, cGMP scale-up and cGMP manufacturing of active pharmaceutical ingredients;

C. Acadia and FIS have entered into a Master Services Agreement, effective as of January 25, 2019 (the "**Master Services Agreement**"), pursuant to which FIS may perform certain non-commercial manufacturing, analysis, and development services for Acadia;

D. Acadia and FIS desire to maintain the Master Services Agreement, and also enter into this Commercial Supply Agreement (this "**CSA**" or "**Agreement**") to provide the terms and conditions upon which FIS shall conduct certain commercial testing and/or manufacturing services for Acadia from and after the Effective Date.

Now, therefore, the Parties agree as follows:

1. **Definitions**

Unless otherwise defined in this Agreement, each of the capitalized terms used in this Agreement (other than the headings of the Articles and Sections) shall have the meanings indicated below. Such meanings shall apply equally to all forms of such terms, including singular and plural forms, unless otherwise clearly indicated.

1.1 **Acadia** shall have the meaning set forth on the front page of this Agreement.

1.2 **Active Ingredient** shall mean any Acadia pharmaceutical or biopharmaceutical agent (whether chemical or biologic) identified in any CSA Attachment.

1.3 **Affiliate** shall mean, with respect to a Party, any corporation or other entity that controls, is controlled by, or is under common control with such Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or controls, directly or indirectly, fifty percent (50%) or more of the share capital or voting rights of such entity or the power to direct or cause the direction of the management or policies of such other corporation or entity, whether through the ownership of voting securities, by contract or otherwise.

1.4 **Agreement** or **CSA** shall mean this Commercial Supply Agreement including its Annexes (and appendices, if applicable), as amended from time to time by mutual written agreement signed by both Parties.

1.5 **Applicable Laws** shall mean (a) all treaties, laws, ordinances, statutes, rules, regulations, or orders in the Territory in which the given activities will be performed and which are applicable to the performance of the Services and to the obligations of the Parties, as the context requires, under this Agreement, and regulations promulgated thereunder, cGMP, and the FD&C Act; and (b) all applicable codes of ethics, principles, and industry standards of the jurisdiction(s) in which the given activities will be performed, including but not limited to the jurisdiction where FIS processes Product, as any of the foregoing may be amended from time-to-time.

1.6 **Background Intellectual Property** or **Background IP** shall mean Intellectual Property that is or becomes Controlled by a Party and that exists on or before the Effective Date or is developed, conceived, created, or otherwise Controlled by a Party during the term of this Agreement, other than in connection with, or in the course of implementing, or arising or resulting from performance of, the Services.

1.7 **Batch** shall mean a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a Batch may correspond to a defined fraction of the production. The Batch size may be defined either by a fixed quantity or by the amount produced in a fixed time interval. As used herein, the term "Batch" may refer to Product.

1.8 **Batch Records** shall mean all supporting documentation to provide objective evidence that the Batch was manufactured under cGMP conditions according to applicable procedures and regulations.

1.9 **Binding Part** shall have the meaning set forth in Section 3.3.

1.10 **Business Day** shall mean any day in which the banks are open for business in Vicenza, Italy.

1.11 **Certificate of Analysis** or **COA** shall mean, for each Product Batch produced, a document showing acceptance criteria and/or Specifications for such Batch, a compilation of the analytical test methods applied, specifications for each test, and test results for Product.

1.12 **Certificate of Compliance** or **COC** shall mean, for each Product Batch, a document confirming that the end product has been manufactured in compliance with cGMP in compliance with the product registration requirement, when applicable, and that quality records associated with such

Batch have been reviewed and approved by Quality Assurance/Quality Unit at FIS. The COC may be integrated in the COA.

1.13 **Change Order** shall mean a separate agreement between the Parties setting out the specific details of any change to the scope of a CSA Attachment and any consequences thereof, such Change Order being in substantially the form attached hereto as in the sample form attached hereto as ANNEX B.

1.14 **cGMP Regulations** shall mean all current Good Manufacturing Practices promulgated by the Regulatory Authorities in the Territories included in Applicable Laws (as applicable to Acadia and FIS respectively) relating to manufacturing practices for pharmaceutical products (including but not limited to ingredients, packaging, testing, storage, distribution, handling, intermediates, bulk and finished products). In the United States, this includes 21 C.F.R. Parts 210, 211, 600, 601, and 610, and in particular the latest edition of the GMP guideline of the Pharmaceutical Inspection Convention (PIC/S) and further guidelines issued by the FDA, PIC/S, the International Conference on Harmonization (ICH) or any relevant Regulatory Authority, as applicable. In the European Union, this includes 2003/94/EC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission) and applicable ICH guidance, as amended, if and as implemented in the relevant constituent country.

1.15 **Consigned Materials** shall mean any of the consigned materials, if any, that are to be provided to FIS (or its Affiliate) by or on behalf of Acadia, as set forth in a CSA Attachment applicable to any particular Services.

1.16 **Controlled** or **Controls** shall mean possession of the right, whether directly or indirectly, and whether by ownership, license, or otherwise (other than by operation of a license under this Agreement), to assign or grant a license, sublicense, or other right or to transfer or provide access to or under, any material, information, or Intellectual Property without violating the terms of any agreement with any Third Party, infringing upon the Intellectual Property of a Third Party, or misappropriating the proprietary information of a Third Party.

1.17 **CSA Attachment** shall mean any separate agreement setting out the specific details of given Services to be conducted by FIS in accordance with this Agreement, such CSA Attachment being in substantially the form attached hereto as ANNEX A, as amended from time to time according to the terms and conditions of this Agreement.

1.18 **Damages** shall have the meaning set for in Section 10.2.

1.19 **Effective Date** shall have the meaning set forth on the front page of this Agreement.

1.20 **EMA** shall mean the European Medicines Agency or any successors to its responsibilities with respect to pharmaceutical products.

1.21 **Facility** shall mean the FIS production facility located at [***], or other facilities of FIS as are mutually agreed upon by the Parties in writing.

1.22 **FDA** shall mean the US Food and Drug Administration or any successors to its responsibilities with respect to pharmaceutical products.

1.23 **FD&C Act** shall mean the United States Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder, as each may be amended from time to time.

1.24 **FIS** shall have the meaning set forth on the front page of this Agreement.

1.25 **Force Majeure Event** shall have the meaning set forth in Section 13.3.

1.26 **Initial Period** shall have the meaning set forth in Section 12.1.

1.27 **Intellectual Property** shall mean all Inventions (whether or not patented or patentable), patents, patent applications, know-how, trade secrets, improvements, copyrights, trademarks, and other intellectual property, including, analytical methods, formulae, compounds, procedures, techniques, software, designs, concepts, technical information, manuals, standard operating procedures, instructions, or specifications.

1.28 **Intermediate** shall mean a material produced by FIS during the synthetic process of a drug substance that undergoes further molecular change or purification or physical transformation before becoming drug substance. Intermediates may or may not be isolated.

1.29 **Invention** shall mean any invention or discovery, whether patentable or not under the applicable patent laws that is conceived or made solely by employees and/or agents of a Party or jointly by employees and/or agents of multiple Parties in the performance of the Services.

1.30 **Latent Defects** shall mean any failure of a Product to conform to the Specifications, such failure not being discoverable upon reasonable physical inspection or standard testing upon receipt of the Product.

1.31 **Marketing Authorization** shall mean any formal documentation filed with a Regulatory Authority for registration and/or approval necessary for the marketing and sale of the Product in the respective country(ies) of the Territory.

1.32 **Market Correction** shall mean repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a Product without its physical removal to some other location.

1.33 **Market Withdrawal** shall mean removal or correction of a distributed Product that involves a minor violation that would not be subjected to legal action by a regulatory agency.

1.34 **Master Batch Records** shall mean detailed protocols of the procedures followed in the preparation of Products which shall be reviewed and approved by Acadia in writing prior to FIS finalizing these documents for use in production. A Master Batch Record includes reference to standard operating procedures, master manufacturing formula, a listing of raw materials, packaging and storage instructions, and testing requirements.

1.35 **Master Services Agreement** shall have the meaning set forth in the Preamble to this Agreement.

1.36 **Materials** shall mean the Consigned Materials and the Raw Materials.

1.37 **Party** or **Parties** shall mean either Acadia or FIS, or both, as the context may require.

1.38 **Product** shall mean any pharmaceutical product, active pharmaceutical ingredient, starting material, Intermediate, precursor to be manufactured by FIS pursuant to this Agreement and a particular CSA Attachment.

1.39 **Quality Agreement** shall mean any of the written agreement(s) between FIS (or its Affiliate) and Acadia (or its Affiliate), which defines the responsibilities of each Party with respect to the practices to be followed to ensure Product quality and compliance with cGMP Regulations.

1.40 **Quality Assurance/Quality Unit** shall mean a unit, department, group, or contractor that has the responsibility and authority to approve or reject all Product components, drug product containers,

closures, in-process materials, packaging material, labelling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated.

1.41 **Raw Materials** shall mean all raw materials, excluding any Consigned Materials, which are necessary or used to manufacture the Product, as set forth in the respective CSA Attachment.

1.42 **Recall** shall mean removal of a distributed drug product comprising the Product that a Regulatory Authority considers to be in violation of the Applicable Laws it administers and against which the Regulatory Authority would initiate legal action (e.g. seizure). Recall does not include a Market Withdrawal, stock recovery, or Market Correction.

1.43 **Regulatory Authority** shall mean any governmental regulatory agency or authority that is responsible for regulating any aspect of the development, manufacture, market approval, sale, distribution, packaging, or use of Product.

1.44 **Rolling Forecast** shall have the meaning set forth in Section 3.3.

1.45 **Safety Stock** shall have the meaning set forth in Section 3.12.

1.46 **Services** shall mean the commercial testing and/or manufacturing services to be performed by FIS under the terms of this Agreement and one or more individual CSA Attachments.

1.47 **Specifications** shall mean the detailed description of technical requirements the Material or Product has to conform to, as agreed by the Parties and set forth in the respective CSA Attachment.

1.48 **Territory** shall mean the [***], and any other countries or jurisdictions that are mutually agreed to by the Parties in writing.

1.49 **Third Party** shall mean any party other than Acadia or FIS or their respective Affiliates.

2. Provision of Services and CSA Attachments

2.1 The Parties conduct business around the globe in their own names or through their respective Affiliates. Affiliates of FIS may opt into the terms of this Agreement through a CSA Attachment signed by the respective parties that may comprise additional terms to comply with local law or practice. References to FIS under this Agreement shall be deemed to refer to the corresponding Affiliate that entered into the respective CSA Attachment. For clarification, in no event may any Services be initiated or performed by FIS or any of its Affiliates, or any subcontractor, except with prior written approval by Acadia which shall not be unreasonably withheld. FIS acknowledges that, prior to initiating any activities at FIS or any of its subcontractors, such sites must be qualified by FIS and approved by Acadia. FIS shall remain responsible for the performance by its Affiliates and subcontractors of any of its obligations under this Agreement.

2.2 Acadia hereby retains FIS to perform the Services specified in the written CSA Attachment(s) in accordance with the terms of this Agreement.

2.3 For Services to be performed in accordance with cGMP Regulations, the Parties agree to enter in a Quality Agreement between the Parties (or its Affiliates) that shall be incorporated herein by reference, as same may be amended from time to time by mutual written agreement between the Parties. The Quality Agreement shall supplement the terms of this Agreement. In the event of

inconsistencies between this Quality Agreement and this Agreement, the terms of the Quality Agreement shall control with respect to quality requirements and this Agreement shall control with respect to all other matters.

2.4 The specific details of all Services to be performed by FIS hereunder shall be separately negotiated and specified in written CSA Attachments. Each CSA Attachment shall include, as appropriate, a description of the Services to be provided, including, if applicable, the Specifications for Product to be manufactured as part of such Services and a timeline, budget and payment schedule for such Services, the scope of the reports of the Services as well as special provisions governing quality matters relating to such Services, as far as such quality matters are not already defined in the Quality Agreement. The terms of this Agreement and of the Quality Agreement shall be deemed incorporated by reference into each CSA Attachment.

2.5 The Parties may mutually agree, from time to time, to change or expand a particular CSA Attachment by executing a Change Order describing such changes. Each such Change Order is hereby integrated by reference into the respective CSA Attachment.

2.6 Each Party shall:

(a) conduct its activities hereunder in compliance with this Agreement and the applicable Quality Agreement, the applicable CSA Attachment, and all Applicable Laws, including any cGMP Regulations in case it has been agreed by the Parties in a particular CSA Attachment to perform any Services under cGMP Regulations (it being acknowledged that all activities relating to manufacture and supply of Product hereunder shall be under cGMP Regulations, unless otherwise specified in the CSA Attachment); and

(b) have and maintain in its own name at all times during its activities hereunder all authorizations, permits, licenses, accreditations and certifications required to perform such activities lawfully; and

(c) provide all personnel, facilities and resources necessary to perform its activities hereunder in accordance with this Agreement and the applicable CSA Attachments.

2.7 Acadia shall disclose and deliver to FIS such information in Acadia's possession relating to the Services or Product which may be reasonably required by FIS in performing the Services, including in particular information concerning any potential hazards or other safety, health or environment related information relating to the Product or Services.

2.8 FIS shall furnish to Acadia a written report that includes the results of the Services within the timeframe set forth in the applicable CSA Attachment. Acadia shall have the right to use such written reports, any and all results of the Services (including data transcribed from the executed Batch Records but not the actual copies of the executed Batch Records) and other information relating to the Services provided by FIS for Acadia’s business purposes, and all such reports, results and other information (except any inclusion of FIS’s Background IP which shall be used consistent with any terms and conditions agreed upon by the Parties herein, in a CSA Attachment or otherwise in writing), shall be Confidential Information of Acadia and subject to Section 11.

2.9 Sections 2.9 and 2.10 shall apply to Services other than manufacture and supply of Product, which is addressed in Sections 3.9 and 3.10. Upon receipt of a written report of the results of the Services performed pursuant to a CSA Attachment, Acadia shall examine the report within [***] days in order to determine compliance with the CSA Attachment. If, in Acadia's opinion, the Services do

not comply in whole or in part with the CSA Attachment, Acadia shall notify FIS in writing thereof within [***] days of receipt of the report. If Acadia does not notify FIS accordingly within the specified time set forth above, the Services shall be deemed to be accepted. Any claims by Acadia regarding the Services shall specify in reasonable detail the nature and basis for the claim and cite FIS's relevant Services. FIS agrees to review any written claim made by Acadia regarding the quality of the Services and to provide Acadia with the results of such review within [***] days of receipt of such claim. If FIS does not notify Acadia in writing that, based on such review, FIS disagrees with Acadia's claim that certain Services did not meet the CSA Attachment within [***] days of receipt of such claim, specifying in reasonable detail the reason that FIS believes such Services met the CSA Attachment, Acadia shall have the right to reject such Services. In this case the Parties shall proceed according to Section 10.1 subject to Section 2.10 below.

2.10 If FIS does notify Acadia in writing that it disagrees with Acadia's claim that certain Services do not comply with the CSA Attachment in accordance with Section 2.9, the Parties agree to have such Services further analyzed by an independent expert in the field selected by written agreement between the Parties and within a commercially reasonable timeframe. The decision of the independent expert shall be deemed final as to any dispute over the compliance of Services with the CSA Attachment. Should the expert determine that the Services performed did not comply with the CSA Attachment in whole or in part, then (i) FIS shall bear all costs for the independent expert and (ii) Acadia shall have the right to reject the noncompliant Services, and (iii) the Parties shall proceed according to Section 10.1. However, if the expert determines that the Services were performed in compliance with the CSA Attachment, then Acadia shall bear all costs of the independent expert and compensate FIS for the Services in question as set out in this Agreement.

3. Manufacture, Purchase and Supply of Product

3.1 FIS shall manufacture the Product in accordance with the cGMP Regulations, the Quality Agreement, and the Specifications using Master Batch Records.

3.2 During the term of this Agreement, Acadia shall purchase the Product from FIS as set forth in the respective CSA Attachment. FIS acknowledges that Acadia may elect (but has no obligation) to purchase additional Product quantities from FIS hereunder in excess of the amounts ordered by Acadia in accordance with the respective CSA Attachment. Unless otherwise agreed to by the Parties in writing, if Acadia requests additional quantities of Product, FIS will notify Acadia of its acceptance or declination of such request, making reasonable commercial efforts to supply Acadia with quantities of Product in excess of those ordered provided that FIS's production capacity allows it and that it would not cause a breach of FIS' obligations towards Third Parties.

3.3 The CSA Attachment shall set forth the terms for forecasts and delivery dates for the Product contained therein, and Acadia shall provide to FIS by the [***] day of the last month in a given calendar quarter (or by the immediately preceding Business Day if the [***] day of the month is not a Business Day), a good-faith rolling forecast for the time period (e.g., 24 months, 36 months, etc.) specified in the applicable CSA Attachment ("**Rolling Forecast**") showing:

(i) [***]for the immediately subsequent period, as agreed to by the Parties and set forth in the CSA Attachment, which shall be binding on Acadia and FIS ("**Binding Part**"); and

(ii) a [***] estimate of the required amounts of Product for an additional [***]immediately following the Binding Part, as agreed to by the Parties and set forth in the CSA Attachment, which shall not be binding on Acadia or FIS and shall be for purposes of reference only.

3.4 Acadia is obligated to issue specific purchase orders for the Product quantity specified in the Binding Part of a Rolling Forecast. If Acadia does not issue purchase orders for the Product quantity specified in a Binding Part, FIS will be remunerated in accordance with the applicable cancellation policy established in the CSA Attachment. To the extent the relevant CSA Attachment does not set forth specific delivery dates for Product, Acadia shall, from time to time, submit specific purchase orders for Product (the "**Firm POs**") in accordance with the Binding Part set forth on the applicable Rolling Forecast. Each Firm PO shall be in writing and shall specify (i) the Product ordered, (ii) the quantity ordered in full Batches, (iii) the price pursuant to the CSA Attachment, and (iv) the requested delivery date, giving FIS a lead time as set forth in the CSA Attachment, in advance of requested delivery to Acadia. Shorter lead times for Product deliveries, if requested by Acadia to cover unexpected demand, shall be reviewed in good faith and agreed upon in writing between the Parties.

3.5 Each Firm PO placed in accordance with Section 3.3 and Section 3.4 shall constitute a firm obligation by Acadia to purchase the ordered Product. Within [***] Business Days from the date of the receipt of a Firm PO from Acadia, FIS shall confirm to Acadia receipt of the Firm PO, provided that if the Firm PO is not placed in accordance with Section 3.3 and Section 3.4, FIS may reject the Firm PO with explanation as to which part of Section 3.3 or Section 3.4 was not complied with and in such a case, the submitted Firm PO shall not be binding on either party. FIS shall supply all Products ordered in Firm POs placed in accordance with Section 3.3 and Section 3.4 in accordance with this Agreement, the applicable CSA Attachment and the Firm PO. Orders exceeding one [***] percent ([***]%) of the corresponding forecast shall be discussed between the Parties, but are only binding upon confirmation by FIS.

3.6 Unless expressly set forth otherwise in a CSA Attachment, delivery of Product shall be on a [***]basis. Unless otherwise agreed in writing between the Parties, FIS shall ensure that the Product is packaged according to the Batch Record and Specifications and delivered in accordance with the Quality Agreement. Acadia assumes all responsibilities and liability arising out of the storage, handling and distribution of the Product after delivery by FIS to Acadia.

3.7 FIS will provide to Acadia or its designee the executed Batch Records as required by the Quality Agreement within [***] Business Days of the completion of FIS's release of the Product (and such executed Batch Records shall be deemed complete and received by Acadia for purposes of this Agreement upon receipt by Acadia). With each shipment of any Batch of Product, FIS shall also provide Acadia or its designee with a Certificate of Analysis and a Certificate of Compliance, which may be integrated in the Certificate of Analysis, with respect to such Batch and other compliance documents as described in the Quality Agreement.

3.8 FIS shall promptly notify Acadia in writing of any anticipated delay or of any circumstance(s) outside of FIS's reasonable control rendering it unable to manufacture and/or supply Product in accordance with the agreed delivery date(s) and the estimated duration of such delay/circumstance(s), including without limitation, with regard to the supply of Raw Material according to Section 6. Upon such written notice, the Parties will work together in good faith to agree upon a revised delivery schedule and the Parties shall proceed according to Section 10.1, provided that the parties acknowledge and agree that the second to last sentence of Section 10.1

shall not apply in the case of a delay that results from a Force Majeure Event. For clarity, neither Party shall be obligated to agree to a revised delivery scheduled under this Section 3.8.

3.9 Upon receipt of the copies of individual fully executed Batch Records (as described in the Quality Agreement) for all Intermediates and Products by Acadia QA, Acadia shall examine the executed Batch Records and other documents specified in the Quality Agreement within [***] calendar days in order to determine compliance with the Specifications. If in Acadia's opinion the Product delivered does not conform to the warranties in Section 9.2, then Acadia shall notify FIS in writing thereof. If Acadia does not notify within [***] calendar days after receipt of the Product by Acadia, the Product shall be deemed accepted, provided that Acadia retains the right to reject the Product at a later time in case of Latent Defects, in which case Acadia shall notify FIS in writing within [***] calendar days of discovering the Latent Defect. Acadia must notify FIS of any known Latent Defects no later than [***] months after receipt of the applicable Product, unless otherwise set forth in the applicable CSA Attachment. Any claims by Acadia regarding Product delivered shall specify in detail the nature and basis for the claim and cite FIS's relevant Batch numbers or other information to enable specific identification of the Product involved. FIS shall review any written claim made by Acadia regarding the quality of the Product and to provide Acadia with the results of such review. If FIS does not notify Acadia in writing that, based on such review, FIS disagrees with Acadia's claim that the identified Product did not conform to the warranties in Section 9.2 within [***] days of receipt of such claim, specifying in detail the reason that FIS believes that the identified Product does confirm to the warranties in Section 9.2, Acadia shall have the right to reject such Product, in which case the Parties shall proceed according to Section 10.1 subject to Section 3.10 below. Acadia shall, at FIS's expense and written direction, dispose of the noncompliant Product or deliver it to such destination as FIS shall specify in writing, provided that such directions are in compliance with applicable environmental laws and regulations. Acadia shall not use or dispose of any Product that does not, or of which Acadia claims that it does not, conform to the warranties in Section 9.2 without FIS's prior written consent.

3.10 If FIS notifies Acadia in writing that it disagrees with Acadia's claim that any identified Product does not conform to the warranties in Section 9.2 in accordance with Section 3.9, unless the Parties reach written agreement on the matter within [***] days after FIS's notice to Acadia of disagreement, then as promptly as practicable, and in any event within [***] days after Acadia receives FIS's notice of disagreement, the Parties shall identify and select by mutual agreement a Third Party testing laboratory or quality/regulatory consultant and have the Batch in dispute further tested and analyzed by such Third Party testing laboratory (with regard to conformity to Specifications) or quality/regulatory consultant (with regard to compliance with cGMP Regulations) selected by written agreement between the Parties. The decision of the Third Party shall be deemed final and binding on both Parties as to any dispute over Product compliance with the warranties in 9.2. Should the Third Party's testing determine that the delivered Product does not conform to the Specifications or other warranties in Section 9.2, then (i) FIS shall bear all costs for the independent laboratory testing, (ii) Acadia shall have the right to reject such Batch of Product, and (iii) the Parties shall proceed according to Section 10.1. However, if said Product is determined by the Third Party to conform to the Specifications and other warranties in Section 9.2, then Acadia shall bear all costs of the independent laboratory and compensate FIS for the rejected Products (if Acadia has not previously paid for it), the replacement delivery (if any), and the transportation costs stated in Section 3.9 as set out in this Agreement.

3.11 A storage fee shall apply for any Product stored by FIS or on behalf of FIS for more than [***] months from the date of release of the Product, such storage fee as set forth in the applicable CSA Attachment.

3.12 No later than [***] months after the Product has obtained regulatory approval, the Parties will negotiate and mutually agree in writing on the quantity of safety stock of Intermediates, and Materials, if any, to be carried by FIS to be utilized by FIS for fulfillment of Services for Acadia at a later date to ensure that there is a continuity of Product supply in the marketplace ("Safety Stock"), at Acadia's expense. FIS will maintain and continually replenish, at Acadia's expense (based on FIFO and FEFO methods to usage) a rolling Safety Stock of Intermediates and Materials, as the case may be, in the quantities agreed to in writing by the Parties, as well as the threshold levels of Safety Stock that must be maintained at all times, taking into account procurement lead time of all Product specific Materials and Product production cycle times. The Safety Stock will be in place at Acadia's expense within [***] months after regulatory approval or within a timeframe mutually agreed upon by both Parties in writing taking into consideration reasonable time to build it. Once Safety Stock is in place, FIS will replace any defective Intermediates and Materials by utilizing Safety Stock. FIS will promptly notify Acadia of any reduction in Safety Stock and the level of any Safety Stock until such time as Safety Stock is replenished to the original agreed upon level. FIS will: (i) store and handle all Safety Stock in accordance with Acadia's handling and storage instructions and cGMP, and will take necessary care to prevent its damage, loss or theft; (ii) clearly identify all such Safety Stock in storage and in its books as goods belonging to Acadia; and (iii) always use FIFO and FEFO methods of usage for Safety Stock.

4. Compensation and Terms of Payment

4.1 The compensation payable to FIS in connection with the Services and supply of Product, and the payment schedule therefore, shall be as set forth in the applicable CSA Attachment, subject to this Section 4.

4.2 All invoices and payments shall be in the currency agreed upon by the Parties and reported in the CSA Attachment. Invoices will be issued by FIS and sent to Acadia after completing of milestones, FIS QA release or shipment of Product and all documentation to be delivered with respect to Product pursuant to the Quality Agreement, if applicable, or as otherwise set out in a CSA Attachment. Acadia shall pay such invoices to FIS within [***] calendar days after the invoice date, unless Acadia in good faith makes a claim regarding non-compliance of the Services pursuant to Section 2.9 or non-conformity of Product with the warranties in Section 9.2 pursuant to Section 3.9, in which case the applicable portion of the invoice shall not be paid until the claim is handled in accordance with Sections 2.9, 2.10, 3.9, 3.10, and 10.1, as applicable. If the applicable documentation pursuant to the Quality Agreement or as otherwise set out in a CSA Attachment is not provided with (or prior to the delivery of) the Product, Acadia will promptly notify FIS in writing and FIS will send Acadia such documentation.

4.3 All FIS's invoices shall be emailed as an individual PDF in text format to [***] (or other address provided by Acadia from time to time), and shall make reference to Acadia's applicable purchase order number.

Unless otherwise agreed between the Parties in writing, all payments to be made by Acadia to FIS hereunder shall be made free and clear of and without deduction for or on account of any present

or future taxes imposed, levied or assessed either by the competent official authorities in the Territory or by any other jurisdiction, unless Acadia is compelled by law to make any payment subject to such tax. Should any payment be subject to any such tax, Acadia shall pay to FIS such additional amounts as may be necessary to ensure that FIS, after deduction or withholding as is required to be made, receives a net amount equal to the full amount which it would have received had payment not been made subject to such tax.

5. **Marketing Authorization and Records**

5.1 Acadia shall have the responsibility for preparing and submitting any application for Marketing Authorization to the Regulatory Authority (including responding to any questions and inquires of the Regulatory Authority subsequent to filing) and for maintaining any granted Marketing Authorization, keeping FIS duly informed, if applicable in accordance with the Quality Agreement. FIS shall, and shall ensure that its Affiliates, as applicable, agree to reasonably cooperate with any inspection by any Regulatory Authority.

5.2 If set out in any particular CSA Attachment, FIS shall provide Acadia upon Acadia's request with the documentation, as available to FIS or any of its Affiliates, in support of Acadia's completing, submitting and obtaining any application filed by or on behalf of Acadia for Marketing Authorization, including subsequent information necessary for maintaining such Marketing Authorization, it being agreed that FIS will provide said documentation and information to the extent it is under FIS' control and availability.

5.3 If set out in any particular CSA Attachment, FIS shall further provide Acadia with reasonable assistance on the terms and conditions in such CSA Attachment in preparing or reviewing the application for Marketing Authorization or formulating responses to any questions and/or inquiries (i.e., deficiency letters) with respect to the above submissions. Acadia shall reimburse FIS for its (or its Affiliates') reasonable out-of-pocket costs incurred in connection with any such assistance provided under this Section 5.3.

5.4 Acadia shall provide, and FIS shall review, those portions of Acadia's proposed regulatory filings relating to FIS's manufacturing procedures or otherwise related to FIS's key obligations hereunder before the regulatory filings are submitted with relevant Regulatory Authorities and Acadia shall consider FIS's comments thereto in good faith.

5.5 The Parties acknowledge that the ultimate decision of whether any Product (or drug product comprising Product) will be approved for marketing and sale in the markets rests with the Regulatory Authority of the respective market and that neither Party will be liable for the failure of the Regulatory Authority to issue such approval provided that such failure is not due in whole or in part to such Party's or its Affiliates' failure to comply with this Agreement or the Quality Agreement, or such Party's negligence or willful misconduct.

5.6 FIS shall keep and shall ensure that its Affiliates, as applicable, keep complete, accurate, up-to-date and authentic accounts, notes, data and records of the Services performed. FIS shall keep samples of Product that FIS supplies to Acadia and maintain manufacturing records, laboratory notebooks containing experimental descriptions and other data as required by cGMP Regulations or as set forth in the Quality Agreement. Upon Acadia's written request, FIS shall allow Acadia to review any such records or other information for the purposes of assuring quality and compliance with cGMP Regulations, as applicable. FIS shall be entitled to keep original copies of all documents

and records relating to any requirements of the Regulatory Authority and for archival purposes in accordance with its policies and procedures.

6. Materials

6.1 FIS shall obtain sufficient quantities of all Raw Materials to manufacture and supply Product in accordance with Binding Part of Rolling Forecast, as set forth in the CSA Attachment, and shall ensure that such Raw Materials comply with the agreed Specifications. For clarity, FIS shall not use any Materials or Intermediates in the manufacture of Product under this Agreement without the prior written consent of Acadia which shall not be unreasonably withheld.

6.2 If Acadia designates certain vendors in accordance with and if set forth in the Quality Agreement, then FIS shall obtain respective Raw Material(s) or services only from such designated vendors.

6.3 Acadia shall procure supply of Consigned Materials in sufficient quantities necessary to enable FIS to manufacture and supply Product in accordance with this Agreement and the applicable CSA Attachment, at Acadia's costs and expenses. At Acadia's option, the Consigned Materials may be delivered directly from Acadia's vendor to FIS at the vendor's or Acadia's costs and expenses.

6.4 Consigned Materials shall be delivered to FIS by the delivery date or timeframe as mutually agreed by the Parties in writing.

6.5 FIS agrees that Consigned Materials shall: (i) be used solely for the purpose of the manufacture and supply of Product; (ii) be used in compliance with all Applicable Laws; and (iii) not be transferred to any Third Party, except to any Affiliate or subcontractor of FIS to which Acadia has consented in writing pursuant to Section 2.1, unless otherwise agreed by the Parties in writing.

6.6 Acadia shall retain all right, title and interest in and to all Consigned Material delivered to FIS. FIS shall be liable for loss of or damage to Consigned Material after delivery to FIS, only if such loss or damage was caused by FIS's willful misconduct or gross negligence.

7. Intellectual Property

7.1 Except as expressly set forth in this Agreement or in a CSA Attachment or as the Parties may otherwise agree in writing, each Party owns, and shall continue to own, its Background Intellectual Property, without conferring or transferring any interests therein on the other Party. Without prejudice to the above, Acadia shall own all right, title, and interest in and to any and all Intellectual Property in accordance with Applicable Laws, including all Inventions, directed to (a) the composition of the Product, Active Ingredient and any modification, improvement, or derivative thereof, (b) the use of the Product, Active Ingredient, and any modifications or improvements thereof, (c) the methods of making the Product and Active Ingredient, including any processes, methods or procedures, related to the processing of the Products including analytical methods directed to the Product and developed in the provision of the Services, and (d) any Intellectual Property that arises from the performance of the Services by either Party ("**Product IP**"), and to the maximum extent allowed by the Applicable Laws FIS shall and hereby does assign all right, title, and interest in and to the Product IP to Acadia or its designated Affiliate. FIS shall, upon the request of Acadia, execute such documents, including any and all applications, assignments, or other instruments, give any testimony, and take such other actions as Acadia deems necessary to apply for, secure, and maintain patent or other proprietary protection in the United States or any

other country with respect to Product IP, provided that Acadia shall compensate FIS and/or FIS' Affiliates, as applicable, for its reasonable and documenteded out-of-pocket costs and expenses associated with such actions. Excluding the Product IP, FIS shall own all Inventions and other Intellectual Property made or conceived in connection with the Services (collectively, "**Vendor IP**"). Further, FIS will not use FIS Background IP for performance of Services under this Agreement unless expressly agreed in writing with Acadia prior to its use. Contingent on Acadia paying FIS all amounts due under this Agreement, FIS hereby grants to Acadia or its designated Affiliate a fully paid-up, royalty-free, perpetual, irrevocable, world-wide, non-exclusive license, and with a right to sublicense (unless Acadia permits FIS Background IP to be used in which case Section 7.2 shall apply) and to use and exploit the Vendor IP as far as necessary for the further development, manufacture and distribution of the Product. Except for the licenses set forth in herein, FIS grants no license, express or implied, to Acadia to use or exploit the Vendor IP (including FIS' Confidential Information) for any other purpose. The license granted to Acadia in this Section shall be irrevocable with respect to the Product. During the term of this Agreement, Acadia hereby grants to FIS a royalty-free, world-wide (unless the relevant Intellectual Property is otherwise limited), non-exclusive license, with the right to sublicense to FIS' approved subcontractors, to use and practice the Intellectual Property Controlled by Acadia solely as necessary for performance of the Services. Except for the license set forth in the foregoing sentence, Acadia grants no license, express or implied, to FIS to use or practice any of the Intellectual Property of Acadia for any other purpose.

7.2 In the event that FIS proposes to use, in the preparation of a Product under a CSA Attachment, any FIS Background IP, FIS shall provide written notice to Acadia describing in reasonable detail FIS's proposed use of such FIS Background IP in the preparation of the Product. Acadia at its sole discretion may elect to incorporate such FIS Background IP into the preparation of the Product by written election to FIS, and upon such election, the applicable terms and conditions for use of such FIS Background IP will be documented in a written agreement of the Parties and in accordance with this paragraph. If so elected, Acadia will pay FIS for the rights to use such FIS Background IP and to that end the Parties shall negotiate in good faith to provide Acadia with license rights to use such FIS Background IP (and any related FIS Background IP patent rights) subject to an adequate fee payment by Acadia to FIS, which shall be on commercially reasonable terms and conditions.

7.3 All project data generated or obtained by FIS or by Acadia, whether obtained solely by one Party or jointly by both Parties, in the performance of this Agreement shall be solely owned by Acadia and shall be deemed to be Confidential Information of Acadia (the "**Project Data**"). Upon completion of Services or a milestone set forth in a CSA Attachment, FIS shall send to Acadia complete copies of all Project Data generated by FIS and its subcontractors and Affiliates. The Project Data shall be prepared, documented, and communicated by FIS in a manner consistent with the Specifications and applicable CSA Attachment or as otherwise mutually agreed by the Parties in writing.

8. Regulatory Matters, Inspections, Audits, Notification and Recall

8.1 Except as required by Applicable Laws, Acadia shall be solely responsible for all contacts and communications with any Regulatory Authority with respect to all matters relating to Products and Services. Notwithstanding anything contained in this Agreement to the contrary, FIS shall not

initiate or participate in any communications with domestic or foreign Regulatory Authority concerning the Services or Products provided for hereunder unless so required by Applicable Laws or requested by Acadia in writing, and then, if and to the extent permitted under Applicable Laws, only upon prior consultation with Acadia. Without limiting the foregoing, the Parties acknowledge that FIS will keep direct contacts with the Italian Regulatory Authorities as required by local laws. At the request of Acadia and at Acadia's expense, FIS shall make appropriate personnel reasonably available for meetings with Regulatory Authorities related to the manufacturing of Products. If and to the extent not prohibited by Applicable Laws FIS shall notify Acadia immediately, and in no event later than [***] Business Days, after receiving any contact or communication from any Regulatory Authority that in any way relates to Consigned Materials, Product, or to Product related Services.

8.2 If and to the extent not prohibited under Applicable Laws, FIS shall notify Acadia in writing of all Regulatory Authority inspections related to Product that take place at the Facility where the Product is manufactured, including any facilities where cGMP operations are performed by FIS on behalf of Acadia, or the testing laboratory where any of the associated Product testing is performed. If and to the extent not prohibited under Applicable Laws, Acadia shall be notified in advance of any scheduled inspections that may impact the Product or its testing. For unannounced inspections relevant to Product, if and to the extent not prohibited under Applicable Laws, FIS shall notify Acadia in a reasonable timeframe but not more than [***] Business Day after the inspection has begun. Acadia shall have the option to be present or have a representative of Acadia present, however, always in the back-office only, during a regulatory inspection related to Product. If during the inspection, a request to collect a sample of Product that FIS supplies to Acadia or Acadia related records from the Facility is made, if and to the extent not prohibited under Applicable Laws, FIS shall immediately (and in any event within [***] Business Day) contact Acadia and ensure a duplicate sample of Product that FIS supplies to Acadia is collected and retained. In all cases, if and to the extent not prohibited under Applicable Laws, a written notification of the results of the inspection shall be provided to Acadia. Such notification shall include: (a) written notification of any observation, if any, including, without limitation, any observation that may impact the manufacture of the Product; (b) where possible, FIS shall provide the actual documentation of such observations. Documentation may be redacted of information that does not relate, directly or indirectly, to Acadia or Product, or any facilities at which Product is manufactured; (c) written notification of all related corrective actions and planned completion dates; and (d) any further correspondence with the Regulatory Authority when relevant to Acadia or the Product. If and to the extent not prohibited under Applicable Laws, any written response to inspectional observations related to the Product shall be submitted to Acadia and subject to Acadia approval in writing prior to submission of the response to any Regulatory Authority. Acadia shall be actively involved in the development and approval of any corrective action plan related to Product.

8.3 Acadia hereby acknowledges that it may not direct the manner in which FIS fulfils its obligations to permit inspection by governmental entities and Regulatory Authorities in accordance with this Agreement. FIS shall comply in all material respects with all regulatory requirements with respect to Product that are imposed upon FIS (as the provider of Services hereunder) by Applicable Laws from time-to-time, including those relating to environmental, health, and safety matters.

8.4 FIS shall allow Acadia representatives to carry out on-site audits by appointment. FIS shall permit all reasonable access to any manufacturing, packaging, warehousing and laboratory areas related to the Product or used in the Services thereof, including pertinent documentation, during normal

business hours on reasonable prior notice. The results of the audit and the observation(s) shall be sent to FIS by means of a written report. FIS must ensure a satisfactory follow up to the observations made during the audit performed by Acadia, and take corrective actions mutually agreed upon by the Parties. Audit observations shall have a written response to Acadia within [***] Business Days. The frequency of the audit shall depend upon the results of the audit and the quality performance of FIS. In the absence of critical quality incidents the frequency shall be not more than [***] audit every [***] years with maximum of [***] auditors and 1 subject matter expert at each audit. Acadia shall have the right to audit more frequently if quality issues arise or if regulatory action is pending. Acadia reserves the right to request additional audits of FIS due to issues related to the quality of the API or manufacturing conditions ("For Cause Audit"). FIS will not unreasonably withhold granting a For Cause Audit.

8.5 Each Party shall notify the other Party promptly of any serious or unexpected adverse reaction from the use of the Materials or Product, as set forth in the relevant Quality Agreement.

8.6 Acadia is ultimately responsible for all Recalls and other similar actions (e.g., field alerts, clinical withdraw). In the event either Party believes it may be necessary to conduct a Recall, or other similar actions, the Parties shall manage the Recall or other similar actions in accordance to the terms outlined in the Quality Agreement. For clarity, Acadia will have the sole right, in its discretion, to determine whether to conduct a Recall or other similar action, and shall notify FIS of any decision of Acadia to conduct a Recall or other similar action. Under no circumstances shall FIS be prohibited hereunder from taking any action that it is required to take by Applicable Law.

9. Representations and Warranties

9.1 Each Party represents and warrants to the other Party that (i) it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein; (ii) this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; (iii) it is not and will not become a party to any agreement, contract, arrangement or the like with any Third Party, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement, and (iv) is not and will not be under any obligation or restriction, including, without limitation, pursuant to its charter document(s) or by-laws, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement.

9.2 FIS warrants that the Products, if any, delivered to Acadia shall (i) be manufactured in accordance with applicable regulatory approvals for the Product, cGMP Regulations and all other Applicable Laws, (ii) conform to the Specifications of such Product then in effect at the time of manufacturing of the Product, (iii) not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug & Cosmetic Act, as amended from time to time, (iv) not contain any defect in material or workmanship or any cross-contamination that would have been discovered by reasonable inspection or by using the agreed-upon testing methods in accordance with the Master Batch Records, and (v) at the time of delivery, be free and clear of any lien or encumbrance.

9.3 Acadia represents and warrants that all quantities of Consigned Material, if any, delivered to FIS shall conform to the Specifications of such Consigned Material at the time of delivery.

9.4 Each Party represents and warrants to the other Party that it shall not employ, contract with, or retain any person directly or indirectly to perform any obligations under this Agreement if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA

pursuant to 21 U.S.C. § 335a or its successor provisions, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. In addition, each Party represents and warrants to the other Party that it has not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the term of this Agreement, a Party or any person employed or retained by such Party to perform under this Agreement (i) comes under investigation by the FDA for a debarment action or disqualification, (ii) is debarred or disqualified by the FDA, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions by the FDA, such party shall immediately notify the other Party of same.

9.5 EXCEPT AS STATED IN SECTION 9 OF THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, MATERIALS OR SERVICES AND DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10. Liability and Indemnity

10.1 If FIS is unable to meet the agreed time lines regarding the delivery of the Product or the rendering of the Services in accordance with the terms of this Agreement and applicable CSA Attachment, or in case the Service or the Product is rejected by Acadia in accordance with Section 2.9 or Section 3.9 of this Agreement (in which case, then this paragraph is subject to Section 2.10 and 3.10 of this Agreement, if applicable), FIS shall either (i) in the case of delay, deliver the delayed Product or render the delayed Services respectively, or (ii) in the case of rejection of the Services or Product, replace the rejected Services with Services that conform to the applicable CSA Attachment or replace the rejected Product with Product that conforms with the warranties in Section 9.2 as soon as possible, reasonably prioritizing the manufacture of Product over the manufacturing of product for other FIS customers until such supply problem has been cured, and in either case of clause (i) or (ii) hereabove at no additional cost to Acadia and FIS shall bear the full manufacturing cost of replacement of any Services or Product, including (a) the purchasing cost of Raw Materials and Consigned Materials and (b) the cost of destruction of any non-conforming Product, or (ii) if delivery of conforming Product or rendering of conforming Services is not possible within reasonable additional time, refund to Acadia within [***] Business Days all amounts theretofore paid by Acadia to FIS for such late or rejected Product or Services and costs of Consigned Materials. If FIS does not fulfill its delivery obligations with regard to Product for any reason other than Acadia's acts or omissions or a Force Majeure Event within [***] calendar days after the scheduled delivery date then, in addition to prioritizing the manufacture of Product over the manufacture of product for other FIS customers, FIS will reduce the price payable by Acadia to FIS for the Product as follows: the purchase price for the Product shall be reduced by [***] percent ([***]%) of the Firm PO price for each Business Day that the delivery is delayed from the expiry of the above [***] calendar day period; provided however, that any such price reduction shall not exceed [***] percent ([***]%) of the total purchase price in the Firm PO. The remedies set forth in this Section 10.1 will not prejudice any other rights or remedies available to either Party under this Agreement or by Applicable Law.

10.2 Acadia Indemnity: Acadia shall indemnify, defend and hold harmless FIS, its directors, officers, employees and agents, from and against liabilities, direct damages, losses, costs (including

reasonable attorneys' fees) and expenses (collectively, "**Damages**") resulting from claims, demands, assessments, investigations, suits, actions or legal proceedings (each a "**Claim**") brought by any Third Party (including, without limitation, directors, officers, employees or agents of Acadia) arising directly out of, or in direct connection with, (i) Acadia's use or sale of the Products, (ii) Acadia's performance of its obligations hereunder, (iii) processing Product using Acadia's Background Intellectual Property, (iv) the gross negligence, bad faith or wilful misconduct of Acadia (or any of its directors, officers, employees or agents), (iv) Acadia's material breach of any of the terms of this Agreement, or (v) Acadia's representations and warranties set forth in this Agreement being untrue in any material respect when made. Notwithstanding the foregoing, FIS and its directors, officers, employees, and agents shall not be entitled to indemnification under this paragraph against any Claim or from any Damages to the extent resulting from (a) the gross negligence, bad faith or wilful misconduct of FIS or any of its directors, officers, employees or agents (including subcontractors), (b) any accident (other than a Force Majeure Event) not chargeable to Acadia which may arise at FIS Facility in the course of FIS's performance of its obligations hereunder, or (c) the breach by FIS or its directors, officers, employees and agents (including subcontractors) of any of the material terms of this Agreement, including without limitation any of its representations, warranties or covenants hereunder.

10.3 FIS Indemnity: FIS shall indemnify, defend and hold harmless Acadia, its directors, officers, employees and agents, from and against Damages resulting from Claims brought by any Third Party (including, without limitation, directors, officers, employees or agents of FIS) arising directly out of or in direct connection with (i) FIS's performance of its Services and obligations hereunder, (ii) the gross negligence, bad faith or wilful misconduct of FIS (or any of its directors, officers, employees or agents, including subcontractors), (iii) processing of Product using FIS Background Intellectual Property, (iv) any accident (other than a Force Majeure Event) at FIS Facility, unless the accident is a result of the negligent actions of Acadia's representatives while on site at the FIS Facility, (v) FIS's representations and warranties set forth in this Agreement being untrue in any material respect when made, and (vi) the material breach by FIS of any of the terms of this Agreement, including without limitation any of its representations, warranties or covenants hereunder. Notwithstanding the foregoing, Acadia and its directors, officers, employees, and agents shall not be entitled to indemnification under this paragraph against any Claim or from any Damages to the extent resulting from (a) the gross negligence, bad faith or wilful misconduct of Acadia or any of its directors, officers, employees or agents, or (b) the breach by Acadia or its directors, officers, employees and agents of any of the material terms of this Agreement, including without limitation any of its representations, warranties or covenants hereunder.

10.4 Should a Party (including its directors, officers, employees or agents) (the "**Indemnitee**") be notified of any Claim in respect of which the other Party (the "**Indemnitor**") may be reasonably liable under the indemnification obligation provided for in this Section 10, the Indemnitee shall (i) give the Indemnitor prompt written notice thereof; and (ii) give the Indemnitor the opportunity to defend, negotiate, and settle (under the Indemnitor's sole control and at the latter's cost and expense) any such Claim. To such extent, the Indemnitee shall provide the Indemnitor with all information reasonably in its possession, and all reasonable authority and assistance necessary to enable Indemnitor to defend, negotiate, compromise or settle any such Claim. The Indemnitee shall further cooperate fully with the Indemnitor and its legal representatives (at the Indemnitor's sole cost and expense) in the investigation, negotiation, compromise, settlement and defense of such Claim. In any case, it is hereby understood that (i) the Indemnitee reserves the right to retain its own counsel

to defend itself (at its own cost and expense) in such Claim; and (ii) in no event shall either Party be responsible to or bound by any settlement made by the other Party without its prior written consent, which shall not be unreasonably withheld, unless the settlement provides for a full release of the Indemnitee, including no admission of fault and no financial or other obligations.

10.5 NOTWITHSTANDING ANY OTHER LANGUAGE HEREIN, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY RIGHTS OR OBLIGATIONS HEREUNDER, INCLUDING BUT NOT LIMITED TO CLAIMS BASED ON LOST PROFITS, LOSS OF TIME, LOSS OF OPPORTUNITY OR ANY OTHER ECONOMIC LOSS SUFFERED OR INCURRED AS A RESULT OF THIS AGREEMENT, WHETHER SUCH LOSS OR DAMAGE MAY BE BASED UPON PRINCIPLES OF CONTRACT, WARRANTY, NEGLIGENCE OR OTHER TORT, BREACH OF ANY STATUTORY DUTY, PRINCIPLES OF INDEMNITY OR CONTRIBUTION, THE FAILURE OF ANY LIMITED OR EXCLUSIVE REMEDY TO ACHIEVE ITS ESSENTIAL PURPOSE OR OTHERWISE; provided, however, that this Section 10.5 shall not be construed to limit either Party's indemnification obligations under Section 10 or liability for breach of Sections 7 (Intellectual Property) or 11 (Confidentiality).

10.6 Except for any liability arising from gross negligence, bad faith, or wilful misconduct, notwithstanding any other provision of this Agreement, FIS's total liability, in the aggregate, for any and all direct claims and losses occurring in a particular calendar year, including without limitation, attorneys' fees and costs of any nature whatsoever or expenses, resulting from this Agreement shall not exceed [***]. Notwithstanding the foregoing, (a) in no event shall this Section 10.6 apply to liability for breach of Section 11 (Confidentiality); and (b) with respect to FIS's indemnification obligations under Section 10, FIS's total liability, in the aggregate, for any and all claims and losses occurring in a particular calendar year shall not exceed [***].

10.7 FIS represents, warrants and covenants that it has and shall maintain in effect adequate commercial and general liability insurance coverage consistent with industry standards for a company performing the types of services FIS performs, provided such insurance shall include liability limits of not less than [***] million U.S. dollars ($[***]) in the aggregate per year. Such insurance shall be issued by duly licensed and financially sound companies that meet industry solvency requirements. If such insurance is written on a claims made basis, FIS shall maintain the described insurance coverage for not less than [***] years from the last commercial sale containing Product produced by FIS under this Agreement. Such insurance policy shall name Acadia as additional insured. Upon written request by Acadia, FIS shall as soon as reasonably possible provide written evidence (e.g., certificates) of such insurance.

10.8 Acadia has and shall maintain in effect adequate commercial and general liability insurance coverage to cover its obligations under this Agreement. Such insurance shall be issued by duly licensed and financially sound companies that meet industry solvency requirements. Upon written request by FIS, Acadia shall provide written evidence (e.g., certificates) of such insurance.

11. **Confidentiality**

11.1 Subject to the terms and conditions of this Agreement, "**Confidential Information**" shall mean all non-public, proprietary or confidential information, of whatever nature and in whatever form expressed, disclosed directly or indirectly by or on behalf of either Party (as the case may be, the "**Discloser**") to the other Party (as the case may be, the "**Recipient**") hereunder, on or after the Effective Date in connection with this Agreement or before the Effective Date in connection with the Master Services Agreement where that Confidential Information is being used in connection with this Agreement, which information includes without limitation any data, research, development, manufacturing, marketing, financial, personnel, and business information, including without limitation, any know-how, knowledge, techniques, methods, formula, expertise, trade secrets, or documents of any type or nature, tangible or intangible, as well as processes, operations, technologies, and forecasts disclosed, supplied, made available, or provided by the Discloser to the Recipient in connection with or relating to this Agreement or a CSA Attachment or a Firm PO. The Discloser shall use commercially reasonable efforts to mark Confidential Information disclosed in written, graphic or electronic form, as "confidential" or, if oral, reduce the Confidential Information to writing and mark it as confidential [***] days of the oral disclosure; provided, however, that if Discloser does not so mark or otherwise reduce Confidential Information to writing, such information shall continue to be deemed confidential if the Recipient knows or should reasonably know, from the context in which the information is disclosed or due to the nature of the type of information disclosed, that such information is confidential. With the exception of FIS's Background IP and the Vendor IP, if applicable, synthetic processes, reagents and Intermediates information for the preparation of each Product developed by FIS on behalf of Acadia hereunder shall be the Confidential Information of Acadia.

11.2 Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, for the term of this Agreement and any extension thereof and for [***] years thereafter, the Recipient (i) shall keep confidential any and all Confidential Information of the Discloser, (ii) shall limit access to the same to only those employees, directors, officers, consultants and agents (collectively, such Recipient's "**Representatives**") who, under the Recipient's direct control, will be engaged in fulfilling the Recipient's obligations under this Agreement and who are aware of the confidential nature of the information and bound in writing (including employment contracts or manuals) to Recipient, or bound by law and aware of such obligation under law, to keep such information confidential on terms no less restrictive than those contained herein, and (iii) shall not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement or in a CSA Attachment or in a Firm PO.

11.3 At no time shall Discloser's Confidential Information be employed or used by Recipient or its Representatives for any purpose other than as described herein or disclosed or provided to any Third Party, other than as provided for herein, without the prior written consent of the Discloser.

11.4 The foregoing obligations of confidentiality and non-use by the Recipient and its Representatives shall not apply to Confidential Information of the Discloser:

(i) which was known to the Recipient prior to this Agreement as evidenced by its written records (except Confidential Information of the Discloser which was known to the Recipient as a result of prior confidential disclosures to the Recipient by the Discloser or work performed by the Recipient for the Discloser and paid by the Discloser);

(ii) which is or becomes generally available to the public by use, publication or the like, through no fault of the Recipient or its Representatives, nor breach of this Agreement;

(iii) which is disclosed to the Recipient by a Third Party who has the legal right to disclose such Confidential Information of the Discloser; or

(iv) which is independently developed by the Recipient without reference to or any other use of any Confidential Information of the Discloser.

11.5 Subject to Section 11.7, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary to comply with Applicable Laws, requirements of any Regulatory Authority, or if compelled under an order of a court or other legal proceeding.

11.6 Each Party will protect the other Party's Confidential Information to the same extent that it protects its own confidential information of a similar nature, and in no event using less than a reasonable degree of care. Each Party will be responsible for any breach of the confidentiality and non-use obligations of this Agreement by its Representatives. In the event of any unauthorized disclosure or use, the Recipient shall promptly notify the Discloser in writing and use reasonable commercial efforts to remediate any damage resulting from such unauthorized disclosure or use.

11.7 Except as otherwise agreed to herein, if a Party is required by Applicable Law, court order or other legal proceeding to disclose any Confidential Information of the Discloser to a Regulatory Authority or to any other party, unless prohibited under Applicable Laws, such Party shall to the extent permitted under Applicable Laws immediately notify in writing to the other Party all details of the required disclosure in order to allow the other Party to intercede and/or oppose and/or limit and/or condition such disclosure prior to the making the same. In the event disclosure is compelled, Recipient shall disclose only the minimum Confidential Information required under Applicable Laws. All information disclosed under this Section shall continue to be deemed confidential for all other purposes.

11.8 Each of the Parties agrees and acknowledges that the breach of the confidentiality and non-use obligations provided in this Section 11 may not result in actual damages and that any remedy at law may be inadequate. Accordingly, each of the Parties further agrees and accepts that the Discloser, in addition to any other relief, may seek injunctive or other provisional relief to preserve its rights under this Agreement upon application to a court of competent jurisdiction.

11.9 Except as otherwise provided in this Section 11, each Party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other Party hereto, except that each Party may disclose the terms of this Agreement that are not otherwise made public as contemplated by this Section 11.9 and as permitted under Sections 11.4 and 11.7. Additionally, either Party shall have the right, if previously agreed in writing with the other Party, to issue press releases relating to future events occurring in connection with this Agreement subject to confidentiality obligations as set forth above. Each Party shall have the right to disclose the terms of this Agreement and any CSA Attachment as required by Applicable Laws including without limitation disclosure requirements of the U.S. Securities and Exchange Commission ("**SEC"**) or any stock exchange on which securities issued by either Party or its Affiliates are traded. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange on which securities issued by a Party or its

Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each Party will ultimately retain control over what information to disclose to the SEC or any stock exchange as the case may be.

11.10 Upon termination or expiration of this Agreement, each Party shall, upon the other Party's request, immediately deliver to the other (and cause any of its Representatives to so deliver), at such Party's expense, all Confidential Information of the other Party, including without limitation any and all copies, duplications, summaries and/or notes thereof or derived thereof, regardless of the format, and all remaining samples of Product that FIS supplies to Acadia or Materials, provided however, that both Parties may keep original documents, copies and samples to the extent such retention is required by any Applicable Laws or for archival purposes subject to a continuing obligation of confidentiality.

11.11 The Recipient shall not obtain, and shall not attempt to obtain, patent coverage or any other sort of proprietary right on the Confidential Information of the Discloser or on any invention, substance, or process that could not have been made but for knowledge of such Confidential Information. Neither Party shall be deemed by this Agreement to have granted to the other Party any right or license under any patent application, issued patent, know-how or other proprietary information of such Party except as expressly set forth herein.

12. **Term and Termination**

12.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated in accordance with this Agreement, shall continue in full force and effect for an initial period of three (3) years (the "**Initial Period**").

12.2 This Agreement shall automatically renew for consecutive two (2) year periods each, unless one of the Parties notifies the other of its election not to renew this Agreement either (a) at least twelve (12) months prior to the renewal date, or (b) if there remains open a binding period set for in a CSA Attachment, then notice to not renew must be at least sixty (60) days greater than the length of the binding period. If such a notice is timely provided prior to the end of the Initial Period or any renewal period then in effect, this Agreement shall terminate upon the expiration of such term.

12.3 Each Party may terminate this Agreement or any outstanding CSA Attachment (i) for material breach by the other Party, (ii) upon [***] calendar days written notice to the other Party specifying the nature of such material breach and (iii) if such breach has not been substantially cured within such [***] day period.

12.4 At any time in which no CSA Attachment remains outstanding, either Party may terminate this Agreement upon thirty (30) calendar days prior written notice to the other Party.

12.5 Acadia may, with or without cause, fully or partially cancel any CSA Attachment without terminating this Agreement, upon ninety (90) calendar days written notice to FIS, provided, that in such case, to the extent the relevant CSA Attachment does not set forth specific terms for amounts payable for cancellation of such CSA Attachment, Acadia shall,

(a) pay FIS for work actually performed up to such termination date, at the full rate applicable under the CSA Attachment;

(b) reimburse FIS the full value of any Products for which a Firm PO and/or Binding Part of a Rolling Forecast were delivered to FIS by or on behalf of Acadia in accordance with Section 3 of this Agreement or the applicable CSA Attachment.

(c) reimburse FIS for all costs incurred or irrevocably committed by FIS prior to the notification date; and

(d) reimburse FIS for the full out-of-pocket costs of any non-returnable auxiliary material (including, without limitation, Raw Materials and packaging material) purchased by FIS for manufacture and release of the Product that cannot be used for the manufacture of other products.

Acadia shall pay FIS's invoice for the aggregate amount payable under this Section 12.5 within [***] calendar days from Acadia's receipt of the invoice.

12.6 Either Party may terminate this Agreement immediately by providing written notice to the other Party:

(i) to the extent allowed by Applicable Laws, upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings by or against the other Party (and if such proceedings are by or against FIS, to the extent and as soon as legally practicable, FIS will provide written notice of such proceedings to Acadia after such filing or institution so that Acadia may take possession of its property, including Product, unless Applicable Laws at the Facility provide for additional legal requirements prior to Acadia taking possession); provided, however, that in the event of any involuntary bankruptcy or receivership proceeding, such right to terminate shall become effective in compliance with Applicable Laws; or

(ii) if the other Party ceases for any reason to carry on its business, or makes an assignment for the benefit of its creditors, or is the subject of any proposal for a voluntary arrangement.

12.7 Upon termination of this Agreement FIS will assist Acadia with regard to the transfer of all technology and information belonging to the latter and relating to (a) the Product, including the processing or manufacturing of the Product; (b) all information belonging to or acquired by Acadia under this Agreement; and (c) any relating documentation (collectively "Technology Transfer") at Acadia's cost, if such termination was caused by ACADIA. In the event termination is caused by FIS, FIS will bear the costs of such Technology Transfer. FIS will complete the Technology Transfer as soon as reasonably possible but no later than [***] Business Days after such expiration or termination, unless Acadia and FIS agree in good faith on different deadlines.

12.8 Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either Party prior to such expiration or termination. In the event of an expiration or termination of this Agreement, FIS shall promptly return to Acadia, at Acadia's expense and direction, any remaining inventory of Product(s), Consigned Materials and Safety Stock.

12.9 Neither the expiration nor the termination of this Agreement or any CSA Attachment, in whole or in part, shall relieve the Parties of their obligations incurred prior to such expiration or termination. All provisions that, by their express or implied terms, are meant to survive termination of this Agreement, in particular all rights and obligations set forth in this Section 12 (Term and Termination) and in Sections 1 (Definitions), 4 (Compensation and Terms of Payment), 7

(Intellectual Property), 9 (Representations and Warranties), 10 (Liability and Indemnity), 11 (Confidentiality) 13 (Miscellaneous) and 14 (Governing Law and Arbitration) shall continue irrespective of such termination.

13. **Miscellaneous**

13.1 *No set-off.* Neither Party shall be entitled to set off any of its rights or obligations under this Agreement against the rights or obligations of another Party without having first obtained the prior written consent (email consent is sufficient) of that other Party.

13.2 *Subcontractor.* FIS shall be entitled to engage any subcontractor for conducting any portion of the Services with the prior written consent of Acadia pursuant to Section 2.1. If a subcontractor is appointed, FIS shall be responsible for all work performed by such subcontractor as if performed by itself.

13.3 *Force Majeure.* Notwithstanding any other provisions herein, a Party shall be excused from performing its obligations under this Agreement (other than obligations of payment for Services actually rendered) to the extent that its performance is delayed or prevented by any cause beyond such Party's reasonable control, including, but not limited to fire, explosion, weather, disease, pandemic, war, terrorist act, insurrection, civil strike, riots, government action, force majeure affecting FIS suppliers (provided that reasonable evidence of the supplier force majeure is provided to Acadia), disruption in relevant transportation, power failure or energy shortages (each, a "**Force Majeure Event**"). Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event. Any deadline or time for performance specified in this Agreement that falls due during or subsequent to the occurrence of any of the Force Majeure Event shall be automatically extended for a period of time equal to the period of such Force Majeure Event. The prevented Party shall immediately notify the other Party if, by reason of any Force Majeure Event, the prevented Party is unable to meet any deadline or time for performance specified in this Agreement. In the event that such Force Majeure Event cannot be removed or overcome within [***] days (or such other period as the Parties jointly shall determine) from the date the Party affected first became affected, then either Party may at any time after the expiration of such period, by written notice to the other Party, either (i) suspend this Agreement for as long as such Force Majeure Event continues to exist, or (ii) terminate this Agreement with immediate effect and Section 12.5 (a), (c) and (d) shall apply and upon payment the title of materials transfers to Acadia.

13.4 *Precedence of Agreement*. Each CSA Attachment shall be subject to the terms and conditions of this Agreement. The terms and conditions outlined in this Agreement shall prevail over any terms and conditions outlined in any CSA Attachment, unless expressly provided to the contrary in an applicable CSA Attachment. Additionally, the terms and conditions outlined in this Agreement shall prevail over any terms and conditions outlined in a purchase order for Services or Product or any general terms and conditions of a Party, and such terms and conditions are hereby expressly excluded from this Agreement. In case of discrepancies between this Agreement and an Annex hereto, the provisions of this Agreement shall prevail.

In the event of inconsistencies between this Agreement and the Quality Agreement, the terms of the Quality Agreement shall control with respect to quality requirements and this Agreement shall control with respect to all other matters.

In the event of inconsistencies between this Agreement and the Master Services Agreement, the terms of the Master Services Agreement shall control with respect to services performed and/or products supplied thereunder and this Agreement shall control with respect to performance of Services or supply of Product contemplated by this Agreement or provided pursuant to any CSA Attachment hereunder.

13.5 *No assignment.* This Agreement, including the performance of any CSA Attachment, shall not be assigned by FIS, without the prior written consent of Acadia which consent shall not be unreasonably withheld. Acadia may assign this Agreement to its successors and assigns or to any Affiliate of Acadia. Any attempted assignment in violation hereof shall be void. Subject to the foregoing restrictions, this Agreement shall be binding on the Parties and their respective successors and permitted assigns.

13.6 *No waiver.* The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same.

13.7 *Independent Parties.* Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party shall have authority to speak for, represent or obligate the other Party in any way without prior written consent of the other Party.

13.8 *Entire Agreement.* This Agreement, together with the CSA Attachments and the Quality Agreement, contains the full understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto except as provided in the next sentence. Acadia and FIS agree that this Agreement does not supersede the Master Services Agreement or the related quality agreement, which shall remain in full force and effect. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by both Parties.

13.9 *Severability.* If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and this Agreement shall be construed as if such portion had not been included herein, provided however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith. The fact that any provision of this Agreement shall be prohibited or unenforceable in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by Applicable Law, the Parties to this Agreement waive any provision of law that renders any provision of this Agreement prohibited or unenforceable in any respect.

13.10 *Notices.* Any notice required under this Agreement shall be effective only if it is in writing and (i) delivered in person or (ii) deposited with a internationally recognized overnight courier service, or (iii) sent by registered mail or (iv) dispatched by e-mail (pdf), in which case if receipt of such notice is not confirmed by the recipient within two (2) Business Days, then the original sender shall confirm notice of delivery by the means outlined above in (i), (ii), or (iii) within five (5) Business Days; in either case any notice is to be addressed to the applicable address set forth below or any other address as designated by either Party.

if to FIS: F.I.S. Fabbrica Italiana Sintetici S.p.A.
Telephone:
Attn.:
Email:

if to Acadia:
Acadia Pharmaceuticals Inc.
Telephone:
Attn.:
Email:

Either Party may change the above addresses, but no such change shall have any effect until the other Party has been properly notified with written notice of the change of the address.

13.11 *Compliance with Laws*. Each Party shall comply with all Applicable Laws governing its performance of the terms of this Agreement, including, but not limited to, those relating to health, safety and the environment, fair labor practices, unlawful discrimination, debarment, anti-corruption and anti-bribery laws.

Each Party represents and warrants to the other Party that it has adopted a code of conduct/code of ethics and agrees and undertakes that during the continuance of this Agreement it shall comply with said code of conduct/code of ethics and shall refrain from engaging in any behaviors or relationships in violation of the principles and/or provisions contained therein.

13.12 *Counterparts*. This Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representatives, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. An electronic signature is the legally binding equivalent of a hand-written signature and shall have the same force and effect as an original signature. Signatures delivered by electronic means, and signed counterpart PDFs delivered by email shall have the same force and effect as original signatures.

14. Governing Law and Arbitration

14.1 This Agreement shall be governed and construed in accordance with the laws of Switzerland irrespective of its conflicts of laws principles.

14.2 Any and all disputes or controversies in way arising out of or in connection with, regarding or concerning or related to, this Agreement, including but not limited those concerning its validity, enforceability, interpretation and/or enforcement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") by [***] appointed by ICC in accordance with the said Rules. The arbitration shall be held in [***] and the arbitration shall be in the English language. The sole arbitrator shall decide the dispute in accordance with Switzerland substantive laws.

List of Annexes

Annex	**Description**

A	Sample CSA Attachment
B	Sample Change Order

[Signature Page Follows]

The undersigned are duly authorized representatives of their respective Party and hereby agree to the terms of this Agreement to be effective as of the Effective Date.

F.I.S. - Fabbrica Italiana Sintetici S.p.A.

By: /s/ Michele Gavino
Name: Michele Gavino
Title: CEO

Acadia Pharmaceuticals Inc.

By: /s/ Bob Mischler
Name: Bob Mischler
Title: SVP, Strategy and Technology Operations

ANNEX A – Sample CSA Attachment

CSA Attachment No. [#]

This CSA Attachment [#] (**CSA Attachment**), effective as of [DATE] (**CSA Effective Date**), is entered into between **[Entity]** (**FIS**) and **Acadia Pharmaceuticals Inc.** (**Acadia**) under the Commercial Supply Agreement dated …… between the parties (the **Agreement**). Pursuant to the Agreement, FIS has agreed to perform certain Services in accordance with written CSA Attachments, such as this one, entered into from time to time. Capitalized terms used in this CSA Attachment and not otherwise defined have the meanings given to them in the Agreement.

The Parties hereby agree as follows:

1. CSA Attachment

This document constitutes a **CSA Attachment** under the Agreement and this CSA Attachment and the Services contemplated herein are subject to the terms and provisions of the Agreement. Except if expressly modified in this CSA Attachment, the terms of the Agreement are hereby incorporated by reference herein.

2. Services, Product, and Materials

A. Services: [TBD]

B. Product: [TBD]

C. Consigned Material: [TBD]

D. Raw Materials: [TBD]

3. Commercial Terms

A Purchase requirements: [TBD]

B. Minimal order quantity: [TBD]

C. Sales price: The below sales price shall apply to each order placed by Acadia under this CSA Attachment.

Volume Range (kg)	Target (____/kg)	Consigned RM Value ($/kg)	Toll manufacturing unit price (____/kg)

D. Storage Fee: [TBD]

E. Price Adjustment: At either Party's request, FIS and Acadia will jointly review cost saving factors at the end of each calendar year, in relation to FIS's or Acadia's investments, and make in writing any necessary adjustments to the price with regard to the benefits coming from such cost savings. In principle, any cost saving arising out of any investment made by a Party shall be passed along to the Party responsible for cost savings.

F. In the event of any increase in the manufacturing cost of the Product, such as the cost to purchase Raw Materials, logistics, energy or utilities, the Parties shall, at the insistence of FIS, forthwith meet and negotiate in good faith to mutually agree in writing on a revision to the price consistent with the increases to the overall Product cost. FIS agrees to provide supporting information and documentation as reasonably requested by Acadia to evidence such increase in the cost to produce [Product]. Notwithstanding anything in this CSA Attachment to the contrary, FIS shall have the right to request negotiations as described in this paragraph no more than once per calendar year or twelve month period, whichever is later, during the term of this CSA Attachment. The Parties will both use commercially reasonable efforts to reach agreement on the revision to the price within sixty (60) days after receipt by Acadia of the request and all such information and documentation.

G. This CSA Attachment may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representatives, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. An electronic signature is the legally binding equivalent of a hand-written signature and shall have the same force and effect as an original signature. Signatures delivered by electronic means, and signed counterpart PDFs delivered by email shall have the same force and effect as original signatures.

H. Rolling Forecast: [TBD]

I. Cancellation Policy: [TBD]

J. Term: This CSA Attachment shall become effective on the CSA Effective Date and, unless earlier terminated in accordance with the Agreement, shall continue in full force and effect through [DATE] ("Initial Period"). [If there's an automatic renewal, add :After the Initial Period, this CSA Attachment shall automatically renew for [1 year or consecutive 2 year periods], unless one of the Parties notifies the other of its election not to renew this CSA Attachment at least [X] months prior to the end of the Initial Period or any renewal period then in effect, in which case this CSA Attachment shall terminate upon the expiration of such term. This CSA Attachment may be terminated earlier subject to and in accordance with the terms and conditions contained in the Agreement.

K. [Period for Latent Defects if other than 24 months from receipt per Section 3.9 of the Agreement.]

L. Miscellaneous. Should any technical issue arise which could not have been foreseen earlier and which should result in a time or cost increase, Acadia and FIS will negotiate and agree on a mutually acceptable resolutions to the issue. FIS declares to have put in place appropriate safety measures as dictated by

current health, safety and environmental regulations and laws and undertakes to scrupulously respect the terms and conditions as defined herein and any Firm PO, except in case the performance of these obligations or undertakings are hindered or prevented by a Force Majeure Event (as defined in the Agreement).

[Signature Page Follows]

The undersigned hereby agree to the terms of this CSA Attachment to be effective as of the CSA Effective Date.

FIS [Entity]

……. …….
Name / function Name / function

Acadia Pharmaceuticals Inc.

……. …….
Name / function Name / function

ANNEX B – Sample Change Order

CHANGE ORDER NO. [#]

This Change Order [#1] (**Change Order**), effective as of [DATE] (**Change Order Effective Date**), is made to the CSA Attachment No [#] dated [Date] (the "**CSA Attachment**"), between **[Entity]** (**FIS**) and **Acadia Pharmaceuticals Inc.** (**Acadia**) under the Commercial Supply Agreement dated …… (the **Agreement**).

The following changes are hereby made to the CSA Attachment (attach additional pages if necessary):

I. Change to Fees and Expenses

How will additional expense be billed? FORMCHECKBOX Time and Material Basis FORMCHECKBOX Lump Sum

CSA Attachment fee due to this Change Order will be increased/decreased by:

$_____

The new total CSA Attachment fee due to this Change Order will be:

$_____

II. Change to Timeline:

The timeline for performance will be increased/decreased by _____calendar days.

The date for completion of all work under this Change Order will be _____.

III. Except as expressly amended by this Change Order, the CSA Attachment shall remain in full force and effect. This Change Order may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the Parties or their representatives, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. An electronic signature is the legally binding equivalent of a hand-written signature and shall have the same force and effect as an original signature. Signatures delivered by electronic means, and signed counterpart PDFs delivered by email shall have the same force and effect as original signatures.

FIS [Entity]

……. …….
Name / function Name / function

Acadia Pharmaceuticals Inc.

……. …….
Name / function Name / function

Exhibit 10.37

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

PRODUCT AGREEMENT

Pursuant to the Master Manufacturing Services Agreement dated August 3, 2015 between **Patheon Pharmaceuticals Inc.**, and **Acadia Pharmaceuticals Inc.,** as amended January 1, 2022 (collectively the "**Master Agreement**"), this Product Agreement (this "**Product Agreement**" or "**PA"**) is effective as of May 1, 2022 (the "**Effective Date**"), and is entered into by Acadia Pharmaceuticals Inc., a Delaware corporation having its principal place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130 ("Acadia" or "Client"), and Patheon Pharmaceuticals Inc., having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237("Patheon") on behalf of itself and its Affiliates, as defined in Section 1.3 of the Master Agreement) within the Thermo Fisher Scientific Inc. Pharma Services Group. Patheon and Acadia may be collectively referred to as the parties and individually as a party.

The terms and conditions of the Master Agreement are incorporated herein and apply with full force and effect except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated herein and will be construed in accordance with the terms of this Product Agreement and the Master Agreement.

1. **Product and Specifications:** Tronfinetide Oral Solution ("Product" or "Tronfinetide") (See Schedule A attached hereto)
2. **Price** (See Schedule B attached hereto)
3. **Key Technical Parameters** (See Schedule C attached hereto) and **Active Materials- Source and Credit Value** (See Schedule D attached hereto)
4. **Technology Transfer Activities and Equipment Requirements:** See the parties' Technology Transfer Services Agreement C-WRC-121145-R5 effective February 6, 2020 and any amendments thereto. Any equipment requirements will be discussed, evaluated, and agreed upon in writing by the parties.
5. **Territory**: [***]
6. **Manufacturing Site**: Patheon Whitby Canada 111 Consumers Drive Whitby, Ontario L1N 5Z5
7. **Governing Law**: Per Section 13.16 of the Master Agreement
8. **Currency**: USD.
9. **Initial Product Term:** From the Effective Date through May 1, 2027
10. **Commercial Launch Date:** February 2023
11. **Notices**: Per Section 13.9 of the Master Agreement

12. Other Modifications to the Master Agreement are listed below by reference to the Master Agreement Section number:

a. **Section 2.1** of the Master Agreement shall be modified for the purposes of this Product Agreement to add language as follows: "The Annual Minimum requirement stated in **Section 2.1** of the Master Agreement shall not apply to the Product Agreement for Trofinetide. Client will allocate to Patheon to manufacture an Annual Minimum of at least [***]% of the projected Product to be manufactured for sale by Client in the Territory in a particular Year. Schedule B, attached hereto and incorporated by reference, shall set forth Patheon's Annual Volume and the costs.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

PATHEON PHARMACEUTICALS INC.

By: /s/ Bobbi Ellis_____

Name: __Bobbi Ellis_____

Title: Senior Director & General Manager_

ACADIA PHARMACEUTICALS INC.

By: /s/ Bob Mischler_____

Name: Bob Mischler

Title: SVP, Strategy and Technology Operations

SCHEDULE A

PRODUCT and SPECIFICATIONS

Product

Trofinetide Oral Solution ("Product").

- Indication: Treatment of the core symptoms of Rett syndrome by reducing neuroinflammation and supporting synaptic function.
- Patheon's preliminary categorisation: Category 2

Table 1. Key Product parameter overview

Product	Strength	Solid Form	Packaging Configuration
Trofinetide Oral Solution	200mg/ml	Oral Solution	[***]

Specifications

Prior to the start of commercial manufacturing of the Product under this Agreement, Acadia will provide Product Specifications.

SCHEDULE B

ANNUAL VOLUME AND PRICE

Annual Volume Forecasts

Projected Annual Volume forecast are outlined in the tables below.

[***]

1. Pricing Tables

[***]

2. Costs Included in Price

[***]**3. Costs Not Included in Price-** The parties may desire to include any of the following costs at a later time by agreement in writing or by amendment to this PA.

[***]**SCHEDULE C**

KEY TECHNICAL PARAMETERS

The following technical parameters apply to the production of Trofinetide Oral Solution and the materials used therein. Pricing may be adjusted upon mutual written agreement to reflect any technical changes foreseen during the Technology Transfer project or after the manufacture of validation batches to reflect any Specification or process changes.

1. **Manufacturing Parameters**

[***]

2. Packaging Parameters

[***]3. Testing Conditions

- Testing for raw materials, packaging components, and finished product are based on information provided by Acadia and Patheon's best estimates.
- It is assumed that QC test methods are fully validated and robust at the time of manufacture.
- The analytical testing included in this PA are listed in the table below:
- [***]Microbiological testing has been included.
- Testing labour may be subject to change after the final agreements on testing Specifications and requirements.

Supply Chain

- Patheon will procure Components for the manufacture of Trofinetide Oral Solution from Patheon qualified suppliers. Should Acadia require Patheon to source any materials from specified suppliers, then these suppliers will remain under the quality audit control of Acadia unless an agreement is reached for Patheon to take on this responsibility.
- Components will be supplied by Patheon in accordance with the Specifications agreed. Patheon will issue formal Patheon specifications for each Component.
- Each lot of incoming Components will be sampled and tested according to the agreed Specifications.
- The API will be provided free issue/released to Patheon by Acadia or its qualified supplier.
- The API and all excipients used for the manufacture will be GMP grade and from TSE/BSE certified sources.
- Shipping INCOTERMS: Exworks – from Patheon's Whitby facility for finished Product in accordance with Section 5.4 of the Master Agreement

SCHEDULE D

ACTIVE MATERIALS

Active Materials	Supplier
Trofinetide and Trofinetide Trihydrate	• FIS, Italy • Corden, Italy

ACTIVE MATERIALS CREDIT VALUE

The Active Materials Credit Value will be as follows:

PRODUCT	ACTIVE MATERIALS	ACTIVE MATERIALS CREDIT VALUE
Trofinetide Oral Solution, 450ml 200mg/ml	Trofinetide	Client's actual cost for Active Materials not to exceed $[***]per kilogram

MAXIMUM CREDIT VALUE

Patheon's liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement for Product in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

PRODUCT	MAXIMUM CREDIT VALUE
Trofinetide Oral Solution, 450ml 200mg/ml	[***]

Subject to Section 13.3 of the Master Agreement, Patheon shall in good faith explore with its internal business units its standard business policies for obtaining and/or assisting Client in obtaining supplemental insurance to insure for potential lost batches and other events causing Product loss. Notwithstanding the foregoing, nothing in this paragraph creates any obligation of Patheon to purchase any supplemental insurance to insure for Client's Product.

Exhibit 10.38

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

COMMERCIAL SUPPLY AGREEMENT

This Commercial Supply Agreement is made as of this 1st day of March, 2023 (the "**Effective Date**"), by and between ACADIA Pharmaceuticals Inc., a Delaware corporation, with a place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130 ("**Client**"), and CoreRx Inc, a Florida corporation, having a place of business at 14205 Myerlake Circle, Clearwater, FL 33760 ("**CoreRx**" or "**Supplier**"). Client and CoreRx may individually be referred to as a "**party"** and collectively as the "**parties.**"

RECITALS

A. Client develops, markets, and sells pharmaceutical products and is the licensor of proprietary Product;

B. CoreRx has the requisite infrastructure, licenses, permits, and capabilities, including trained and experienced personnel and technical skills, for the development, manufacture and supply the Products (as defined herein) to Client for the purposes stated herein pursuant to the terms and conditions of this Agreement;

C. Client desires that CoreRx perform certain services related to the processing, manufacture, and supply of the Product pursuant to the Specifications and the terms and conditions of this Agreement, and Supplier confirms being able to properly perform such activities.

THEREFORE, in consideration of the circumstances described above and the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3(B).

1.2 "**Adverse Event**" shall mean any adverse event associated with the use of any Product in humans, whether or not considered drug-related, including an adverse event occurring in the course of the use of a Product in professional practice, in studies, in investigations or in tests or an adverse event occurring from Product overdose (whether accidental or intentional), from Product abuse, or from Product withdrawal, as well as any toxicity, sensitivity, failure of expected pharmacological action, or laboratory abnormality that is, or is thought by the reporter to be, serious or associated with relevant clinical signs or symptoms.

1.3 "**Affiliate(s)**" means, in the case of Client, any third party, any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with such entity. For the purposes of this definition, "**control**" means the ownership of at least 50% of the voting share capital of an entity or any other comparable equity or ownership interest. In the case of CoreRx, the term "Affiliates" means any subsidiary or sister company of CoreRx, and shall not

include CoreRx's parent or any portfolio companies or holding companies managed by CoreRx's parent company.

1.4 "**Agreement**" as referred to herein means this document, including all its attachments and other Appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.5 "**API**" means the compound Trofinetide as further described in the Specifications listed in Attachment A .

1.6 "**Applicable Laws**" means, all treaties, laws, ordinances, statutes, rules, regulations, or orders in the Territory (s) in which the given activities will be performed and which are applicable to the performance of the services and to the obligations of the parties, as the context requires, under this Agreement, and regulations promulgated thereunder, cGMP, and the FD&C Act.

1.7 "**Batch**" means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.8 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and CoreRx respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended. If the any manufacturing will occur outside of the U.S. or Canada, the parties will amend this Agreement and reference applicable laws and quality standards and/or agreements.

1.9 "**Claims**" means all third party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, reasonable legal costs and other reasonable expenses of any nature whatsoever.

1.10 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.11 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.12 "**Client Inventions**" has the meaning set forth in Article 11.

1.13 "**Client IP**" has the meaning set forth in Article 11.

1.14 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to CoreRx as described in Attachment A for the purposes of providing services pursuant to this Agreement. Such materials are limited to API and reference standards unless otherwise agreed in writing by the parties.

1.15 "**Commencement Date**" means the first date upon which a Regulatory Authority in the Territory approves CoreRx as a manufacturer of Product.

1.16 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by either Party with respect to any requirement and/or objective as stated herein, [***].

1.17 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.18 "**Contract Year**" means the consecutive [***] period beginning on the Commencement Date or any anniversary of the Commencement Date during the Term, as applicable.

1.19 "**CoreRx**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.20 "**CoreRx Cause**" has the meaning set forth in Section 5.2.

1.21 "**CoreRx Indemnitees**" has the meaning set forth in Section 13.2.

1.22 "**CoreRx Inventions**" has the meaning set forth in Article 11.

1.23 "**CoreRx IP**" has the meaning set forth in Article 11.

1.24 "**Defective Product**" has the meaning set forth in Section 5.2.

1.25 "**Discloser**" has the meaning set forth in Section 10.1.

1.26 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.27 "**EMA**" means the European Medicines Agency, and any successor agency in the European Union.

1.28 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.29 "**Facility**" means CoreRx's facility located at [***] including all buildings at this address per FDA registration number or such other facility as agreed by the parties in writing.

1.30 "**FD&C Act**" shall mean the United States Federal Food, Drug and Cosmetic Act and regulations promulgated thereunder, as each may be amended from time to time.

1.31 "**FDA**" means the United States Food and Drug Administration, and any successor agency in the United States.

1.32 "**Firm Commitment**" has the meaning set forth in Section 4.1.

1.33 "**Intellectual Property**" means all intellectual property (whether or not patented or patentable) including without limitation inventions, patents, patent applications, know-how, trade secrets, improvements, copyrights, trademarks, designs, concepts, technical information, analytical methods, procedures, techniques, software, manuals, standard operating procedures, instructions, specifications, processes, and data.

1.34 "**Invention**" has the meaning set forth in Section 11.1.

1.35 "**Inventory Report**" has the meaning set forth in Section 3.4.

1.36 "**Latent Defect**" means a defect in a Product that (a) could not reasonably be discovered by visual inspection of its outer packaging and/or any accompanying documentation upon reasonable inspection during the Review Period, and (b) Client provides CoreRx written notice of such defect within no more than [***] months after delivery of such Product.

1.37 "**Losses**" means collectively, any and all claims, liabilities, losses, costs, awards, fines, penalties, expenses, obligations, liens, assessments (including reasonable attorney's fees, court fees and other reasonable professional expenses) and damages of any nature whatsoever reasonably foreseeable and unavoidable, imposed upon or incurred by an Indemnified Party; however, always excluding any loss of profit or anticipated profit, loss of revenue and loss of goodwill or reputation.

1.38 **"Manufacture"** or "**Manufacturing**" means, as applicable, any and all operations, including without limitation receipt of API, Product and/or materials, Processing, testing, quality control, releasing, storing, sample retention, serialization, labelling, and packaging for shipment, carried out by or on behalf of Supplier in accordance with the Specifications and the preparation and supply of the Product(s) pursuant to this Agreement and the Quality Agreement.

1.39 "**Minimum Commitment**" has the meaning set forth in Section 4.1.

1.40 "**PPI**" has the meaning set forth in Section 7.2.

1.41 "**Process**" or "**Processing**" means the compounding, filling, and producing of Client-supplied Materials and Raw Materials into Product by CoreRx, in accordance with the Specifications and under the terms of this Agreement.

1.42 "**Product**" means the pharmaceutical product containing the API, as more specifically described in the Specifications.

1.43 "**Purchase Order**" has the meaning set forth in Section 4.3(A).

1.44 "**Quality Agreement**" has the meaning set forth in Section 9.6.

1.45 "**Raw Materials**" means all raw materials, supplies, components and packaging necessary to Process and ship Product in accordance with the Specifications, but excluding Client-supplied Materials.

1.46 "**Recall**" has the meaning set forth in Section 9.5.

1.47 "**Recipient**" has the meaning set forth in Section 10.1.

1.48 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.49 "**Regulatory Authority**" means an international, federal, state or local governmental or regulatory body, agency, department, bureau, court or other entity in the Territory that is responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. In the United States, this includes the FDA; and in the European Union, this includes the EMA.

1.50 "**Representatives**" of an entity means such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.51 "**Review Period**" has the meaning set forth in Section 5.2.

1.52 "**Rolling Forecast**" has the meaning set forth in Section 4.2.

1.53 "**Safety Stock**" has the meaning set forth in Section 3.2(A).

1.54 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment A, as modified from time to time in accordance with Article 8.

1.55 "**Term**" has the meaning set forth in Section 16.1.

1.56 "**Territory**" means [***].

1.57 "**Unit**" means a single bottle.

1.58 "**United States**" means the United States of America and its territories and possessions.

1.59 "**Unit Pricing**" has the meaning set forth in Section 7.1(B).

1.60 "**Validation Services**" has the meaning set forth in Section 2.1.

1.61 "**Vendor**" has the meaning set forth in Section 3.2(B).

ARTICLE 2
VALIDATION, MANUFACTURING, SUPPLY OF PRODUCT, & RELATED SERVICES

2.1 Validation Services. CoreRx shall perform the Product qualification, testing, validation services, and other related services (the "**Validation Services**") pursuant to a Quality Agreement and in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement. Validation Services will be mutually agreed to by the parties and set forth in an attachment that is incorporated through an amendment to this Agreement.

2.2 Manufacturing and Supply of Product. CoreRx shall Manufacture Product in accordance with the Specifications, Applicable Laws, and the terms and conditions of this Agreement, including, but not limited to, Article 4 (Purchase Orders & Forecast) and Article 6 (Delivery).

2.3 Other Related Services. CoreRx shall provide Product-related services, other than the Validation Services, Manufacturing, and related services stated herein as agreed in writing by the

parties from time to time. Such writing shall include the scope and fees for any such service(s) and shall be set forth in an attachment that is incorporated through an amendment to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services unless otherwise agreed in writing by the parties.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to CoreRx for Manufacturing, at Client's cost, Client-supplied Materials in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than [***] days (but not earlier than [***] days) before the scheduled delivery date. Client shall be responsible at its expense for securing any necessary DEA, export, import or other governmental clearance, permit or certification required in respect of such supply of Client-supplied Materials. CoreRx shall use Client-supplied Materials solely for the purposes of providing services pursuant to this Agreement and/or a related written agreement. CoreRx will use all Client-supplied Materials on a first-in first-out (FIFO) basis in Manufacturing Products under this Agreement, unless specified by Client prior to Manufacturing. Prior to delivery of any Client-supplied Materials, Client shall provide to CoreRx a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the Client-supplied Materials, and thereafter shall provide promptly any update thereto. Client will provide safety and potency ratings for Client- supplied API and CoreRx assumes the materials have been assigned a level 3 (or lower) SafeBridge or equivalent safety rating. Rating shall be provided by SafeBridge or an equivalent certified consultant.

B. CoreRx shall inspect and test all Client-supplied Materials received to verify their identity (identity is a test with a specific method number), or a qualified third-party lab managed by CoreRx will be required to perform full release testing on Client-supplied Materials. In the event that CoreRx detects a nonconformity in the Client-supplied Materials with the Specifications, CoreRx shall give Client prompt, written notice of such nonconformity. CoreRx shall not be liable for any nonconformity in Client-supplied Materials, or in Product as a result of nonconforming Client-supplied Materials, unless CoreRx did not perform the obligations stated in this Section 3.1(B) in accordance with the Specifications. CoreRx shall follow Client's reasonable written instructions regarding the return or disposal of non-conforming Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss of any such Client-supplied Materials. Subject to Section 9.5, CoreRx shall permit Client to have escorted access to Facility and/or any premises where Client-supplied Materials are stored in order to inspect and/or repossess Client-supplied Materials. CoreRx shall immediately inform Client of any loss or damage to Client-supplied Materials and promptly provide in writing all explanations and evidence.

Upon termination or expiration of this Agreement, CoreRx shall, upon Client's direction and expense, either: (i) deliver all unused Client-supplied Materials provided by Client within th[***] days after termination, or (ii) dispose of the Client-supplied Materials. If Client does not request the return or disposal of Client-supplied Material within [***] days of the Agreement's termination, then CoreRx will provide written notice to Client of any such unused Client-supplied Materials and shall return the Client-supplied Material to Client, at Client's cost, without any further liability or obligation to Client.

3.2 Raw Materials.

A. CoreRx shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the parties in writing, and, without limiting the foregoing, shall order and hold sufficient Raw Materials as may be agreed in writing by the parties in an attachment that is incorporated through an amendment to this Agreement. Due to potential issues with the availability of certain Raw Materials, CoreRx shall purchase Client-specified Raw Materials in advance of the Firm Commitment Period ("**Safety Stock**") if requested in writing by Client. CoreRx will invoice for those Raw Materials purchased as requested by Client outside of the Firm Commitment. In the event that Client does not issue Purchase Orders requesting sufficient Product to meet the Firm Commitment during any Firm Commitment Period (on a rolling basis) and any Raw Materials expire or require retesting, such Raw Materials shall be replaced or retested as Client directs at Client's sole cost and expense, including charges for disposal of the expired Raw Materials when applicable, without any liability to CoreRx.

B. If Client requires a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material, then such Vendor will be identified in Attachment A, "Specifications" or as otherwise identified in writing by Client in an amendment to this Agreement.

C. CoreRx shall store the Raw Materials and packaging materials at room temperature, unless stated otherwise. Client will be charged [***] for any materials stored outside of the Firm Commitment Period.

3.3Packaging, Artwork and Labeling. CoreRx will package the Products as set out in the Specifications and the applicable master packaging records approved in writing by Client. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Manufacturing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content and compliance with all Applicable Laws in connection thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by CoreRx in any manner other than performing its obligations hereunder without Client's written consent. CoreRx will imprint the Batch numbers and expiration dates for each Product shipped. The expiration dates must be determined in accordance with the Specifications. The Batch numbers and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and the Quality Agreement (QAG), cGMPs and Applicable Laws. Client may make changes to the content on labels, product inserts, cartons, and other packaging for the Products by submitting a Change Control to CoreRx, and upon CoreRx's receipt, CoreRx shall make and implement such changes. Those

changes will be submitted by Client to all applicable Regulatory Authorities. Any other Client requested changes to the labels, product inserts, cartons, and other packaging for the Products that impact the physical characteristics of the Product will require a risk assessment prior to implementing the changes.

3.4 API Yield.

A. CoreRx will give Client a quarterly inventory report of the API held by CoreRx ("**Inventory Report**") within [***] business days of the end of the most recent [***]-month period in a Contract Year which contains the following information for such period: (a) quantity of API conforming to Specifications that is received at the Facility ("**Quantity Received**"), (b) quantity of API dispensed in Manufacturing Product at the Facility calculated by adding the Quantity Received to the inventory of API that complies with the Specifications and is held by CoreRx at the beginning of the applicable period, less the inventory of API that complies with the Specifications and is held by CoreRx at the end of the period ("**Quantity Dispensed**"), and (c) the total amount of API contained in the Product manufactured with the Quantity Dispensed delivered by CoreRx and not rejected, recalled or returned due to CoreRx Cause as defined below ("**Quantity Converted**").

B. Within [***] days after the end of each Contract Year, CoreRx will prepare an annual reconciliation of API that sets out the "Actual Annual Yield" or "AAY" for the Product at the Facility during the Contract Year. AAY is the percentage of the Quantity Dispensed that was converted to Product and is calculated as follows: Quantity Converted in Contract Year/Quantity Dispensed during Contract Year * 100. The parties agree that the target AAY will be determined as follows:

i. Initial Target Yield - will be the actual yield of the initial pre-validation and validation batches of Product that is Processed for Client and calculated as follows: Quantity Converted in the initial pre-validation and validation batches /Quantity Dispensed in the initial pre-validation and validation batches * 100 (the "**Initial Target Yield**"). The Initial Target Yield will be in effect until there is enough campaign experience to calculate an Adjusted Target Yield as defined below.

ii. Adjusted Target Yield - will be the actual average yield of the initial ten commercial batches of Product that is Processed for Client and calculated as follows: average Quantity Converted in the first [***] post validation batches /average Quantity Dispensed in the first [***]post validation [***] batches * 100 (the "**Adjusted Target Yield**").

iii. Without limiting Client's other rights or remedies, if AAY falls more than [***] below the Adjusted Target Yield in a Contract Year in which Client

Processes as least [***] batches of Product for Client, then within [***] days after the end of the applicable Contract Year, CoreRx will credit to Client's account the amount of the shortfall, calculated as follows: [(Initial or Adjusted Target Yield – [***]%) – AAY] * API cost * Quantity Dispensed.

ARTICLE 4
FORECAST & PURCHASE ORDERS

4.1 Forecast. On or before the [***] day of each calendar month, beginning at least [***] months prior to the anticipated Commencement Date, Client shall furnish to CoreRx a written [***] month rolling forecast for the quantities of Product that Client intends to order from CoreRx during such [***] month period (the "**Rolling Forecast**"). The first [***] months of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast (the "**Firm Commitment**" and with each applicable [***]-month period, the "**Firm Commitment Period**"). The following [***] months of the Rolling Forecast shall be non-binding, good-faith estimates. Client shall purchase and CoreRx shall supply to Client all quantities of Product set forth in the Firm Commitment in accordance with this Agreement. Provided that CoreRx can confirm and assure Product supply pursuant to the Firm Commitment, as provided for by Section 4.2(C), then during the first [***] calendar years of the Term, Client shall purchase a minimum of [***] percent of the total annual volume of Product from CoreRx ("**Minimum Commitment**") during each of the [***] calendar years.

4.2 Purchase Orders.

A. Concurrently with the start of each Firm Commitment Period, Client will provide a Purchase Order that shall specify the number of Product Batches to be Processed, the Batch size (#) and the requested delivery date for each Batch (each, a "**Purchase Order**"). Purchase Orders for quantities of Product in excess of the Firm Commitment, per the Rolling Forecast, shall also be submitted by Client concurrently with the start of each Firm Commitment Period.

B. Promptly (and in any event within [***] business days) following receipt of a Purchase Order, CoreRx shall issue a written acknowledgement (each, an "**Acknowledgement**") of such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, as agreed in writing in advance with Client. CoreRx may only reject a Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement. If CoreRx fails to send an Acknowledgement to Client within the applicable [***] business day period, then the amount set forth in the Purchase Order will be deemed to have been accepted by CoreRx.

C. Notwithstanding Section 4.2(B), CoreRx shall accept Purchase Orders for quantities specified in the Firm Commitment, and make Commercially Reasonable Efforts to supply Client with quantities of Product set forth in a Purchase Order which are up to [***] (rounded up to the nearest whole Batch) in excess of the quantities specified in the Firm

Commitment subject to CoreRx's other supply commitments and manufacturing, packaging, and equipment capacity.

D. If CoreRx rejects a Purchase Order for Product that is included in a Firm Commitment submitted in accordance with this Agreement, then without limiting Client's other rights and remedies hereunder, Client may obtain the Product set forth in such Purchase Order from another supplier, and the relevant Minimum Commitment will be reduced by [***]. If CoreRx during a single calendar year rejects [***] or more Purchase Orders for Product that is specified in a Firm Commitment, then the Minimum Commitment for such calendar year will no longer apply.

E. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.3 Client's Cancellation of Purchase Orders.

Client may cancel any Purchase Order. If Client cancels any Purchase Order(s), a cancellation fee shall be assessed as follows:

i. Between [***] and [***] from Purchase Order delivery date – [***] of Purchase Order value;

ii. Less than [***] from Purchase Order delivery date – [***] of Purchase Order value.

4.4 Unplanned Delay of Manufacturing. CoreRx shall provide Client with as much advance notice as practicable prior to the scheduled date of Manufacturing if CoreRx determines that any Manufacturing will be delayed for any reason.

4.5 Observation of Manufacturing. In addition to Client's audit right pursuant to Section 9.4, Client may send up to [***] representatives to the Facility to observe Manufacturing upon at least [***] days prior notice, at reasonable times during regular business hours. Such representatives shall abide by all CoreRx safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance.

ARTICLE 5
TESTING; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties in writing, after CoreRx completes Manufacturing of a Batch, CoreRx shall provide Client with copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, CoreRx shall provide such Batch records promptly based on QAG out-of-Specification result. After CoreRx completes Manufacturing of a Batch, CoreRx shall also provide Client with CoreRx's certificate of analysis for such Batch. CoreRx and Acadia will release and disposition the batch per details specified in the QAG. For the avoidance of doubt, CoreRx may use third party testing Client- approved facilities to satisfy its obligations hereunder. Client shall be responsible for final release of Product (including testing, at its cost) to the market.

5.2 Testing; Rejection. No later than [***] business days after Client's receipt of the Batch and the certificate of analysis ("**Review Period**"), Client shall notify CoreRx whether the Batch

conforms to the Specifications and meets cGMP (for purposes of this Article 5, "conformity/conform(s) to Specifications"); provided, however, that in the case of Latent Defects in the Batch such Review Period shall be no later [***] months after delivery of the Product. Upon receipt of notice from Client that a Batch conforms to the Specifications, or upon failure of Client to provide any written notice to CoreRx by the end of the Review Period the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch. If Client notifies CoreRx in writing by the end of the Review Period (an "**Exception Notice**") that a Batch does not conform to the Specifications ("**Defective Product**"), and provides a sample of the alleged Defective Product, then CoreRx shall promptly conduct an appropriate investigation pursuant to reasonable industry standards to determine whether CoreRx agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. CoreRx shall provide written notice to Client as promptly as reasonably possible, but in any event within [***] business days after completing its internal investigation, and in any event no later than [***] days after date of the Exception Notice, whether CoreRx agrees that Product is Defective Product ("**Response Period**"). If CoreRx agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to CoreRx's negligence or willful misconduct (a "**CoreRx Cause**"), or if CoreRx fails to respond within the Response Period, then Section 5.4 shall apply.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is a CoreRx Cause, and such disagreement is not resolved within [***] days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed to by CoreRx and Client in writing, the costs associated with such testing and review shall be borne by the party against whom the third party rules. The outside third party shall be required to enter into written undertakings of confidentiality no less stringent than those set forth herein. CoreRx shall furnish the outside third party such instructions regarding the storage, handling, and potential hazards of any samples of such Batch of Product as are provided to or developed by CoreRx for or on behalf of Client, as applicable.

5.4 Remedy for Defective Product. CoreRx shall, at the option of Client, either (A) replace such Defective Product, at CoreRx's cost with Product that conforms to the Specifications, or (B) if such replacement cannot be accomplished within [***] days from the later of (i) the date of Client's request or (ii) the date that Client-supplied Materials are made available to Process such replacement Product (if there are not sufficient amounts already available to CoreRx), credit any payment made by Client for such Defective Product..

5.5 Supply of Client-Supplied Material for Defective Product. In the event CoreRx replaces Defective Product pursuant to Section 5.4, Client shall supply CoreRx with sufficient quantities of Client-supplied Materials in order for CoreRx to complete such replacement.

5.6 Client and CoreRx agree that the parties will have proportionate liability to the extent that a Defective Product is due to any action or inaction on the part of (i) CoreRx, its Affiliate(s) and/or any third-party under CoreRx's control or contract, and (ii) Client, any Affiliate of Client, or any third party under contract with or subject to the control or direction of Client.

ARTICLE 6
DELIVERY

6.1 Delivery. In accordance with Section 4.2(B), Supplier will deliver Product that is included in a Firm Commitment, to which Supplier issued an Acknowledgment in response to a Purchase Order, and an agreed on excess of the Firm Commitment, on the applicable delivery date that is set forth in such Acknowledgment. The Parties agree that they will work together in good faith to expedite deliveries of Product as needed, including, without limitation, any samples of Product and Product for initial launch, and manage the scheduling of the initial Product launch.

CoreRx shall deliver Product ExWorks (Incoterms 2020) the Facility promptly following CoreRx's release of Product and in accordance with Acknowledgments made in accordance with Section 4.2(B). CoreRx shall segregate and store all Product until tender of delivery. To the extent not already held by Client, title to Product shall transfer to Client upon CoreRx's tender of delivery. If CoreRx provides storage services, title to such items shall pass to Client upon transfer to storage. Client shall be responsible for coordinating the use of a qualified carrier to ship Product. In the event CoreRx arranges shipping or performs similar loading and/or logistics services for Client at Client's request, such services are performed by CoreRx as a convenience to Client only and do not alter the terms and limitations set forth in this Section 6.1. CoreRx shall not be responsible for Product in transit, including any cost of insurance or transport fee for Product, or any risk associated with transit or customs delays, storage and handling.

6.2 Storage Fees. CoreRx shall store the API and Product at 2°C to 8°C, unless stated otherwise. Client will be charged [***] for any materials stored outside of the Firm Commitment Period for the API. Client will be charged [***] for any Product not shipped to Client designate site if the Product remains in storage at CoreRx for more than [***] days after the certificate of analysis has been provided to Client, excluding initial launch quantities.

Assuming Client pays for the buildout of the cold storage space, storage charges will not begin until [***] years from the Effective Date. If Client does not build out the cold storage space, charges for storage will begin following execution of this Agreement. If Client fails to take delivery of any Product on any scheduled delivery date, CoreRx shall store such Product and have the right to invoice Client monthly following such scheduled delivery for reasonable administration and storage fees.

6.3 **Late Delivery**.

A. If in a single calendar year Supplier fails [***] or more of the time to meet the delivery dates set forth in Acknowledgments to Purchase Orders for Product that is included in a Firm Commitment, then the Minimum Commitment for the next calendar year shall be suspended without prejudice to any other rights and remedies that Client may have under this Agreement.

B. Without prejudice to the Client's rights and Supplier's obligations under this Agreement, in the event that Supplier is unable to deliver Product set forth in a Purchase Order by the delivery date set forth in the Acknowledgment, regardless of whether Product or samples of Product, Supplier shall notify Client as soon as possible and the Parties will work together in good faith to agree upon a mutually acceptable resolution. If Product set forth in a Purchase Order is not received by Client within [***] days from the delivery date set forth in the applicable Acknowledgment, except where Supplier can reasonably demonstrate that (i) the delay is not due to its fault (e.g. unavailability of Materials), or (ii) include batches not released due to an investigation that are ultimately released within [***] days of scheduled delivery, then Client shall have the right to a discount for such late delivery as follows:

- Greater than [***] days late delivery [***]: [***] discount on the late delivered Product.

The foregoing discount amount will be deducted by Client from any amounts invoiced to Client related to the relevant late-delivered Product. The rights and remedies contained in this Section 6.3 are non-exclusive and without prejudice to Client's right to terminate this Agreement pursuant to Article 16 or any other remedy under this Agreement; provided, however, the above late delivery penalty shall be deducted from any claim of Client for damages arising from late delivery by Supplier of a Product under a Firm Commitment.

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for CoreRx performing services hereunder:

A. Client shall pay to CoreRx the fees for Validation Services (including cost of validation Batches) set forth in an attachment that is incorporated through an amendment to this Agreement. Payment shall become due to CoreRx within [***] after CoreRx submits an invoice to Client for Validation Services.

B. Client shall pay CoreRx the unit pricing for Product set forth on Attachment B (the "**Unit Pricing**"). Client shall pay the Unit Pricing that is in effect on the date of delivery pursuant to Section 6.1. Payment shall become due to CoreRx within [***] days after CoreRx submits an invoice to Client for Product.

C. Client shall pay CoreRx the annual fees for Annual Product Review as set forth in Section 9.3. Payment shall become due to CoreRx within [***] days after the Commencement Date and thereafter, upon the [***] day of each Contract Year.

D. Other Fees. Client shall pay CoreRx for all other fees and expenses of CoreRx owing in accordance with the terms of this Agreement, including pursuant to Sections 4.1, 6.2 and 16.3, within [***] days after CoreRx submits an invoice to Client.

7.2 Unit Pricing Increase. The Unit Pricing may be adjusted on an annual basis according to a change in the PPI as described herein, effective on [***] of each year after the Effective Date beginning on March 1st, 2024, for Product in Purchase Orders placed on or after March 1st, upon [***] days prior written notice from CoreRx to Client before March 1st of each calendar year during the Term. In no event shall the amount of the adjustment for Products in any year exceed

an amount equal to the change in the Producer Price Index ("**PPI**"), [***], not seasonally adjusted, as published by the U.S. Department of Labor, Bureau of Labor Statistics, over the most recent [***]period preceding such adjustment date for which the PPI is available. In addition, price increases or decreases for Raw Materials (including those Raw Materials referenced in Section 3.2(B)) shall be passed through to Client at the time of such price increase or decrease through an adjustment to the Unit Pricing.

7.3 Payment Terms, Disputes, Late Payments. Payment of all undisputed portions of CoreRx invoices shall be due [***] days after the date of receipt of invoice. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. An invoice is considered disputed, if Client provides written notice to CoreRx of an issue around a Purchase Order or a Product. In the event Client disputes an invoice or a portion thereof, Client shall, in good faith, (1) submit a written notice to CoreRx within [***] business days of receiving the invoice from CoreRx specifying the disputed amount and the basis for the dispute in reasonable detail; and (2) timely pay all undisputed portions of the amount due and payable. Any invoices that are not disputed within [***] business days after receipt are deemed correct by Client.

7.4 Late Payment. If Client is late or delinquent in payment of any portion of an invoice that it has not disputed in good faith, CoreRx may, in addition to other remedies it may have in law or equity, charge late fees on late or delinquent amounts at the rate of [***]% per month (or, if lower, the maximum amount permitted by law) for so long as an undisputed payment is overdue. If CoreRx takes any legal action to collect any undisputed delinquent amounts, Client shall reimburse CoreRx for costs incurred in pursuing such action, including, but not limited to, legal fees and court costs.

7.5 Taxes. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of Client-supplied Materials, services or Product prior to or upon provision or sale pursuant to this Agreement, as the case may be, whether assessed on CoreRx or Client, are the responsibility of Client, and either Client shall reimburse CoreRx for all such taxes, duties or other amounts paid by CoreRx or such sums will be added to invoices directed at Client. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to CoreRx such greater sum as will leave CoreRx, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.6 Client and Third-Party Expenses. Client shall be responsible for [***] of its own and all Client-approved third-party expenses associated with development, Regulatory Approval, and market commercialization of Product, including regulatory filings and post-approval marketing studies. If CoreRx uses a third-party for any activities not included under this Agreement and Client previously approved in writing of such third party expense(s), CoreRx shall invoice Client for the charges (to include a markup of [***] for the pass-through charges).

7.7 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Manufacturing has been validated.

Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless CoreRx was grossly negligent or failed to comply with Applicable Laws in the Manufacturing of the out-of-Specification Batch. CoreRx and Client shall cooperate in good faith to resolve any problem causing the out-of-Specification Batch. For clarity, when a validation Batch is ultimately used for commercial purposes, such Batch shall no longer be considered a development batch.

ARTICLE 8
CHANGES TO SPECIFICATIONS

All Specifications, and any change to the Specifications agreed by the parties from time to time, shall be in writing, dated and signed by the parties. No change in the Specifications shall be implemented by CoreRx, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing) and any Regulatory Approvals required by Applicable Laws have been obtained (a "Change Control"). CoreRx shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use Commercially Reasonable Efforts and good-faith efforts to agree to the terms of such change in a timely manner. As soon as practicable after a request is made for any change in Specifications, CoreRx shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with agreed changes to the Specifications. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. CoreRx reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the Change Control.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. CoreRx shall maintain materially complete and accurate Batch, laboratory data and other technical records relating to Manufacturing in accordance with CoreRx standard operating procedures. Such information shall be maintained for a period of at least [***] years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. CoreRx shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which CoreRx Processes Product. Client will have the sole right and responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the manufacture, import, export, distribution, marketing, sale, pricing and/or reimbursement of the Products. Client shall not identify CoreRx in any NDA application or other such initial regulatory filing or submission without CoreRx's prior written consent. Such consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both parties. Upon written request, Client shall provide CoreRx with a copy of each Regulatory Approval required to distribute, market or sell Product in the Territory. During the Term, CoreRx will assist Client with all regulatory matters relating to Manufacturing, at Client's request and expense. The parties shall

cooperate to allow each party to satisfy their respective obligations under Applicable Laws relating to Manufacturing under this Agreement.

9.3 Annual Product Review. CoreRx shall provide services as required to support annual product review of the Product (the "**APR**") during the Term and all times after the Term while the Product remains on stability or CoreRx is otherwise required to support the APR. See Article 7, Section 7.1c regarding payment terms, and Attachment B for APR related fees.

9.4 Government/Regulatory Inspections and Requests. CoreRx shall notify Client in writing of all Regulatory Authority inspections related to Product that take place at the Facility where Product is Manufactured, including any facilities where cGMP operations are performed by CoreRx on behalf of Client, or the testing laboratory where any of the associated testing is performed. Client shall be notified in advance of any scheduled inspections that may impact Client's Product or testing. For unannounced inspections, CoreRx shall notify Client in a reasonable timeframe but not more than [***] hours after the inspection has begun. Client shall have the option to be present or have a representative of Client present during a regulatory inspection related to Product. If during the inspection, a request to collect a sample of Product or records from CoreRx is made, CoreRx shall immediately (and in any event within [***] hours) contact Client and ensure a duplicate sample is collected and retained. In all cases, a written notification of the results of the inspection shall be provided to Client. Such notification shall include: (a)written notification of any observation, if any, related to the Manufacture of the Product (b) where possible, CoreRx shall provide the actual documentation of such observations; provided that such Documentation may be redacted of information that does not relate, directly or indirectly, to Client or Product, or the Facility at which Product is Manufactured (c) written notification of all Product-related corrective actions and planned completion dates. Any written response to inspectional observations related to the Product shall be submitted to Client prior to submission of the response to any Regulatory Authority and CoreRx will consider Client's comments and amendments unless these are inconsistent with regulatory requirements or CoreRx's obligations under the Applicable Law. Client shall be consulted correspondingly in the development and approval of any corrective action plan related to Product.

9.5 Client Facility and Financial Audits.

A. Facility Audit. CoreRx shall permit Client personnel and representative(s) to (and shall ensure that Client personnel and representative(s) shall be entitled to): (a) to inspect, observe, and audit the Processing, including the Manufacturing of Product, the Facility, and other locations at which Product is Processed and/or Manufactured, (b) to examine the condition of the Raw Materials and Product stored at the Facility, and (c) to examine all results and all other documentation related to this Agreement, including maintenance logs for the purposes of ensuring compliance with cGMP. Subject to any agreed procedures in the Quality Agreement, Client shall also be entitled to conduct audits following issuance of Form 483 or similar reports delivered by Regulatory Authorities to CoreRx pertaining to the Manufacturing of Product or the occurrence of other events which are likely to materially and adversely affect the Manufacturing of Product upon reasonable notice, during CoreRx's regular business hours for reasonable duration (which may not exceed [***] business days) until CoreRx has corrected such deficiencies. CoreRx shall have no obligation to disclose third-party Confidential Information in connection with any audit.

B. Financial Audit. During the Term of this Agreement, Client shall be entitled to conduct financial audits limited to the Purchase Orders and invoices for Product provided under this Agreement. Client shall provide reasonable advance written notice to CoreRx of its intent to audit, and any such financial audit shall be conducted no more than once per calendar year unless otherwise agreed to by the parties in writing. The financial audit shall be conducted at CoreRx's Facility and during CoreRx's regular business hours. Client shall give CoreRx reasonable advance written notice specifying the scope of the audit, which shall not include POs, invoices, and any other information that has previously undergone a prior Client financial audit under this Section. CoreRx shall have no obligation to disclose third-party Confidential Information in connection with any audit.

9.6 Recall. If a Regulatory Authority orders or requires the recall of Product supplied pursuant to this Agreement or if either CoreRx or Client believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly within [***] business day notify the other party in writing, or provide such notice as otherwise stated in the Quality Agreement as applicable. CoreRx shall not initiate a Recall without the express prior written approval of Client, unless required by Applicable Laws. With respect to any Recall, CoreRx shall provide all necessary cooperation and assistance to Client. If such Recall was due to Client's acts or omission, Client shall reimburse CoreRx at a reasonably agreed upon in writing rate for CoreRx's time and assistance. Client shall provide CoreRx with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, such copy being provided no less than [***] business days prior to submission to a Regulatory Authority. Client shall consider in good faith any comments from CoreRx relating to such submission. The cost of any Recall shall be borne by Client, and Client shall reimburse CoreRx for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by CoreRx's breach of Product warranties in Section 12.2 under this Agreement, in which case CoreRx shall reimburse Client for the reasonable, actual and documented out-of-pocket costs (*e.g.*, printed materials, postage, cost of shipment of return product) incurred by Client for such Recall not to exceed the cost of replacing Product returned to CoreRx pursuant to such Recall.

9.7 Quality Agreement. Within [***] month after the Effective Date, and in any event prior to the first Manufacturing of Product under this Agreement, the parties shall negotiate in good faith and enter into a quality agreement (the "**Quality Agreement**"). The Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth in that agreement. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to any commercial matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.8 Adverse Events; Product Complaints. Client shall be responsible for all reporting to regulatory authorities of Adverse Events associated with the use of any Product supplied by CoreRx hereunder. If CoreRx becomes aware of any Adverse Events associated with the use of such Products, it shall report all information in its possession regarding such event to Client as

soon as practicable but no later than [***] business [***] days after becoming aware of such information, and shall cooperate with Client as necessary to report such event to regulatory authorities.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of CoreRx or Client (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (as the case may be, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other Intellectual Property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement, and each party shall be considered the Discloser and the Recipient with respect thereto.

10.2 Exclusions. Notwithstanding anything in Section 10.1 to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient or its Affiliate at the time of disclosure as evidenced by Recipient's written records, (C) becomes available to Recipient or its Affiliate on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for Recipient or its Affiliate without reference to Discloser's Confidential Information as evidenced by Recipient's written records.

10.3 Mutual Obligation. Recipient (A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement and (C) will not disclose to any third party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (1) need to know such Confidential Information for the purpose of performing obligations or exercising rights under this Agreement, (2) are advised of the contents of this Article and (3) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. Notwithstanding Section 10.3, a party may disclose the Confidential Information of the other party only to the extent such disclosure is reasonably necessary: to comply with Applicable Laws, requirements of any Regulatory Authority or other regulatory agency, or court order. Prior to making any disclosures, however, the Recipient shall give reasonable advance written notice to the Discloser with as much detail as possible in relation to the disclosure. Each party shall cooperate fully and in a timely manner with the other party with respect to all disclosures permitted by this Section, including determining what information should be released and requests for confidential treatment of Confidential Information of either party included in any such disclosure; provided that in no event shall a party be required to delay any filing or release unreasonably hereunder.

10.5 Disclosure of this Agreement. Except for disclosures expressly permitted under this Agreement, no party may release any information to any third party regarding the existence of and/or the terms of this Agreement without the prior written consent of the other party. This provision, however, shall not apply to any disclosures regarding this Agreement or related information to regulatory agencies (such as Regulatory Authorities, Federal Trade Commission, Department of Justice) that may be required by law, including requests for a copy of this Agreement or related information by tax authorities; provided that in making such disclosure, the party shall comply with this Article in all respects. Notwithstanding the foregoing, the terms of this Agreement may be disclosed to current or prospective acquirors of, investors in, lenders to or licensees or collaborators of a party or to professional advisors (e.g., attorneys, accountants, and consultants) under appropriate conditions of confidentiality.

10.6 No Implied License. Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information, the parties agree that monetary damages would not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a party shall be entitled to specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

10.8 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within [***] days either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy of such information, except for a single copy, which may be retained under a continuing obligation of confidentiality for the sole purpose of ensuring compliance with its obligations under this Agreement. Notwithstanding the foregoing, nothing in this Agreement shall require the Receiving Party to return or destroy any Confidential Information contained in computer back-up copies retained for security purposes.

10.9 Survival. The obligations of this Article will terminate [***] years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 As used in this Agreement, "**Client IP**" means all Intellectual Property and related embodiments owned by or licensed to Client as of the Effective Date or developed by Client other than in connection with this Agreement; "**CoreRx IP**" means all Intellectual Property and related embodiments owned by or licensed to CoreRx as of the Effective Date or developed by CoreRx other than in connection with this Agreement. **"Invention"** means any Intellectual Property developed by either party or jointly by the parties in connection with this Agreement. Client IP is the Confidential Information of Client, and CoreRx IP is the Confidential Information of CoreRx.

11.2 All Inventions, ideas, discoveries, developments, methods, data, information, improvements, and biological or chemical materials, (whether or not reduced to practice and whether or not it can be protected under state, federal or foreign patent ,copyright, trade secrecy or similar laws) generated or derived by Client or CoreRx whether alone or together in the course or performing the services pursuant to this Agreement which are related directly to Client's Product, Client IP, or Client Confidential Information shall be the exclusive property of Client (**"Client Arising IP"**). Client hereby grants to CoreRx a non-exclusive, non-assignable, paid-up, royalty-free, non-transferable license to use Client Arising IP solely for the performance of the services pursuant to this Agreement. Client Arising IP is the Confidential Information of Client.

11.3 All Inventions, ideas, discoveries, developments, methods, data, information, improvements, and biological or chemical materials, (whether or not reduced to practice and whether or not it can be protected under state, federal or foreign patent, copyright, trade secrecy or similar laws) generated or derived by Client or CoreRx whether alone or together in the course or performing the services pursuant to this Agreement which are not Client Arising IP, that relates directly to CoreRx IP or CoreRx Confidential Information, or relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing drug products other than the Product, shall be the exclusive property of CoreRx (**"CoreRx Arising IP"**). CoreRx Arising IP is the Confidential Information of CoreRx. CoreRx hereby grants to Client a non-exclusive, non-assignable, paid-up, royalty-free, non- transferable license, with the right to sublicense, to use the CoreRx Arising IP solely to the extent necessary to use for the performance of the services hereunder and as far as necessary for the further development, manufacture, and distribution of the Product.

11.4 Each party shall promptly and fully disclose, in writing, to the other any and all Arising IP respectively. Each party hereby assigns and agrees to assign to the other all applicable right, title and interest in and to any such Arising IP. Each party agrees to cooperate fully in obtaining patent, copyright or other proprietary protection for such Arising IP, all in the name of the applicable party and at such applicable party's cost and expense, and shall execute and deliver all requested applications, assignments and other documents, and take such other measures as reasonably requested in order to perfect and enforce rights in such Arising IP.

11.5 Each party will cause its employees or contractors who perform activities pursuant to this Agreement to enter into agreements that protect the other party's Intellectual Property and Confidential Information and enable compliance with this Article 11.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties. Each party hereby represents and warrants to the other party that:

(a) it is a corporation duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation; and

(b) the execution, delivery and performance of this Agreement by such party has been duly authorized by all requisite corporate action; and

(c) it has full corporate authority to enter into this Agreement and the Agreement is binding upon it in accordance with its terms; and

(d) no transaction or dealing under this Agreement shall be conducted with or for an individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States; and

(e) it shall comply with all Applicable Laws that affects its performance and activities under this Agreement.

12.2 Client's Representations and Warranties. Client hereby represents and warrants that:

(a) no specific safe handling instructions are applicable to any Client-supplied materials, except as disclosed in advance of delivery to CoreRx in writing by the Client as stated in Section 3.1; and

(b) to the best of its knowledge, as of the Effective Date, Client has the title and/or right to any and all Client IP and all Client Confidential Information (including for the avoidance of doubt the manufacturing process) provided to Supplier in accordance with this Agreement for the Processing and Manufacture of the Product(s), and further that it has the title and/or right to grant Supplier the right to use such Intellectual Property in accordance with the terms of this Agreement and the use by Supplier or its Affiliates of Client IP and Arising Client IP will not infringe the Intellectual Property or any other rights of any third party; and

(c) as of the Effective Date, Client has the right to grant Supplier any license(s) stipulated under this Agreement, and will notify Supplier if at any time during the term of this Agreement that Client no longer has the right to grant such licenses; and

12.3 CoreRx's Representations and Warranties. CoreRx hereby represents and warrants that:

(a) At the time of delivery by CoreRx, the Product(s), if and to the extent it is required to be Manufactured under cGMP conditions and a validated manufacturing process, (i) will conform to Specifications; (ii) has been Manufactured, stored, transported, tested, labelled, and packaged in accordance with Applicable Laws including cGMP and any applicable environmental or biohazard laws in the country where the Manufacturing by Supplier takes place; (iii) will not be adulterated within the meaning of Section 501 (a)(2)(B) of the U.S. Food, Drug and Cosmetic Act or similar provisions of any Applicable Laws in the country where the Manufacturing by Supplier takes place; and (iv) Supplier will convey to Client good title to the Product(s), free and clear of any security interests, lien or encumbrances;

(b) It has the title and/or right to any and all CoreRx IP used in connection with providing services pursuant to this Agreement including but not limited to Manufacturing the Product(s) in accordance with this Agreement at the Effective Date. As of the Effective Date, and to Supplier's knowledge, there are no third-party claims against Supplier or its Affiliates asserting that CoreRx IP and CoreRx's Confidential Information to be used in the performance of the services and/or Manufacturing infringe the Intellectual Property of any third party. Supplier will promptly notify Client in writing should it become aware of any claims asserting such infringement in the performance of services pursuant to this Agreement; and

(c) As of the Effective Date neither Supplier nor any of its employees performing services under this Agreement has been debarred, nor is subject to a pending debarment. Neither Supplier nor any of its employees will knowingly use in any capacity in connection with the services and/or Manufacturing under this Agreement any person, who has been debarred pursuant to Section 306 of the FDCA. 21 U.S.C. § 335a, or who is the subject of a conviction described in such Section. Supplier agrees to notify Client in writing immediately if it comes to its knowledge that Supplier or any person who is performing services and/or Manufacturing under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FDCA or if any action, suit, claim, investigation, or proceeding is pending, or to Supplier' s knowledge, is threatened, relating to the debarment or conviction of Supplier or any person performing services and/or Manufacturing under this Agreement.

12.4 Compliance with Customs and Foreign Trade Laws. Supplier will comply with appropriate and applicable Customs and Foreign Trade laws, regulations, guidelines and standards. Upon request of Client, Supplier shall provide Client with a declaration as to its compliance with this term as requested by Client.

12.5 Change in Control or Name of Business Entity. Supplier will provide prompt written notice to Client in the event of any change in control and/or name of its business entity including without limitation, a change(s) resulting from a merger and/or acquisition.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by CoreRx. CoreRx shall defend, indemnify and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (collectively "**Client**

Indemnitees") harmless against any and all Losses and Claims to the extent arising out of: (i) any breach of the representations, warranties or obligations of CoreRx set forth in this Agreement by CoreRx or its Affiliates; (ii) any negligence or willful misconduct of CoreRx or its Affiliates; (iii) any alleged or actual infringement or misappropriation of third party intellectual property rights with respect to Supplier's Manufacturing process(es) in each case except to the extent that any such Claim(s) or Losses arise out of, relate to or result from: (A) any breach of representations, warranties or obligations of Client set forth in this Agreement by Client or its Affiliates; (B) any negligence or willful misconduct of Client or its Affiliates; or (C) any Claim or Loss otherwise not covered by the indemnity in Art 13.2 below.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless CoreRx, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**CoreRx Indemnitees**"), from and against any and all Losses and Claims arising out of, relating to or resulting from: (i) any breach of representations, warranties or obligations of Client set forth in this Agreement by Client or its Affiliates, (ii) any manufacture (other than by CoreRx), packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, or (iii) any negligence or willful misconduct by Client or any of its Affiliates; in each case except to the extent of any Claim(s) or Losses arise out of, relate to or result from: (A) any negligence or willful misconduct by CoreRx or its Affiliates; (B) any breach of the representations, warranties or obligations of CoreRx as set forth in this Agreement by CoreRx or its Affiliates; or (C) any Claim or Loss otherwise not covered by the indemnity in Art 13.1.

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, *however*, that failure to provide such notice within a reasonable period shall not relieve the indemnifying party of its obligations under this Article 13 except to the extent, if any, the indemnifying party is materially prejudiced by such failure, (B) allowing the indemnifying party to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), *provided*, that the indemnifying party shall promptly provide and continuously maintain such defense, (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party. In any case, it is hereby understood that (i) the Indemnitee reserves the right to retain its own counsel to defend itself (at its own cost and expense) for such Losses and/or Claims; and (ii) in no event shall either party be responsible to or bound by any settlement made by the other party without its prior written consent, which shall not be unreasonably withheld, unless the settlement provides for a full release of the Indemnitee, including no admission of fault and no financial or other obligations.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 Lost Batches or Lost, Damaged or Destroyed Client-Supplied Material Limitation

EXCEPT FORCLAIMS ARISING OUT OF CORERX'S GROSS NEGLIGENCE, FRAUD, OR WILLFUL MISCONDUCT, CORERX'S MAXIMUM LIABILITY TO

CLIENT FOR ANY CLAIM FOR CLIENT-SUPPLIED MATERIAL THAT IS LOST, DAMAGED, OR DESTROYED EITHER (I) DUE TO THE FAULT OR NEGLIGENCE OF CORERX WHILE IN CORERX'S CONTROL OR POSSESSION, OR (II) AS A RESULT OF CORERX AND/OR CORERX DEFECTIVE MANUFACTURING DURING THE MANUFACTURING OF ANY GIVEN BATCH OF PRODUCT, CORERX'S LIABILITY FOR ANY SUCH LOST, DAMAGED, OR DESTROYED CLIENT-SUPPLIED MATERIALS SHALL BE BASED UPON:

(A) FOR THE API, THE COST OF [***] FOR THE AMOUNT OF API LOST, DAMAGED, OR DESTROYED, OR

(B) FOR OTHER CLIENT-SUPPLIED MATERIALS, THE [***] FOR THE AMOUNT OF CLIENT-SUPLIED MATERIALS LOST, DAMAGED, OR DESTROYED;

PROVIDED, HOWEVER, THAT CORERX'S LIABILITY FOR SUCH API OR OTHER CLIENT-SUPPLIED MATERIALS SHALL NOT EXCEED THE COST OF THE APPLICABLE BATCH OR BATCHES OF PRODUCT.

14.2 Limitation of Liability not related to 14.1. EXCEPT IN THE EVENT OF (I) THE GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT OF CORERX, ITS AFFILIATES, AND PERSONNEL, (II) CORERX'S WILLFUL BREACH OF THIS AGREEMENT, OR (III) A BREACH BY CORERX OF ARTICLE 10 AND/OR ARTICLE 11, CORERX'S AGGREGATE LIABILITY TO CLIENT, AND ANYONE CLAIMING BY OR THROUGH CLIENT, AS APPLICABLE UNDER THIS AGREEMENT FOR THE [***] PERIOD IMMEDIATELY FOLLOWING THE EFFECTIVE DATE, AND FOR ANY [***] PERIOD THEREAFTER DURING THE TERM, SHALL NOT EXCEED, ON A CUMULATIVE BASIS, THE AMOUNT THAT IS [***] TIMES THE AGGREGATE AMOUNTS PAID OR PAYABLE BY CLIENT TO SUPPLIER PURSUANT TO THIS AGREEMENT IN THE PRECEDING [***] PERIOD PRECEDING THE LOSS DATE BUT SOLELY WITH RESPECT TO THE SUPPLY HEREUNDER OF THE BATCH(ES) PRODUCT FOR WHICH SUCH CORRESPONDING LIABILITY AROSE (THE "**AFFECTED PRODUCTS**") AND NOT ANY OTHER PRODUCTS.

14.2.1 FOR CLARITY IF, AS OF THE TIME THE LIABILITY ARISES, THIS AGREEMENT HAS NOT BEEN IN EFFECT FOR [***], THEN THE AMOUNTS PAID OR PAYABLE BY CLIENT TO SUPPLIER HEREUNDER DURING THE PERIOD FROM THE EFFECTIVE DATE UNTIL SUCH TIME THE LIABILITY ARISES, SHALL BE ANNUALIZED TO A FULL [***] BUT SOLELY WITH RESPECT TO THE SUPPLY HEREUNDER OF THE AFFECTED PRODUCT(S) AND NOT ANY OTHER PRODUCTS.

14.3 Consequential Damages. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT TO THE CONTRARY, EXCEPT FOR DAMAGES OR CLAIMS ARISING OUT OF (I) A PARTY'S BREACH OF ARTICLE 10 OR ARTICLE 11 OF THIS AGREEMENT, (II) A PARTY'S OR ITS PERSONNEL'S GROSS

NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, OR (III) A PARTY'S WILLFUL BREACH OF THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL DAMAGES, SPECIAL DAMAGES, INCIDENTAL OR INDIRECT DAMAGES, LOSS OF REVENUE OR PROFITS, DIMINUTION IN VALUE, WHETHER OR NOT FORESEEABLE, OR WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, OF ANY KIND HOWEVER CAUSED, WHETHER BASED ON CONTRACT, NEGLIGENCE, OR OTHER THEORY OF LAW, ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF) OR ANY PURCHASE ORDER, AS APPLICABLE.

ARTICLE 15
INSURANCE

CoreRx shall, at its own cost and expense, obtain and maintain in full force and effect, at all times during the term of this Agreement the following insurance for not less than any limits of liability specified herein or as required by Applicable Law, whichever is greater. All insurance carriers shall have a minimum of "A-" A.M. Best rating. Supplier shall have the right to provide the total limits required by any combination of self-insurance, primary and umbrella/excess coverage during the Term of this Agreement and any and all related agreement(s) and/or Purchase Orders made pursuant to this Agreement and for a period of [***] years thereafter; said insurance to include the following:

(i) Products, Operations, Completed Operations, and Professional Liability Insurance- [***] aggregate per annum
(ii) Commercial General Liability, including Personal Injury and Property Damage covering Supplier's own operations arising out of or connecting to this Agreement - [***] aggregate.

(iii) Umbrella Liability -[***]aggregate

(iv) Workers' Compensation as required by any applicable law or regulation and in accordance with the provisions of the laws of the nation, state, territory or province having jurisdiction over CoreRx's employees.
(v) Employment Practices liability insurance with a limit of not less than [***].

Where allowed by Applicable Law, Client and its Affiliates shall be provided a waiver of subrogation, except for losses due to the sole negligence of Supplier.

All of the above listed insurance shall be issued by duly licensed and financially sound companies that meet industry solvency requirements. If such insurance is written on a claims made basis, CoreRx shall maintain the described insurance coverage for not less than [***] years after destruction of all of the last Batch of Product Manufactured under this Agreement. Such insurance policy shall include Client and their respective affiliates, and their respective directors, officers, employees, agents, and representatives, as additional insureds. The certificate of insurance shall state that all coverages provided by CoreRx shall be primary to any insurance carried by such additional insureds for their own account. Upon written request from the Client, CoreRx shall as

soon as reasonably possible provide a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. CoreRx will further provide Client a minimum of [***] days written notice of a cancellation of, or material change in, the above-referenced insurance. In such case, CoreRx and Client shall engage in good faith negotiations in order to amend this Article to provide adequate insurance and assurances to comply with this Article.

During the Term of this Agreement and for [***] years thereafter, Client shall obtain and maintain at its own cost and expense from a qualified insurance company, comprehensive general liability insurance including, but not limited to product liability coverage, in the amount of at least [***]USD per claim. Client shall provide CoreRx with a certificate of such insurance upon reasonable request.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the end of the fifth (5th) Contract Year, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive two (2)-year periods unless and until one party gives the other party at least eighteen (18) months prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within [***] days, or takes any equivalent or similar action in consequence of debt in any jurisdiction;

B. By either party if the other party materially breaches this Agreement and such breach is not cured within [***] days after the giving of written notice requiring the breach to be remedied; or

C. by Client (i) upon [***] days' prior written notice to CoreRx in the event a Regulatory Authority takes an enforcement or other regulatory action against the Facility which affects CoreRx's ability to Process the Product, or (ii) upon [***] days' prior written notice if any Regulatory Authority takes any action or raises any objection that prevents Client from manufacturing, importing, exporting, purchasing or selling Product, or (iii) if Client otherwise does not obtain Regulatory Approval of Product in the United States or (iv) upon [***] days' prior written notice if Client determines not to launch Product or to discontinue commercialization of Product, in the United States due to safety or efficacy reasons.

16.3 Effect of Expiration or Termination. Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either party prior to such expiration or termination. In the event of an expiration or termination of this Agreement:

A. CoreRx shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding undisputed invoices have been paid in full;

B. Client shall pay CoreRx all invoiced amounts outstanding hereunder unless disputed in good faith. Client shall also pay, upon receipt of invoice therefor and pursuant to the terms of this Agreement, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed or Manufactured pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product being Processed or Manufactured pursuant to Purchase Orders (or, alternatively, Client may instruct CoreRx to complete such work in process, and the resulting completed Product shall be governed by clause (ii)); and

C. in the event that this Agreement is terminated for any reason, Client shall pay CoreRx for all costs and expenses incurred, and all noncancellable commitments made, in connection with CoreRx's performance of this Agreement, so long as such costs, expenses or commitments were made by CoreRx consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.4 Survival. Expiration or termination of this Agreement shall not relieve the parties of any obligation or right accruing prior to such expiration or termination. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.3 (Payment Terms), 7.5 (Taxes), 7.6 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.6 (Recall), 16.3 (Effect of Termination), and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (C) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (D) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client: ACADIA Pharmaceuticals Inc.
Attn:
E-Mail:

Facsimile:

With a copy to: ACADIA Pharmaceuticals Inc.
Attn:
E-Mail:
Facsimile:

To CoreRx: CoreRx, Inc.

Attn:
Facsimile:
Email:

With a copy to: CoreRx, Inc.

Attn:
Facsimile:
Email:

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement and any related attachment, appendices, exhibits, schedules, constitutes the entire understanding between the parties, and supersedes any contract, agreement or understanding (oral or written) of the parties, with respect to its subject matter. Without limitation of the foregoing, any contrary or different term(s) contained in any Purchase Order or other request or communication by Client pertaining to the Product(s), will not modify this Agreement or be binding on the Parties unless mutually agreed to in writing in an Amendment to this Agreement. Similarly, no term of this Agreement may be modified, deleted and/or otherwise amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular include the plural, and vice versa, (D) the words “include(s)” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation” or words of similar import, (E) the word “or” shall be deemed to include the word “and” (*e.g.*, “and/or”), and (F) references to “Article,” “Section,” “subsection,” “clause” or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties shall execute, acknowledge and deliver such further instruments and take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement and any purchase order made pursuant to this Agreement.

18.4 No Waiver. Failure by either party to enforce any term of this Agreement or insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to subsequently enforce such provisions and/or insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect. The parties shall endeavor to negotiate additional terms if necessary and as is feasible, in a timely manner, so as to fully effectuate the original intent of the parties, to the extent possible.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debt or make any commitment for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint venturers, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor. CoreRx understands and agrees that no payroll or employment taxes of any kind for CoreRx's employees or contractors shall be withheld or paid by Client, unless otherwise required by Applicable Law. Payroll and employment taxes referred to in the preceding sentence include, but are not limited to, FICA, FUTA, federal personal income tax, state personal income tax, state disability insurance tax, and state unemployment tax.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party; provided, however that, except in the event of bankruptcy, a party may assign this Agreement and its rights and obligations hereunder without consent in connection with the transfer or sale of all or substantially all of such party's business to which this Agreement relates to an affiliate or third party, whether by merger, sale of stock, sale of assets or otherwise. CoreRx may not subcontract or otherwise delegate its obligations under this Agreement without Client's prior written consent. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties, and the name of a party appearing herein will be deemed to include the name of such party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any right or remedy upon any individual or entity other than the parties and their respective successors and permitted assigns, except that the Client Indemnitees and the CoreRx Indemnitees may invoke the benefits of the indemnification provisions of this Agreement.

18.9 Governing Law. The Agreement will be governed by the laws of Delaware without regard to its or any other jurisdiction's choice of law rules that will result in the application of any other substantive laws.

18.10 Waiver of Jury Trial. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT, INCLUDING ANY EXHIBITS, SCHEDULES, ATTACHMENTS, AND APPENDICES ATTACHED TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY.

18.11 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a "**Dispute**"), shall be submitted for negotiation and resolution to the senior executives of CoreRx and the senior executives of Client, by delivery of written Notice (each, a "**Dispute Notice**") from either of the Parties to the other Party. Such persons shall negotiate in good faith to resolve the Dispute. If the Parties are unable to resolve any Dispute within [***] days after delivery of the applicable Dispute Notice, the parties shall work together to mutually agree to a mediator and engage in mediation for no more than [***] hours or such other time period as mutually agreed to by the parties at the time of mediation. If mediation fails to resolve the Dispute, the parties shall discuss submitting the Dispute to binding arbitration before a mutually agreed to panel of [***] arbitrators at a location mutually agreed to and if no agreement, then [***]. Any such arbitration shall be for no more than [***] days, and the arbitration shall be conducted pursuant to the rules established by the American Arbitration Association. The laws of the [***] shall apply. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. Nothing contained herein shall prevent either party from obtaining an injunction. Attorneys' fees may be awarded pursuant to applicable law as part of any arbitration award or settlement agreement.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall obtain the prior written approval of the other party, which shall not be unreasonably withheld or delayed, as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Force Majeure. Each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control including but not limited to acts of God, fire, explosion, weather, disease, a World Health Organization recognized pandemic and/or epidemic, war, insurrection, civil strife, riots, government action, earthquake, terrorism, or power failure; provided that such performance shall be excused only to the extent of and during such disability and the affected party shall use Commercially Reasonable Efforts to resume performance as soon as reasonably practicable. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused, or materially

contributed to the occurrence of, such event(s). Notice of a party's failure or delay in performance due to force majeure must be given to the other party as soon as reasonably practicable after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure.

18.14 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original. Each party acknowledges that an original signature, a copy thereof transmitted by .pdf, or an electronic signature shall constitute an original signature for purposes of this Agreement.

18.15 Other Products. This Agreement does not limit CoreRx's right to manufacture or sell to any third party, or enter into any agreement with any other third party, related to the manufacture or sale of other goods or products that are similar to or competitive with the Products.

18.16 Grant of Exclusivity. During the Term of this Agreement, CoreRx shall not manufacture Product on its own or for any other third-party or customer without Acadia's prior written permission.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized Representatives to execute this Agreement effective as of the Effective Date.

CORERX INC. **ACADIA PHARMACEUTICALS INC.**

By: /s/ Ajay Damani By: /s/ Benir Ruano

Name: Ajay Damani Name: Benir Ruano

Title: CEO Title: SVP, Tech. Development and Operations

By: /s/ Mark Schneyer

Name: Mark Schneyer

Title: CFO and SVP

ATTACHMENT A
SPECIFICATIONS

[***]

ATTACHMENT B

UNIT PRICING; MILESTONES; APR & CPV

[***]

AMENDMENT NO. 1 TO
COMMERCIAL SUPPLY AGREEMENT

This Amendment No. 1 ("**Amendment**") to the Commercial Supply Agreement, effective as of August 1, 2023 ("**Amendment Effective Date**") is entered into by and between CoreRx, Inc., having an address at 14205 Myerlake Circle, Clearwater, Florida 33760 ("**CoreRx**") and ACADIA Pharmaceuticals Inc., having an address at 12830 El Camino Real, Suite 400, San Diego, California 92130 ("**Client**" or "**Acadia**"). Client and CoreRx may individually be referred to as a "**party"** and collectively as the "**parties.**"

WHEREAS, CoreRx and Client entered into that certain Commercial Supply Agreement dated effective March 1, 2023 (the "**Agreement**"). Terms used in this Amendment but not otherwise defined in this Amendment shall have the meanings ascribed to such terms in the Agreement. CoreRx and Client now desire to amend the Agreement upon the terms and conditions noted below;

WHEREAS, the Agreement provides that the parties may mutually agree in writing to amend the Agreement;

WHEREAS, the Parties have agreed to amend the Agreement as set forth herein. Unless otherwise amended as stated below, all terms and conditions of the Agreement shall remain in full force and effect.

In consideration of the mutual covenants and premises contained in this Amendment, the receipt and sufficiency of which are hereby expressly acknowledged, CoreRx and Client hereby agree as follows:

1. **Section 3.2 Raw Materials** of the Agreement shall be amended as follow:

Section 3.2 A. The first sentence shall be amended by revising the first sentence as shown below, deleting the second sentence, and revising the third sentence as shown below. The remainder of Section 3.2 A shall remain such that the amended Section 3.2 A shall be as follows:

Unless otherwise agreed to by the parties in writing, CoreRx shall be responsible for procuring, inspecting, managing, and releasing adequate Raw Materials as necessary to meet the Firm Commitment and shall procure, manage, inspect, test, and store sufficient Raw Materials to manufacture a minimum of [***] Batches in excess of the Firm Commitment ("**Safety Stock**"). CoreRx will invoice for Safety Stock Raw Materials purchased and any other Raw Materials as requested by Client outside of the Firm Commitment. In the event that Client does not issue Purchase Orders requesting sufficient Product to meet the Firm Commitment during any Firm Commitment Period (on a rolling basis) and any Raw Materials expire or require retesting, such Raw Materials shall be replaced or retested as Client directs at Client's sole cost and expense, including charges for disposal of the expired Raw Materials when applicable, without any liability to CoreRx.

Section 3.2 C. shall be deleted in its entirety and replaced with the following:

CoreRx shall store the Raw Materials, Safety Stock, and packaging materials at controlled room temperature as instructed by Client, unless stated otherwise. During the Term of this Agreement, CoreRx agrees to provide a minimum of [***] pallet spaces for Raw Materials, Safety Stock, and packaging materials needed to support the Product manufacturing campaign. Client agrees to pay CoreRx the amount of [***] per calendar year (to be prorated for 2023 as stated below) to cover the procurement, management and storage of Safety Stock and other Raw Materials ("**Safety Stock Fee**"). Storage costs of Raw Materials are deemed to be a part of and incorporated into the Safety Stock Fee. The prorated Safety Stock Fee for calendar year 2023 (August through December 2023) is [***], and this prorated fee is due to CoreRx upon full execution of this Amendment. Subsequent Safety Stock Fees are due to CoreRx on January 31st of each calendar year beginning calendar year 2024 (CoreRx may submit invoice sooner). This Amendment to Section 3.2(C) can be cancelled within a [***] notice by the Client and in such event, the Agreement reverts back to the original Agreement 3.2 (C) provision.

2. The following new terms are hereby added to **Attachment B,** of the Agreement:

4.0 Unused Material Fee: Client agrees to pay CoreRx an amount of up to [***] for costs incurred by CoreRx for materials that were to be used for other CoreRx client projects ("**Unused Material Fee**") pursuant to the following terms and conditions:

i. CoreRx shall use reasonable commercial efforts to sell or use any or all of the unused materials of other CoreRx clients ("**Unused Third Party Materials**") by or before February 1, 2024 ("**Sale or Reuse Date**"); and

ii. CoreRx shall document in writing its efforts to sell or use any or all of the Unused Third Party Materials and retain written records of the relevant quantities, prices, fees, and values of any sale(s) or use of the Unused Third Party Materials; and

iii. CoreRx shall provide the records specified in (ii) above, redacted as needed to comply with confidentiality requirements, to Acadia shortly after the Sale or Reuse Date and Acadia shall pay the Unused Material Fee minus any documented amounts and/or values received by CoreRx for the sale or use of the Unused Third Party Materials within 30 days of receipt of such records.

5.0 Premium Price: Except as provided in this Section 5 and its subparts, Acadia shall pay [***] per bottle premium on the applicable Unit Price ("**Premium Price**") on up to [***] Batches that CoreRx Releases to Client on or after [***]. "Release" and/or "Released" shall mean CoreRx issuing a Certificate of Analysis ("COA") for the relevant batches. Client shall pay the Premium Price on the following Orders pursuant to the terms and conditions set forth in this Section 5 and its subparts:

Table 1.

Order No.	
1	[***]
2	[***]
3	[***]
4	[***]

5.1 CoreRx must Release the specified amount of Batches within [***] business days of the stated release date ("**Release Deadline**") for each Order identified above for the Premium Price to be paid and be valid. In the event that CoreRx Releases a lesser amount of Batches than the specified Order amount by the Release Deadline, then Client shall only pay the Premium Price for those Batches that meet the Release Deadline. Accordingly, any Batches that are Released subsequent to the Release Deadline do not qualify for the Premium Price and cannot be rolled over into the next Order's Release Deadline. For illustration and for example only, if CoreRx Releases [***] out of the [***] Batches specified in Order No. [***] by the Release Deadline, the Premium Price shall be paid on the 4 Batches. The other [***] Batches even if Released before or by Order [***]'s Release Deadline are not eligible for the Premium Price.

5.2 API Delay. In the event that Client does not provide some or all of the API necessary for CoreRx to manufacture the specified amount of Batches in an Order, the parties shall timely engage in good faith discussions to determine a mutually agreed upon different Release date for the applicable Order that shall be set forth in a mutually agreed upon writing. The Premium Price shall apply to any new mutually agreed upon Release date for an Order pursuant to the terms and conditions stated in herein in Section 5 and its subparts.

6.0 Deposit: Client agrees to pay CoreRx a deposit in the amount of [***] ("**Deposit**"). The Deposit is due to CoreRx upon full execution of this Amendment. CoreRx shall use the Deposit as a credit towards Purchase Orders for Batches shipped on or after November 1, 2023, and will continue to use the Deposit as a credit towards Purchase Orders until the cost of the Batches in the amount of the full Deposit have been shipped by CoreRx (approximately [***] Batches). CoreRx shall account for the Deposit credit on its invoices until the total amount of the Deposit (that is [***]) has been credited.

3. **Full Force and Effect; Conflict.** Other than as amended herein, all terms and conditions of the Agreement shall remain in full force and effect. In the event of any conflict between the terms of this Amendment and the MSA, this Amendment shall control.

4. **Counterparts.** This Amendment may be executed in counterparts which, when taken together, shall constitute one instrument. Electronic replication of signature or electronic signature will have the same legal effect as original signatures and may be used as evidence of execution.

[*Signatures follow on next page]*

IN WITNESS WHEREOF, the parties have executed this Amendment as of the Amendment Effective Date by their duly authorized representatives.

Agreed and Accepted:

CoreRx, Inc.

By /s/ Ajay Damani_____

Name: Ajay Damani

Title: CEO

Agreed and Accepted:

ACADIA Pharmaceuticals Inc.

By: /s/ Benir Ruano_____

Name: Benir Ruano

Title: SVP Tech Dev. and Operations

By: /s/ Doug Williamson_____

Name: Doug Williamson

Title: EVP, Head of Research & Development

By /s/ Mark Schneyer_____

Name: Mark Schneyer

Title: EVP & CFO

Exhibit 21.1

List of Subsidiaries

NAME OF SUBSIDIARY	JURISDICTION OF INCORPORATION
ACADIA Pharmaceuticals A/S	Denmark
ACADIA Pharmaceuticals GmbH	Switzerland
ACADIA Pharma Limited	United Kingdom
CerSci Therapeutics Incorporated	Delaware
Amorsa Therapeutics Inc.	Delaware
Acadia Pharmaceuticals Holdings Inc.	Delaware
Levo Therapeutics, Inc.	Delaware
Pandeia Therapeutics	United Kingdom

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-171722, 333-185639, 333-248401, and 333-265205) of Acadia Pharmaceuticals Inc.,

(2) Registration Statement (Form S-8 No. 333-115956) pertaining to the 1997 Stock Option Plan, 2004 Equity Incentive Plan, and 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(3) Registration Statements (Form S-8 Nos. 333-128290, 333-137557, 333-146398, 333-153346, and 333-161057) pertaining to the 2004 Equity Incentive Plan and 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(4) Registration Statements (Form S-8 Nos. 333-168667, 333-190400, 333-213109, and 333-232981) pertaining to the 2010 Equity Incentive Plan and the 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.,

(5) Registration Statements (Form S-8 Nos. 333-176212, 333-183151, 333-197872, 333-241711) pertaining to the 2004 Employee Stock Purchase Plan of Acadia Pharmaceuticals Inc.;

(6) Registration Statements (Form S-8 Nos. 333-207971, 333-219785, 333-226834, amd 333-266680) pertaining to the 2010 Equity Incentive Plan of Acadia Pharmaceuticals Inc.; and

(7) Registration Statement (Form S-8 No. 333-269611) pertaining to the 2023 Inducement Plan of Acadia Pharmaceuticals Inc.

of our reports dated February 27, 2024, with respect to the consolidated financial statements and schedule of Acadia Pharmaceuticals Inc. and the effectiveness of internal control over financial reporting of Acadia Pharmaceuticals Inc. included in this Annual Report (Form 10-K) of Acadia Pharmaceuticals Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California
February 27, 2024

EXHIBIT 31.1

CERTIFICATION
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Stephen R. Davis, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 of Acadia Pharmaceuticals Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

/s/ STEPHEN R. DAVIS

Stephen R. Davis
Chief Executive Officer
(Registrant's Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION
Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Mark C. Schneyer, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 of Acadia Pharmaceuticals Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

/s/ MARK C. SCHNEYER

Mark C. Schneyer
Executive Vice President, Chief Financial Officer
(Registrant's Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Acadia Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Stephen R. Davis, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 27, 2024

/s/ STEPHEN R. DAVIS

Stephen R. Davis
Chief Executive Officer
(Registrant's Principal Executive Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Acadia Pharmaceuticals Inc. (the "Company") on Form 10-K for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Mark C. Schneyer, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 27, 2024

/s/ MARK C. SCHNEYER

Mark C. Schneyer
Executive Vice President, Chief Financial Officer
(Registrant's Principal Financial Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 97.1

ACADIA PHARMACEUTICALS INC. DODD-FRANK CLAWBACK POLICY

Acadia Pharmaceuticals Inc. ("Company") has adopted this clawback policy (the "Policy") as an amendment and restatement of any other clawback policies in effect now at the Company. To the extent this Policy applies to compensation payable to a person covered by this Policy, it shall be the only clawback policy applicable to such compensation and no other clawback policy shall apply. Other than with respect to Section 6 hereof, this Policy shall be interpreted to comply with the clawback rules found in 17 C.F.R. §240.10D and the related listing rules of the national securities exchange or national securities association ("Exchange") on which the Company has listed securities, and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

1. Definitions. 17 C.F.R. §240.10D-1(d) defines the terms "Executive Officer," "Financial Reporting Measure," "Incentive-Based Compensation," and "Received." As used herein, these terms shall have the same meaning as in that regulation.

2. Application of the Policy. This Policy shall only apply in the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

3. Recovery Period. The Incentive-Based Compensation subject to clawback is the Incentive-Based Compensation Received during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in Section 2, provided that the person served as an Executive Officer at any time during the performance period applicable to the Incentive-Based Compensation in question. The date that the Company is required to prepare an accounting restatement shall be determined pursuant to 17 C.F.R. §240.10D-1(b)(1)(ii).

(a) Notwithstanding the foregoing, the Policy shall only apply if the Incentive-Based Compensation is Received (1) while the Company has a class of securities listed on an Exchange and (2) on or after October 2, 2023 (the "Effective Date").

(b) See 17 C.F.R. §240.10D-1(b)(1)(i) for certain circumstances under which the Policy will apply to Incentive-Based Compensation received during a transition period arising due to a change in the Company's fiscal year.

4. Erroneously Awarded Compensation. The amount of Incentive-Based Compensation subject to the Policy ("Erroneously Awarded Compensation") is the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive Based-Compensation that otherwise would have been Received had it been determined based on the restated amounts and shall be computed without regard to any taxes paid.

(a) For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (1) the amount shall be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was

received; and (2) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

5. Recovery of Erroneously Awarded Compensation. The Company shall recover reasonably promptly any Erroneously Awarded Compensation except to the extent that the conditions of paragraphs (a), (b), or (c) below apply. The Compensation Committee (the "Committee") shall determine the repayment schedule for each amount of Erroneously Awarded Compensation in a manner that complies with this "reasonably promptly" requirement. Such determination shall be consistent with any applicable legal guidance, by the Securities and Exchange Commission (the "SEC"), judicial opinion, or otherwise. The determination of "reasonably promptly" may vary from case to case and the Committee is authorized to adopt additional rules to further describe what repayment schedules satisfy this requirement.

(a) Erroneously Awarded Compensation need not be recovered if the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered and the Committee has made a determination that recovery would be impracticable. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange.

(b) Erroneously Awarded Compensation need not be recovered if recovery would violate home country law where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation and shall provide such opinion to the Exchange.

(c) Erroneously Awarded Compensation need not be recovered if recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

6. Recovery of Additional Covered Compensation. Notwithstanding anything to the contrary in this Policy, and in addition to the other provisions within this Policy, in the event that the Committee determines that any current or former Executive Officer committed Misconduct in connection with an accounting restatement, then, in addition to any Erroneously Awarded Compensation otherwise subject to forfeiture and/or repayment pursuant to this Policy, the Committee may, in its discretion, seek forfeiture and/or repayment of all or a portion of any Additional Covered Compensation received by such person during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in Section 2. For purposes of this Section 6, Additional Covered Compensation will be treated as received when such compensation is granted, earned, vested, paid or settled. For the avoidance of doubt, the Committee may seek forfeiture and/or repayment of Additional Covered Compensation for Misconduct by such person in connection with an accounting restatement even if such accounting restatement did not result in an award or payment greater than would have been awarded absent such accounting restatement. "Additional Covered Compensation" means incentive compensation, whether

cash-based or equity-based, which may be discretionary, service-based or performance-based, but not including salary or employee retirement or welfare benefits, computed without regard to any taxes paid (i.e., on a pre-tax basis), that was received (a) on or after the Effective Date, (b) after the person became an Executive Officer and (c) at a time that the Company had a class of securities listed on a national securities exchange or a national securities association. "Misconduct" means any of the following that causes or could reasonably be expected to cause material harm to the Company: (1) a material act of dishonesty, fraud or misrepresentation, (2) a willful violation of a material Company policy or law, (3) knowing violation of SEC rules or regulations, or (4) intentional breach of fiduciary duty or duty of loyalty to the Company, in each case that causes the applicable accounting restatement."

7. Committee decisions. Decisions of the Committee with respect to this Policy shall be final, conclusive and binding on all Executive Officers subject to this policy, unless determined to be an abuse of discretion.

8. No Indemnification. Notwithstanding anything to the contrary in any other policy of the Company or any agreement between the Company and an Executive Officer, no Executive Officer shall be indemnified by the Company against the loss of any Erroneously Awarded Compensation.

9. Agreement to Policy by Executive Officers. The Committee shall take reasonable steps to inform Executive Officers of this Policy and obtain their agreement to this Policy, which steps may constitute the inclusion of this Policy as an attachment to any award that is accepted by the Executive Officer.

ACADIA PHARMACEUTICALS INC.

DODD-FRANK CLAWBACK POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Acadia Pharmaceuticals Inc. Dodd-Frank Clawback Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Acadia Pharmaceuticals Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Committee (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

EXECUTIVE OFFICER

By: _

Name: __

Title: ___

Date: ___

ACADIA PHARMACEUTICALS INC.

By: _

Name: __

Title: ___

Date: ___