



## First Quarter 2020 Earnings Call

MAY 7, 2020

# 1Q 2020 Earnings Call Agenda

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## INTRODUCTION

Mark Johnson | Vice President, Investor Relations

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## OPENING REMARKS

Steve Davis | Chief Executive Officer

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## COMMERCIAL UPDATE

Michael Yang | Chief Commercial Officer

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## R&D UPDATE

Serge Stankovic, M.D., M.S.P.H. | President

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## FINANCE UPDATE

Elena Ridloff | Chief Financial Officer

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## CLOSING REMARKS

Steve Davis | Chief Executive Officer

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## Q&A

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# Forward-Looking Statement

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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; (v) our estimates regarding our future financial performance, cash position or capital requirements; and (vi) currently anticipated impacts of COVID-19 on ACADIA's business, including its commercial sales operations, current and planned clinical trials, supply chain, and guidance for full-year 2020 NUPLAZID net sales and certain expense line items.

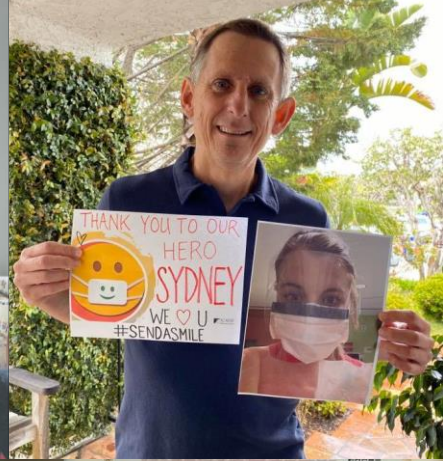
In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions (including the negative thereof) intended to identify forward-looking 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, 2019 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.

# Opening Remarks

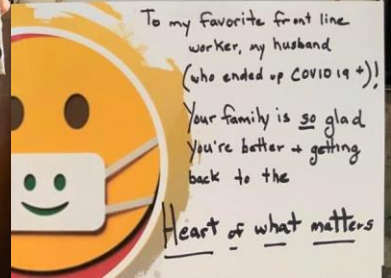
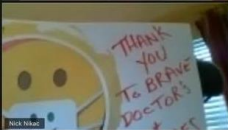
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Steve Davis  
CEO





I would like to recognize Bhavin, my son, a Pre-Med Student at Rutgers had been supporting RWJ University hospital, Somerset as CCT for clinical exposure. He is now Covid-19 volunteer staff at RWJ. I am proud of his passion for Humanity, and wish him be safe.  
# Sendasmile



# Robust Response to COVID-19

## Long-term business fundamentals strong

### SALES & MARKETING



VIRTUAL HCP ENGAGEMENTS  
& ONLINE PRESCRIBING CAPABILITIES  
FOR NUPLAZID®

PROVIDING EDUCATIONAL RESOURCES  
TO HCPs AND PATIENTS  
TO NAVIGATE TELEMEDICINE

### SUPPLY CHAIN



DELIVERING UNINTERRUPTED  
SUPPLY OF NUPLAZID TO PATIENTS

SPECIALTY PHARMACY CHANNEL  
PROVIDES RXs VIA MAIL

SPECIALTY DISTRIBUTION CHANNEL  
PROVIDES RXs DIRECTLY TO FACILITIES

### RESEARCH & DEVELOPMENT



COMMITTED TO ADVANCING  
LATE-STAGE CLINICAL PROGRAMS

QUALIFYING SITES IN ALL ONGOING  
TRIALS TO CONTINUE ENROLLMENT OF  
NEW PATIENTS

## 2020 Strategic Pillars

### **Drive** NUPLAZID® Growth in PDP



### **Deliver** DRP Opportunity to the Market



### **Develop** Innovative Treatments For Unmet Needs



**2020: A Transformational Year**

## Drive NUPLAZID® Growth in PDP

### 1Q 2020

- **1Q 2020 Net Sales = \$90.1M; 43% YoY growth**
- Strong commercial execution drove NUPLAZID performance

### FY 2020

- **FY 2020 Net Sales Guidance: \$420 - \$450M; +28% YoY<sup>1</sup>**
- Providing best-in-class virtual education and engagement

### Long-term

- Significant market opportunity
- New patient share continues to exceed overall market share



## Deliver Dementia-Related Psychosis (DRP) Opportunity to the Market

✓ Pre-sNDA Meeting  
with FDA in Q1

➤ On-track for sNDA submission  
this summer

➤ Expecting priority review as pimavanserin has  
Breakthrough Therapy designation for DRP



**Potential Approval for DRP Around Year-End 2020**

# Develop Innovative Treatments For Unmet Needs

## Late-Stage Pipeline

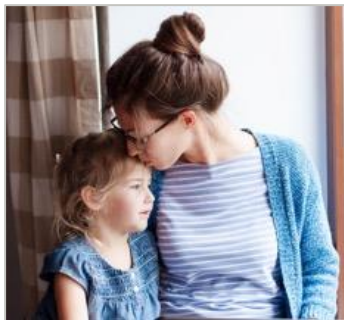
### Adjunctive Treatment of Major Depressive Disorder:

Pursuing a strategy to not enroll additional patients and instead combine identical Phase 3 studies, CLARITY-2 and CLARITY-3, into one study with data in 3Q20

### Negative Symptoms of Schizophrenia:

Plan to initiate Phase 3 ADVANCE-2 study in 2H20

## Trofinetide: RPD Designation



FDA granted *Rare Pediatric Disease (RPD)* designation to trofinetide for the treatment of Rett syndrome

Phase 3 LAVENDER study data expected in 2021

## Vanderbilt Partnership



Exclusive license agreement and research collaboration

Novel CNS therapeutic program targeting muscarinic M1 receptors (M1 PAM program)

Lead compound in Phase 1

# Commercial Update

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Michael Yang  
Chief Commercial Officer

# 1Q Commercial Performance

## Continuing Patients



Sustained consistently high monthly bottle fulfillment rates for established patients

## New Patients



Delivered new-to-brand patients consistent with previous quarters from both specialty pharmacy and specialty distribution channels

## COVID-19 Impact



- Short-term pressure from a decline in physician visits
- NUPLAZID® new patient starts have outpaced the overall market<sup>1</sup>



# NUPLAZID® 2020 Growth Initiatives in PDP

## New Patient Identification: Pivot to Virtual Engagements

Virtual peer-to-peer educational programs

Treatment forms for NUPLAZID  
now available to HCPs online

Utilizing digital patient and caregiver  
consumer campaigns

## Establishing NUPLAZID as Standard of Care for PDP

The inclusion of NUPLAZID in the  
Movement Disorders Society guidelines

Long-term (open-label) NUPLAZID safety data

Data highlighting caregiver burden of disease<sup>1</sup>

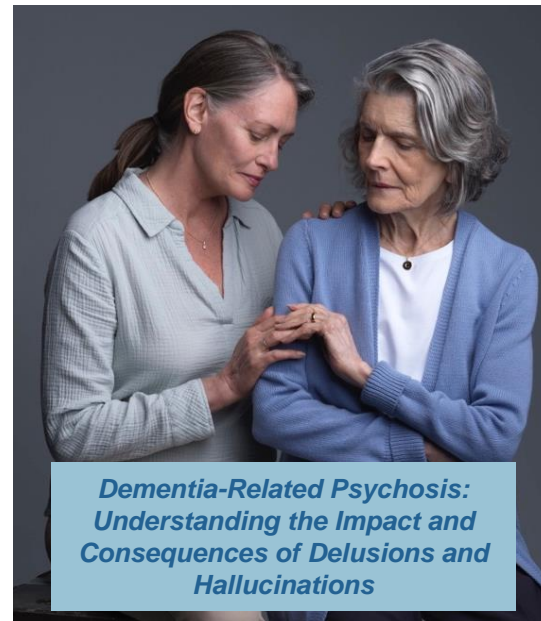
34 mg capsule benefits

**PDP represents a serious medical condition and requires treatment**  
**Continued significant growth opportunity**



# DRP Launch Preparations On-track

- Potential to be the first and only FDA-approved treatment for DRP
- Focus on market research and disease awareness, including:
  - Advisory boards
  - Payer engagements
- Disease education website: [www.morethancognition.com](http://www.morethancognition.com)



**DRP: 1.2M treated population<sup>1</sup> that is currently 10X larger than PDP**

# R&D Update

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Serge Stankovic, M.D., M.S.P.H.  
President

# Regulatory Update on Dementia-Related Psychosis

- ✓ **Pre-sNDA meeting completed in Q1**
- **On-track to submit sNDA in summer 2020**

*sNDA will include the following:*

## Pivotal Efficacy

Positive Phase 3  
HARMONY Study

## Supportive Efficacy

Positive Phase 2 (019)  
Alzheimer's Disease  
Psychosis Study<sup>1</sup>  
&  
Positive data in PDP (020)  
patients with dementia<sup>2</sup>

## Large Safety Database

Safety and  
Tolerability Data  
from Completed  
& Ongoing Studies

**Pimavanserin has Breakthrough Therapy Designation  
for the Treatment of DRP**

# Adjunctive Treatment for Major Depressive Disorder

## High Unmet Need



- ~17M patients in the U.S. have MDD<sup>1</sup>
- ~2.5M treated with adjunctive therapy<sup>2</sup>
- **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

## CLARITY-2 and CLARITY-3:

- Two identically designed ~280 patient, 6 week, randomized, double-blind, placebo-controlled, multi-center studies
- Primary endpoint: Change from baseline on Hamilton Depression Rating Scale (HAM-D-17)

## Adjunctive Treatment for Major Depressive Disorder

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**Both Phase 3 studies, CLARITY-2 and CLARITY-3, slightly over 50% enrolled; enrollment currently paused due to COVID-19**

- Ready to re-initiate new patient enrollment, *however...*
- Pursuing strategy to not enroll any new patients and combine existing data from identical Phase 3 studies into one study with pre-specified analyses
  - Scheduled FDA discussion in 2Q20
  - Potential top-line results in 3Q20
    - If positive, submit sNDA with combined results and positive CLARITY-1 study
    - If negative, initiate additional Phase 3 study in 2H20



# Negative Symptoms of Schizophrenia

## High Unmet Need



- **No FDA-approved treatment for the negative symptoms of schizophrenia**
- **~40 - 50% of schizophrenia patients experience predominant negative symptoms<sup>1</sup>**
- **Negative symptoms include** social withdrawal, lack of emotion, restricted speech, and blunted affect and can lead to:
  - Low social functioning
  - Long-term disability
  - Significant caregiver burden

## Current Status:

Phase 3 ADVANCE-2 study expected to commence in 2H20

# Trofinetide for the Treatment of Rett Syndrome

## High Unmet Need



- No FDA-approved treatment for Rett syndrome
- Debilitating rare neurologic disease
- 6,000 to 9,000 patients in the U.S.<sup>1</sup>
- Symptoms manifest primarily in young females:
  - Cognitive, sensory, emotional, and motor impairment
  - Loss of independence
  - Loss of purposeful hand use
  - Loss of spoken communication

## Current Status:

Results from Phase 3 LAVENDER study anticipated in 2021

# Innovative Development Pipeline

COMPOUND/ PROGRAM	INDICATION	PHASE 1	PHASE 2	PHASE 3	MARKETED
NUPLAZID® (pimavanserin) <sup>1</sup>	Parkinson's Disease Psychosis				
Pimavanserin	Dementia-Related Psychosis				
Pimavanserin	Major Depressive Disorder <i>Adjunctive Therapy</i>				
Trofinetide <sup>2</sup>	Rett Syndrome				
Pimavanserin	Negative Symptoms of Schizophrenia				
M1 PAM <sup>3</sup>	CNS Disorders				

<sup>1</sup>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.

<sup>2</sup>ACADIA has an exclusive license to develop and commercialize trofinetide in North America from Neuren Pharmaceuticals.

<sup>3</sup>ACADIA has an exclusive worldwide license to develop and commercialize compounds in the M1 PAM program from Vanderbilt University.

Provided May 7, 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.

# Finance Update

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Elena Ridloff  
Chief Financial Officer

# 1Q 2020 Financial Highlights

Millions, Except EPS	1Q20 (GAAP)	1Q19 (GAAP)	YoY Change
<b>Total Revenue</b>	\$90.1	\$63.0	+43%
<b>Cost of Product Sales, License Fees and Royalties</b>	\$5.0	\$4.6	+9%
<b>R&amp;D<sup>1</sup></b>	\$72.6	\$52.9	+37%
<b>SG&amp;A</b>	\$102.0	\$93.1	+10%
<b>Net Loss</b>	(\$88.0)	(\$85.3)	+3%
<b>Weighted Average Basic Shares Outstanding</b>	155.4	144.0	+8%
<b>EPS</b>	(\$0.57)	(\$0.59)	+3%
<b>Cash Balance<sup>2</sup></b>	\$651.4		



# FY2020 Financial Guidance

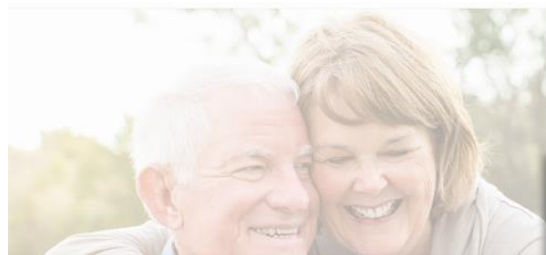
FY 2020	Previous Guidance	Revised Guidance	Commentary
<b>NUPLAZID® Net Sales</b>	<b>\$440 to \$470M</b>	<b>\$420 to \$450M</b>	+28% YoY Growth <sup>1</sup>
<b>Gross-to-Net</b>	<b>17-18%</b>	<b>17-18%</b>	-
<b>GAAP R&amp;D Expense</b>	<b>\$270 to \$285M</b>	<b>\$270 to \$285M</b>	<i>Expect to be towards the low-end of the range</i>
<b>GAAP SG&amp;A Expense</b>	<b>\$440 to \$460M</b>	<b>\$425 to \$445M</b>	<i>Reflects naturally lower costs due to current virtual environment</i>
<b>Non-Cash Stock-Based Compensation Expense</b>	<b>\$90 to \$100M</b>	<b>\$90 to \$100M</b>	
<b>Projected Year-End Cash Balance<sup>2</sup></b>	<b>\$470 to \$500M</b>	<b>\$470 to \$500M</b>	

# Closing Remarks

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Steve Davis  
CEO

# ACADIA in 2020 – Building a Leading CNS Platform



DRIVE NUPLAZID®  
GROWTH IN PDP

**\$420 - \$450M**  
FY2020 Net Sales Guidance



DELIVER DRP OPPORTUNITY  
TO THE MARKET

POTENTIAL APPROVAL:  
~YE 2020



DEVELOP INNOVATIVE TREATMENTS  
FOR UNMET NEEDS

MULTI-YEAR CADENCE OF  
POTENTIAL APPROVALS



**2020: A Transformational Year**



## Q&A

### First Quarter 2020 Earnings

MAY 7, 2020

