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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2020

ACADIA Pharmaceuticals Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50768**	**06-1376651**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3611 Valley Centre Drive, Suite 300 **San Diego, California** **(Address of principal executive offices)**	**92130** **(Zip Code)**

Registrant's telephone number, including area code: (858) 558-2871

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 13, 2020, in advance of meetings and its presentation at the J.P. Morgan Healthcare Conference in San Francisco, California, ACADIA Pharmaceuticals Inc. is making publicly available a corporate presentation that includes information and updates regarding its business. A copy of the presentation is attached as Exhibit 99.1 hereto.

The information in this Item 2.02 and the exhibit hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation of ACADIA Pharmaceuticals Inc., made available on January 13, 2020.
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 13, 2020

ACADIA Pharmaceuticals Inc.

By: /s/ Austin D. Kim
Name: Austin D. Kim
Title: Executive Vice President, General Counsel & Secretary

Exhibit 99.1

ACADIA® Pharmaceuticals

Steve Davis, CEO

38th Annual J.P. Morgan Healthcare Conference

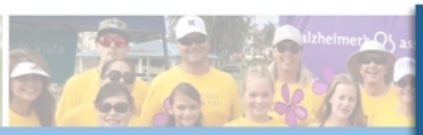
JANUARY 14, 2020

Forward-Looking Statement

This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed in or implied by such forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about (i) plans for, including timing and progress of commercialization of, NUPLAZID® or for the clinical development of our product candidates, including pimavanserin and trofinetide; (ii) benefits to be derived from and efficacy of our product candidates, including the use of pimavanserin in dementia-related psychosis, schizophrenia, depression or other neurological or psychiatric indications, potential advantages of NUPLAZID versus existing antipsychotics or antidepressants, and expansion opportunities for NUPLAZID; (iii) estimates regarding the prevalence of PD, PD Psychosis, dementia-related psychosis, schizophrenia or depression and the potential use of trofinetide in Rett syndrome; (iv) potential markets for any of our products, including NUPLAZID and trofinetide; and (v) our estimates regarding our future financial performance, cash position or capital requirements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions (including the negative thereof) intended to identify forward-looking statements. Given the risks and uncertainties, you should not place undue reliance on these forward-looking statements. For a discussion of the risks and other factors that may cause our actual results, performance or achievements to differ, please refer to our annual report on Form 10-K for the year ended December 31, 2018 as well as our subsequent filings with the SEC. The forward-looking statements contained herein are made as of the date hereof, and we undertake no obligation to update them for future events.

ACADIA in 2020 – Building a Leading CNS Platform



Transforming standard of care for PDP patients

50% NUPLAZID® net sales growth YoY[1]

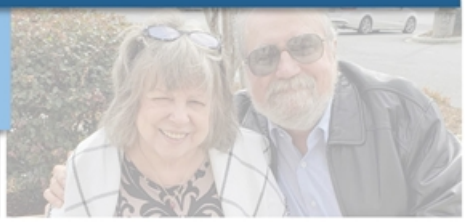
Innovative pipeline

4 late-stage pipeline programs

3 positive pivotal studies

Pimavanserin focused on significant patient need

35X Potential increase in addressable market beyond PDP[2]



Dedicated to Improving Lives of Patients, Families, and Caregivers

[1]2019 net sales guidance of $330-340M, represents a 50% increase in revenue and 38% volume growth year-over-year at the mid-point of the range.
[2]ACADIA Market Research based on estimated U.S. treated populations for patients with dementia-related psychosis (DRP), adjunctive treatment for major depressive disorder (MDD), and the negative symptoms of schizophrenia (NSS).
Provided January 14, 2020 as part of an oral presentation and is qualified by such; contains forward-looking statements; actual results may vary materially; ACADIA disclaims any duty to update.

ACADIA® Pharmaceuticals

2020 Strategic Pillars

Drive
NUPLAZID® Growth in PDP

Deliver
DRP Opportunity to the Market

Develop
Innovative Treatments For Unmet Needs

Successful Execution and Strong Balance Sheet Position ACADIA for Significant Long-term Growth

ACADIA® Pharmaceuticals

The Potential of Pimavanserin
A Novel Selective Serotonin Inverse Agonist

Current – NUPLAZID®

- First and only FDA-approved treatment for PDP
- FDA Breakthrough Therapy
- Patent protection into 2030[1]

Future – Pimavanserin

- Robust efficacy in pivotal studies across 3 additional CNS indications:
  - DRP (FDA Breakthrough Therapy)
  - MDD (adjunctive treatment)
  - Negative symptoms of schizophrenia

Safety in Late-Stage Clinical Trials

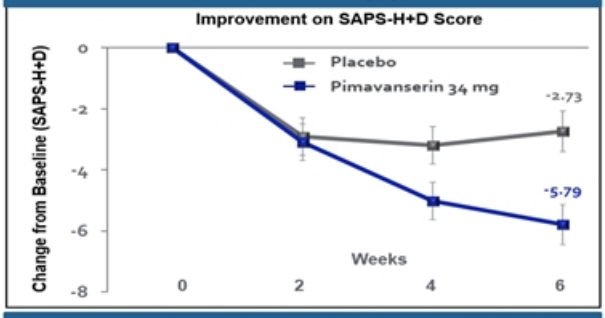
- DRP - No negative impact on cognition or impairment of motor function
- MDD - Improved symptoms of sexual dysfunction with no increased sedation or weight gain
- Schizophrenia - No effect on vital signs, weight, and metabolic syndrome

[1]2030 reflects composition of matter patent including Hatch-Waxman patent term extension.
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.
Provided January 14, 2020 as part of an oral presentation and is qualified by such, contains forward-looking statements, actual results may vary materially; ACADIA disclaims any duty to update.

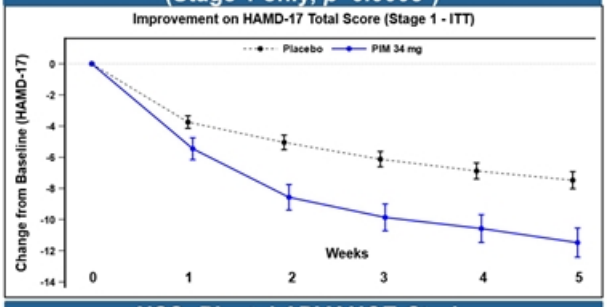
ACADIA® Pharmaceuticals

Pimavanserin – Robust and Consistent Efficacy Across Four Disease Areas

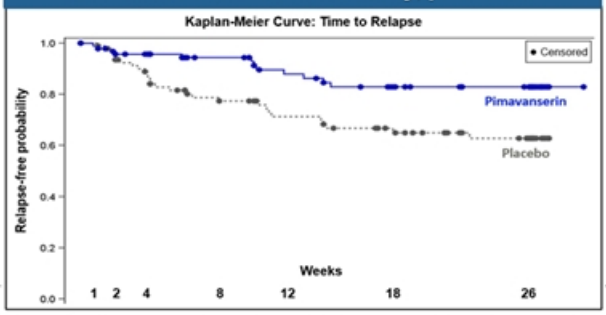
PDP: Pivotal -020 Study, *p=0.0014*



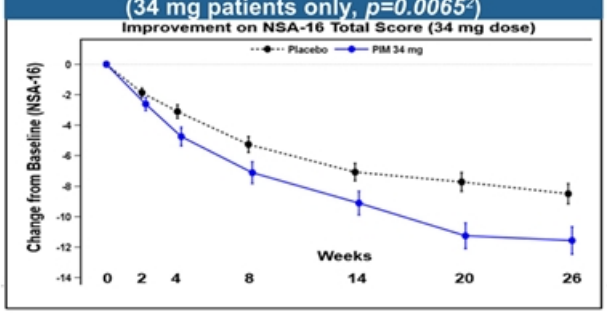
MDD: Pivotal CLARITY Study (Stage 1 only, *p=0.0003*[1])



DRP: Pivotal HARMONY Study, *p=0.0023*



NSS: Pivotal ADVANCE Study (34 mg patients only, *p=0.0065*[2])



[1]Primary endpoint was HAMD-17 total score compared to placebo (wgt. avg. of Stage 1 + 2) in a sequential parallel comparison design (*p=0.039*). Graph shows results from Stage 1.
[2]Primary endpoint was NSA-16 total score at 26-weeks in patients that received either 20 mg or 34 mg pimavanserin + background antipsychotic vs placebo + background antipsychotic (*p=0.043*). Graph shows results for patients that received the higher 34 mg dose.
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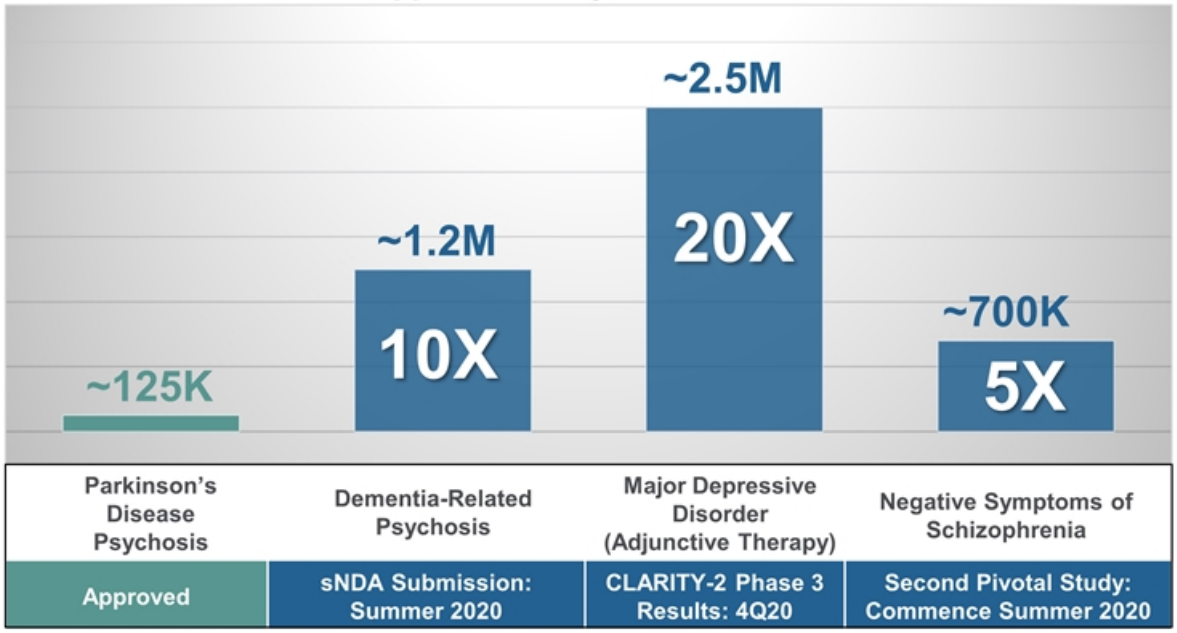
ACADIA® Pharmaceuticals

Pimavanserin – Potential to Provide Meaningful Advances for Patients

U.S. Addressable Market Opportunities by Indication[1]



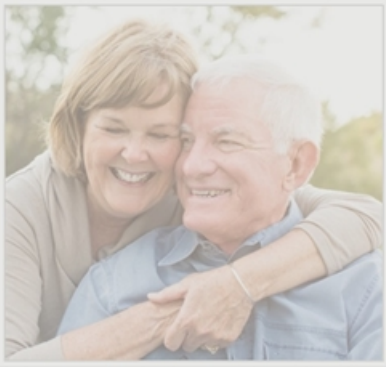
[1]ACADIA Market Research based on estimated U.S. treated populations for patients with Parkinson's disease psychosis, dementia-related psychosis, adjunctive treatment for major depressive disorder, and the negative symptoms of schizophrenia.

ACADIA® Pharmaceuticals

2020 Strategic Pillars

Drive
NUPLAZID® Growth in PDP

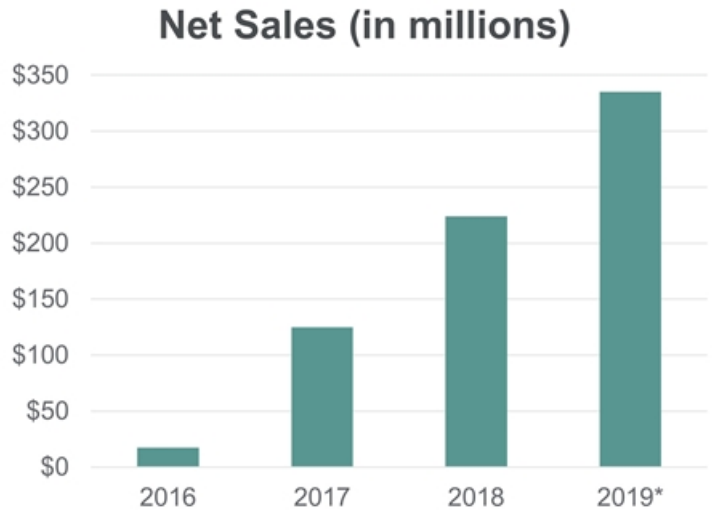
Deliver
DRP Opportunity to the Market



Develop
Innovative Treatments For Unmet Needs

ACADIA® Pharmaceuticals

Drive NUPLAZID® Growth in Parkinson's Disease Psychosis



- **2019 net sales guidance: $330-340M[1]**
  +50% revenue / +38% volume YoY
- **High teens market penetration exiting 2019**
- **Continued growth leveraging:**
  - MDS Evidence based guidelines[2]
    - *NUPLAZID only therapy recognized as clinically useful and acceptable level of safety risk without specialized monitoring*
  - New caregiver burden and long-term clinical safety data
  - Digital and patient/caregiver campaigns

Significant Future Growth Opportunity in PDP

[1]2019 net sales guidance of $330-340M, represents a 50% increase in revenue and 38% volume growth year-over-year at the mid-point of the range; *$335M represents mid-point of the range.
[2]*"Update on Treatments for Non-motor Symptoms of Parkinson's Disease"*. Seppi et al. Movement Disorders 2019 Volume 34, Issue 2;180-198.
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.
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ACADIA® Pharmaceuticals

Deliver New Opportunity for Dementia-Related Psychosis

No FDA-approved treatments for DRP

Pimavanserin has Breakthrough Therapy Designation for the treatment of DRP

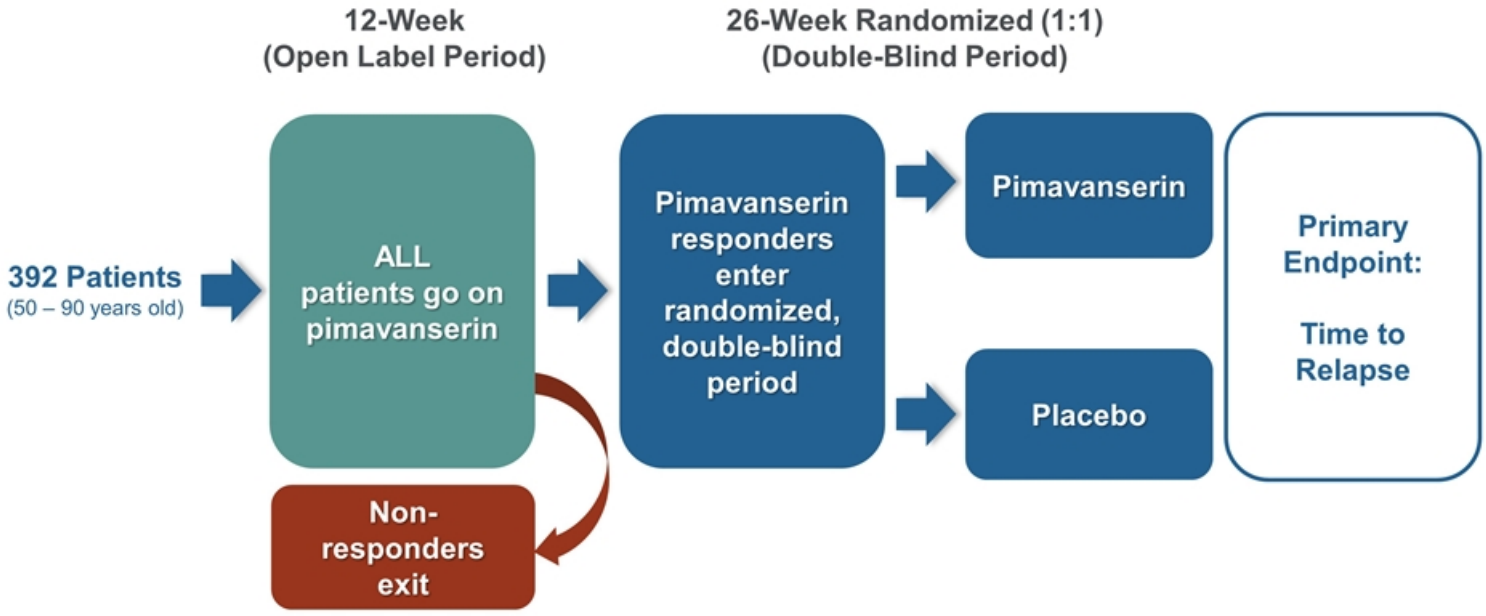
Today, antipsychotics used off-label[1]:

- Accelerate cognitive decline
- Impair motor function
- Cause extrapyramidal symptoms
- Increase sedation
- Cause orthostatic hypotension

[1] Peluso MJ1, Lewis SW, Barnes TR, Jones. Extrapyramidal motor side-effects of first- and second-generation antipsychotic drugs. *Br J Psychiatry* 2012 May;200(5):387-92. doi: 10.1192/bjp.bp.111.101485. Epub 2012 Mar 22. Schneider LS, Tariot PN, Dagerman KS, et al, CATIE-AD Study Group. Effectiveness of atypical antipsychotic drugs in patients with Alzheimer's disease. *N Engl J Med* 2006; 355: 1525–38.

ACADIA® Pharmaceuticals

Phase 3 HARMONY Relapse Prevention Study in DRP



Robust Positive Phase 3 HARMONY Results

1 Achieved Meaningful Primary Endpoint

- *Pimavanserin significantly reduced the risk of relapse of psychosis by **2.8 fold***
- ***Hazard Ratio = 0.353***
- ***One-sided p-value = 0.0023***

2 Strong Open-Label Efficacy Results

- ***61.8%** of eligible patients met the pre-specified response criteria at weeks 8 and 12*
- ***75.2%** improvement from baseline on SAPS-H+D[1] score at week 12*

3 9-Month Safety and Tolerability Results

- *Well-tolerated in chronic treatment of frail and elderly patients with significant comorbidities*
- *No worsening of **cognition**[2]*
- *No worsening of **motor function**[3]*

[1]SAPS-H+D (Scale for the Assessment of Positive Symptoms-Hallucinations and Delusions). As measured by MMSE (Mini-Mental State Examination)[2] and ESRS-A (Extrapyramidal Symptom Rating Scale A) scores[3].
Data originally presented at CTAD 2019 on 12/4/2019.
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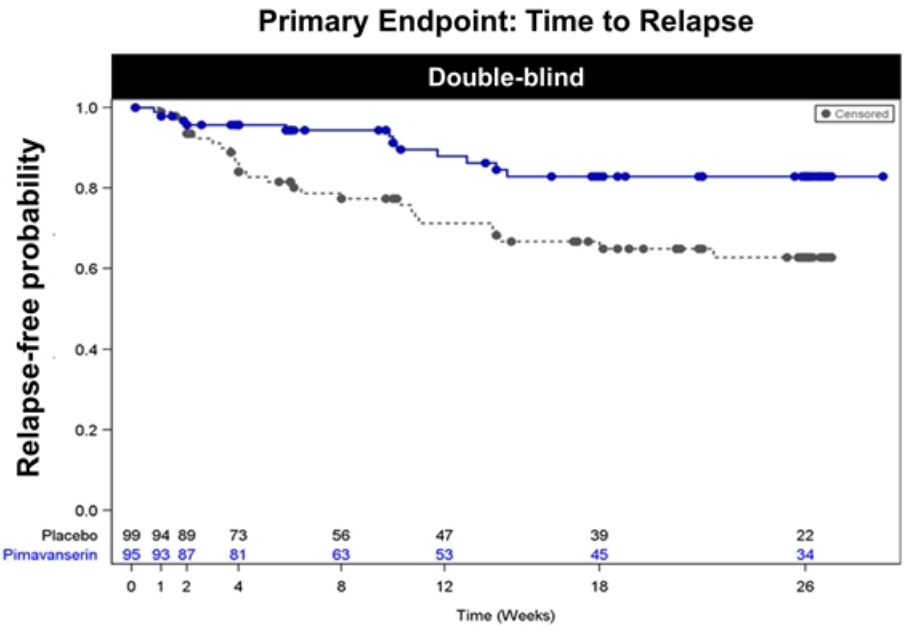
ACADIA® Pharmaceuticals

2.8 Fold Reduction in Risk of Relapse of Psychosis



Hazard Ratio = 0.353

One-sided p-value = 0.0023

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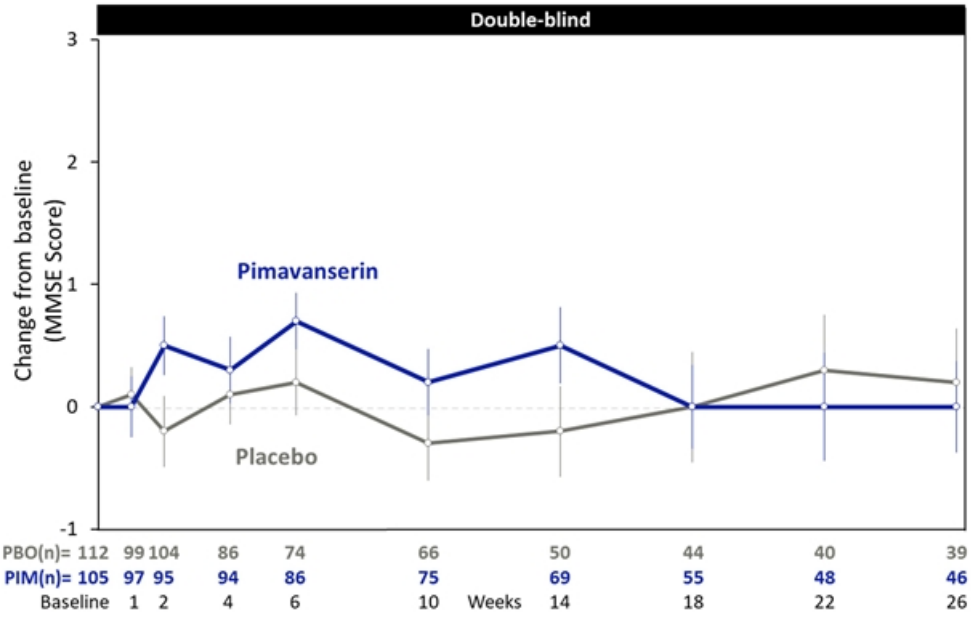
No Negative Impact on Cognition (MMSE) Over 6 Months Compared to Placebo[1]



[1][Mean +/- SE] (OC) DB safety dataset respectively. MMSE = Mini-Mental Status Examination, a test of cognitive function. Data originally presented at CTAD 2019 on 12/4/2019.
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.
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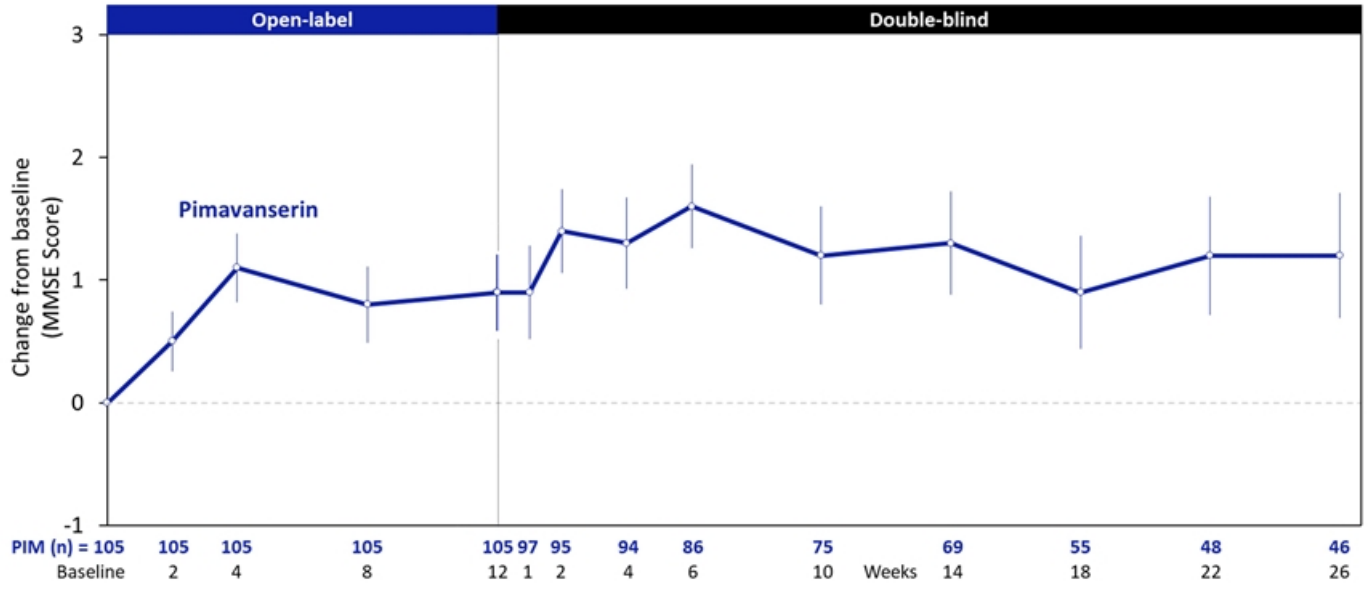
ACADIA® Pharmaceuticals

No Negative Impact on Cognition (MMSE) Over 9 Months of Treatment[1]



[1][Mean +/- SE] (OC) OL and DB safety dataset respectively. MMSE = Mini-Mental Status Examination, a test of cognitive function. Data originally presented at CTAD 2019 on 12/4/2019.
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DRP Next Steps

1. **Pre-sNDA meeting request submitted** ✓
2. **Plan to submit sNDA in summer 2020**

sNDA will include the following:

Pivotal Efficacy	Supportive Efficacy	Large Safety Database
Positive Phase 3 HARMONY Study	Positive Phase 2 (019) Alzheimer's Disease Psychosis Study[1] & Positive data in PDP (020) patients with dementia[2]	Safety and Tolerability Data from Completed & Ongoing Studies

Pimavanserin has Breakthrough Therapy Designation for the Treatment of DRP

[1]Ballard C, et al. Lancet. 2018;17:213-222.
[2]NUPLAZID Prescribing Information; Cummings J, et al. Lancet. 2014;383:533-540.
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.
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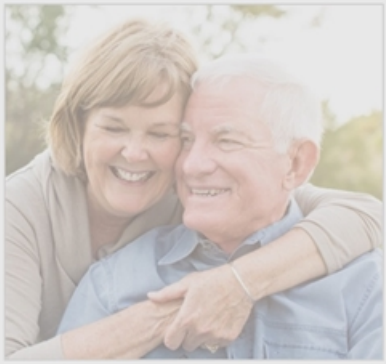
2020 Strategic Pillars

Drive
NUPLAZID® Growth in PDP

Deliver
DRP Opportunity to the Market



Develop
Innovative Treatments For Unmet Needs

ACADIA® Pharmaceuticals

Innovative Late-Stage Pipeline

COMPOUND/ PROGRAM	INDICATION	PHASE 1	PHASE 2	PHASE 3	MARKETED
NUPLAZID® (pimavanserin)[1]	Hallucinations and Delusions associated with PD Psychosis				
Pimavanserin	Dementia-Related Psychosis				
Pimavanserin	Major Depressive Disorder *Adjunctive Therapy*				
Trofinetide[2]	Rett Syndrome				
Pimavanserin	Negative Symptoms of Schizophrenia				

[1]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.
[2]ACADIA has an exclusive license to develop and commercialize trofinetide in North America from Neuren Pharmaceuticals.
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Major Depressive Disorder – Adjunctive Therapy

High unmet need for differentiated adjunctive therapy

- **~17M patients in the U.S. have MDD**[1]
  - Majority of patients with MDD do not respond to initial antidepressant therapy
- **~2.5M treated with adjunctive therapy**[2]
- **Adjunctive use of existing antipsychotics can lead to significant side effects:**
  - Sexual dysfunction
  - Sedation
  - Weight gain
  - Cognitive impairment
  - Extrapyramidal symptoms
  - Rare but serious tardive dyskinesia

[1]National Institute of Mental Health. (2017). Major Depression. Retrieved from http://www.nimh.nih.gov/health/statistics/major-depression.shtml.
[2]IMS NSP, NPA, NDTI MAT-24 month data through Aug-2017; *PLOS One*, Characterization of Treatment Resistant Depression Episodes in a Cohort of Patients from a US Commercial Claims Database, Oct 2013, Vol 8, Issue 10.

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Advancing Adjunctive Treatment for MDD

CLARITY Results

Meaningful Efficacy:

Primary endpoint achieved – Depression[1]

- **HAMD-17 (*p-value=0.039*)**

Robust effect in the parallel design Stage 1

- **HAMD-17 (*p-value = 0.0003;* Effect size = 0.63*)***

Key secondary endpoint achieved - Disability[1]

- **SDS (*p-value=0.004*)**

Secondary Outcome Findings:

- Early and sustained antidepressant treatment effect[2]
- Improvement in sexual dysfunction symptoms
- Improvement in daytime sleepiness
- No meaningful weight gain
- No cognitive side effects observed
- No extrapyramidal symptoms observed
- No tardive dyskinesia observed

CLARITY-2 Phase 3 Study Results Expected 4Q 2020

Two ongoing Phase 3 studies with only one additional positive study necessary for sNDA

[1]HAMD-17: 17-item Hamilton Depression Rating Scale; SDS = Sheehan Disability Scale.
[2]Week 1 separation from placebo observed in Stage 1 (n=207) and Week 10 separation from placebo observed in Stage 1 patients who were not re-randomized in Stage 2 (n=174).
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Negative Symptoms of Schizophrenia

No FDA-approved treatment for the negative symptoms of schizophrenia

- **~40 - 50% of schizophrenia patients experience predominant negative symptoms**[1]
- **Negative symptoms include** apathy, lack of emotion, social withdrawal, restricted speech, and blunted affect and can lead to:
  - Low social functioning
  - Long-term disability
  - Significant caregiver burden

[1]Studies suggest that ~40-50% of schizophrenia patients experience predominant negative symptoms; Patel et al. 2015, Haro et al., 2015, Bobes et al. 2010, and Chue and Lalonde, 2014. [2]According to National Institute of Mental Health; Martin Lepage et al. The Prevalence of Negative Symptoms Across the Stages of the Psychosis Continuum, Schizophrenia Bulletin. Mar 2017, Vol 43 and ACADIA market research.

ACADIA® Pharmaceuticals

Summary of Top-line ADVANCE Results

1 **The study achieved statistical significance on the primary endpoint**

- Improvement in NSA-16[1] total score compared to placebo at 26 weeks
  p-value = 0.043
- Greater improvement on NSA-16 was observed in patients on the higher 34 mg dose (n=107) vs. placebo ***unadjusted p-value = 0.0065***
- **Second pivotal study will evaluate 34 mg vs. placebo**
  - ***Study to commence in summer 2020***

2 **Pimavanserin was well-tolerated when added to background antipsychotic therapy with low rates of AEs, SAEs, and discontinuations**

[1]NSA-16: Negative Symptom Assessment-16.

ACADIA® Pharmaceuticals

Trofinetide for the Treatment of Rett Syndrome

No FDA-approved treatment for Rett syndrome

- **Debilitating neurologic rare disease**
- **6,000 to 9,000 patients in the U.S.**[1]
- **Symptoms manifest primarily in young females:**
  - Cognitive, sensory, emotional, and motor impairment
  - Loss of independence
  - Loss of purposeful hand use
  - Loss of spoken communication

[1]U.S. prevalence estimate based on incidence rates from the National Institutes of Health – National Institute of Neurological Disorders and Stroke.

ACADIA® Pharmaceuticals

Trofinetide Clinical Program

Phase 2 Study

Phase 2 study:

- Statistically significant improvements in **RSBQ** and **CGI-I**
- Positive Phase 2 study results published in ***Neurology***®[1]

Clinical Program

LAVENDER Phase 3 study ongoing:

- ~180 females (ages 5 – 20) with Rett syndrome
- Double-blind, placebo-controlled
- Co-primary endpoints: RSBQ and CGI-I
- 12-week study duration

LILAC 9-month extension study:

- To evaluate LT tolerability and safety of trofinetide

LAVENDER Results Expected in 2021

RSBQ = Rett Syndrome Behaviour Questionnaire (caregiver assessment) in girls 5 –15 years of age.
CGI-I = Clinical Global Impression Scale-Improvement (physician assessment) in girls 5 –15 years of age.

[1]Glaze D, et al. *Neurology*. Apr 2019, 92 (16) e1912-e1925.

Upcoming Clinical and Regulatory Milestones

COMPOUND	INDICATION	MILESTONE	EXPECTED TIMING
Pimavanserin	Dementia-Related Psychosis	Pre-sNDA Meeting Request Submitted	1Q20 ✓
		sNDA Submission	Summer 2020
Pimavanserin	Major Depressive Disorder *Adjunctive Therapy*	CLARITY-2 Results Expected	4Q20
		CLARITY-3 Results Expected	1H21
Pimavanserin	Negative Symptoms of Schizophrenia	Initiate ADVANCE-2	Summer 2020
Trofinetide	Rett Syndrome	LAVENDER Results Expected	2021

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ACADIA® Pharmaceuticals

ACADIA® Pharmaceuticals

Improving lives for patients, caregivers and families