ACADIA Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results

February 26, 2020

- Full Year 2019 Net Sales Grew to $339.1 Million, a 52% Increase over Full Year 2018

- 2020 Net Sales Guidance of $440 to $470 Million

- On-Track to Submit Supplemental New Drug Application for Dementia-Related Psychosis in Summer 2020

SAN DIEGO--(BUSINESS WIRE)--Feb. 26, 2020-- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD) today announced financial results for the fourth quarter and full year ended December 31, 2019.

“In 2019 ACADIA demonstrated strong execution from our commercial and R&D teams, driving the continued growth of NUPLAZID and advancing our late-stage pipeline,” said Steve Davis, Chief Executive Officer. “2020 will be a transformational year for ACADIA highlighted by a potential approval in dementia-related psychosis, additional pivotal study results in major depressive disorder, commencement of a second pivotal study for the negative symptoms of schizophrenia and the continued enrollment of the Phase 3 trofinetide study for Rett syndrome. This exciting momentum has created a multi-year cadence of pivotal study readouts and potential regulatory approvals that position the company for long-term growth.”

Company Highlights

- Presented positive top-line results from the Phase 3 HARMONY study of pimavanserin for the treatment of dementia-related psychosis at the Clinical Trials on Alzheimer's Disease (CTAD) meeting on December 4, 2019.
    - The Company plans to submit a supplemental NDA for pimavanserin for the treatment of dementia-related psychosis in the summer of 2020. Pimavanserin previously received Breakthrough Therapy Designation for this indication.
- Announced positive top-line results from the pivotal Phase 2 ADVANCE study of pimavanserin for the negative symptoms of schizophrenia in November 2019.
    - The Company plans to initiate a second pivotal study, ADVANCE-2, of pimavanserin for the negative symptoms of schizophrenia during the summer of 2020.
- The Company expects to announce top-line results from its Phase 3 CLARITY-2 study of pimavanserin as an adjunctive treatment for major depressive disorder in the fourth quarter of 2020.
- Appointed Ponni Subbiah, M.D., M.P.H., as Senior Vice President, Global Head of Medical Affairs and Chief Medical Officer and Stephanie Fagan as Senior Vice President, Corporate Affairs and Chief Communications Officer.

Financial Results

Revenue

Net sales of NUPLAZID® (pimavanserin) were $98.3 million for the fourth quarter of 2019, an increase of 65% as compared to $59.6 million reported for the fourth quarter of 2018. End of fourth quarter days-on-hand channel inventory increased relative to the third quarter 2019, which resulted in approximately $2.5 million increase in fourth quarter 2019 net sales. For the years ended December 31, 2019 and 2018, ACADIA reported net product sales of $339.1 million and $223.8 million, respectively, an increase of 52% year-over-year.

Research and Development

Research and development expenses for the fourth quarter of 2019 were $57.5 million, compared to $48.2 million for the same period of 2018. For the years ended December 31, 2019 and 2018, research and development expenses were $240.4 million and $187.2 million, respectively. The increase during the 2019 periods as compared to 2018 was primarily due to development costs associated with trofinetide and additional clinical study costs for pimavanserin.

Selling, General and Administrative

Selling, general and administrative expenses for the fourth quarter of 2019 were $91.9 million, compared to $74.3 million for the same period of 2018. For the years ended December 31, 2019 and 2018, selling, general and administrative expenses were $325.6 million and $265.8 million, respectively. This increase during the 2019 periods as compared to 2018 was primarily due to increased general and administrative expenses including charitable contributions and personnel costs.

Net Loss

For the fourth quarter of 2019, ACADIA reported a net loss of $53.0 million, or $0.34 per common share, compared to a net loss of $65.5 million, or $0.50 per common share, for the same period in 2018. The net losses for the fourth quarters of 2019 and 2018 included $19.8 million and $20.4 million, respectively, of non-cash stock-based compensation expense. For the years ended December 31, 2019, ACADIA reported a net loss of $235.3

million, or $1.60 per common share, compared to a net loss of $245.2 million, or $1.94 per common share, for the same period in 2018. The net losses for the years ended December 31, 2019 and 2018 included $82.2 million and $81.6 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At December 31, 2019, ACADIA's cash, cash equivalents, and investment securities totaled $697.4 million, compared to $473.5 million at December 31, 2018. The increase was primarily due to net proceeds of $271.5 million from ACADIA's September 2019 public offering of common stock as well as additional cash proceeds from employee option exercises of $91.6 million.

2020 Financial Guidance

ACADIA's 2020 net sales guidance reflects annual revenue growth of approximately 34% for NUPLAZID, at the mid-point of the range. 2020 GAAP R&D guidance reflects the progression of four phase 3 studies this year. 2020 GAAP SG&A guidance reflects a similar level of investment to 2019 in PDP with new investments in preparing for a launch in DRP including disease-state educational initiatives and plans for the expansion of our commercial and medical affairs functions.

- NUPLAZID net sales are expected to be between $440 and $470 million.
- GAAP R&D is expected to be between $270 and $285 million.
- GAAP SG&A is expected to be between $440 and $460 million.
- Non-cash stock-based compensation expense is expected to be between $90 and $100 million.
- 2020 year-end cash, cash equivalents, and investment securities are expected to be between $470 and $500 million.

Conference Call and Webcast Information

ACADIA management will review its fourth quarter and full year 2019 financial results and operations via conference call and webcast today at 5:00 p.m. Eastern Time. The conference call may be accessed by dialing 855-638-4820 for participants in the U.S. or Canada and 443-877-4067 for international callers (reference passcode 6692587). A telephone replay of the conference call may be accessed through March 11, 2020 by dialing 855-859-2056 for callers in the U.S. or Canada and 404-537-3406 for international callers (reference passcode 6692587). The conference call also will be webcast live on ACADIA's website, www.acadia-pharm.com, under the investors section and will be archived there through March 26, 2020.

About NUPLAZID® (pimavanserin)

NUPLAZID is the first and only FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. NUPLAZID is a selective serotonin inverse agonist/antagonist preferentially targeting 5-HT_{2A} receptors that are thought to play an important role in Parkinson's disease psychosis. NUPLAZID is an oral medicine taken once a day with a recommended dose of 34 mg. NUPLAZID is not FDA-approved for dementia-related psychosis, schizophrenia, major depressive disorder, or depressive symptoms in patients with Parkinson's disease. ACADIA discovered and developed this new chemical entity and holds worldwide rights to develop and commercialize NUPLAZID.

About Trofinetide

Trofinetide is an investigational drug. It is a novel synthetic analog of the amino-terminal tripeptide of IGF-1 designed to treat the core symptoms of Rett syndrome by potentially reducing neuroinflammation and supporting synaptic function. In the central nervous system, IGF-1 is produced by both of the major types of brain cells – neurons and glia. IGF-1 in the brain is critical for both normal development and for response to injury and disease. Trofinetide has been granted Fast Track Status and Orphan Drug Designation in the U.S. and Orphan Drug Designation in Europe for both Rett syndrome and Fragile X syndrome.

About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. ACADIA has developed and commercialized the first and only medicine approved for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. ACADIA also has ongoing clinical development efforts in additional areas with significant unmet need, including dementia-related psychosis, the negative symptoms of schizophrenia, major depressive disorder, and Rett syndrome. This press release and further information about ACADIA can be found at: www.acadia-pharm.com.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements related to: the potential opportunity for future growth in sales of NUPLAZID; the timing of ongoing and future clinical studies for pimavanserin; the development and commercialization of trofinetide; and guidance for full-year 2020 NUPLAZID net sales and certain expense line items. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the uncertainty of future commercial sales and related items that would impact net sales during 2020, the risks and uncertainties inherent in drug development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to ACADIA's annual report on Form 10-K for the year ended December 31, 2018 as well as ACADIA's subsequent filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and ACADIA undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenues				
Product sales, net	$ 98,326	$ 59,571	$ 339,076	$ 223,807
Total revenues	98,326	59,571	339,076	223,807
Operating expenses				
Cost of product sales, license fees and royalties [(1)]	5,334	4,392	19,598	18,330
Research and development [(1)]	57,520	48,183	240,385	187,163
Selling, general and administrative [(1)]	91,871	74,271	325,638	265,758
Total operating expenses	154,725	126,846	585,621	471,251
Loss from operations	(56,399)	(67,275)	(246,545)	(247,444)
Interest income, net	3,272	1,670	11,165	5,348
Other expense	491	127	997	(1,840)
Loss before income taxes	(52,636)	(65,478)	(234,383)	(243,936)
Income tax expense	400	14	876	1,256
Net loss	$ (53,036)	$ (65,492)	$ (235,259)	$ (245,192)
Net loss per common share, basic and diluted	$ (0.34)	$ (0.50)	$ (1.60)	$ (1.94)
Weighted average common shares outstanding, basic and diluted	154,492	131,627	147,199	126,583

[(1)] Includes the following share-based compensation expenses

Cost of product sales, license fees and royalties	$ 592	$ 838	$ 2,936	$ 3,863
Research and development	$ 8,072	$ 8,421	$ 32,533	$ 32,038
Selling, general and administrative	$ 11,099	$ 11,142	$ 46,796	$ 45,663

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2019	December 31, 2018
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 697,429	$ 473,520
Accounts receivable, net	35,781	26,090
Interest and other receivables	2,093	1,699
Inventory	6,341	4,070
Prepaid expenses	18,606	20,727
Total current assets	760,250	526,106
Property and equipment, net	3,180	3,309
Operating lease right-of-use assets	9,524	—
Intangible assets, net	2,585	4,062
Restricted cash	4,787	4,826
Other assets	2,857	1,899
Total assets	$ 783,183	$ 540,202
Liabilities and stockholders' equity		
Accounts payable	$ 7,222	$ 3,167
Accrued liabilities	67,604	56,398
Total current liabilities	74,826	59,565
Operating lease liabilities	6,361	—
Long-term liabilities	2,861	1,558
Total liabilities	84,048	61,123
Total stockholders' equity	699,135	479,079
Total liabilities and stockholders' equity	$ 783,183	$ 540,202

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