ACADIA Pharmaceuticals Reports First Quarter 2020 Financial Results

May 7, 2020

- 1Q20 Net Sales of $90.1 Million, a 43% Increase Over 1Q19

- On-track to submit supplemental NDA for pimavanserin for the treatment of dementia-related psychosis (DRP) this summer

- Announced worldwide license agreement and collaboration with Vanderbilt University for new central nervous system (CNS) therapeutic program

- 2020 revenue guidance reduced by approximately 5% due to currently anticipated COVID-19 impact

SAN DIEGO--(BUSINESS WIRE)--May 7, 2020-- ACADIA Pharmaceuticals Inc. (Nasdaq: ACAD), a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders, today announced its financial results for the quarter ended March 31, 2020.

"ACADIA entered 2020 with positive momentum. Successful execution of our commercial efforts led to continued strong performance of NUPLAZID ® for Parkinson's disease psychosis and our plans remain on track for delivering a potential second indication with pimavanserin for the treatment of DRP. We also continue to invest in our late-stage pipeline and business development opportunities to shape our mid and long-term growth strategy," said Steve Davis, ACADIA's Chief Executive Officer. "Our results this quarter reflect the dedication of our employees and I am proud of our team's commitment to the patients we serve while adapting to the challenges of the global COVID-19 pandemic."

Company Updates

- ACADIA completed a pre-sNDA meeting with the U.S. Food and Drug Administration and is on-track to submit a supplemental NDA this summer for pimavanserin as a potential breakthrough therapy for DRP.
- The FDA granted Rare Pediatric Disease designation to trofinetide for the treatment of Rett syndrome, a serious and rare neurological disorder.
- ACADIA entered into an exclusive worldwide license agreement and research collaboration with Vanderbilt University, adding an early clinical stage program focused on positive allosteric modulators (PAMs) of the M1 receptor to potentially treat a range of CNS disorders.

Financial Results

Revenue

Net sales of NUPLAZID (pimavanserin) were $90.1 million for the three months ended March 31, 2020, an increase of 43% as compared to $63.0 million reported for the three months ended March 31, 2019.

Research and Development

Research and development expenses for the three months ended March 31, 2020 were $72.6 million, compared to $52.9 million for the same period of 2019. The increase was primarily due to an upfront payment of $10.0 million to Vanderbilt University for the M1 PAM program and increased development costs associated with trofinetide.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended March 31, 2020 were $102.0 million, compared to $93.1 million for the same period of 2019. The increase was largely due to increased personnel and medical affairs costs.

Net Loss

For the three months ended March 31, 2020, ACADIA reported a net loss of $88.0 million, or $0.57 per common share, compared to a net loss of $85.3 million, or $0.59 per common share, for the same period in 2019. The net losses for the three months ended March 31, 2020 and 2019 included $22.3 million and $19.9 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At March 31, 2020, ACADIA's cash, cash equivalents, and investment securities totaled $651.4 million, compared to $697.4 million at December 31, 2019.

2020 Financial Guidance

ACADIA is revising 2020 net sales and expense guidance to reflect the currently anticipated impact of the COVID-19 pandemic. ACADIA's 2020 net sales guidance reflects annual revenue growth of approximately 28% for NUPLAZID, at the mid-point of the range.

- NUPLAZID net sales guidance is decreased to $420 to $450 million from the previous range of $440 to $470 million.

- GAAP R&D guidance of $270 to $285 million is unchanged from prior guidance.
- GAAP SG&A guidance is decreased to $425 to $445 million from the previous range of $440 to $460 million.
- Non-cash stock-based compensation expense guidance of $90 to $100 million is unchanged compared to prior guidance.
- 2020 year-end cash, cash equivalents, and investment securities of $470 to $500 million is unchanged compared to prior guidance.

Conference Call and Webcast Information

ACADIA management will review its first quarter financial results and operations via conference call and webcast today at 4:30 p.m. Eastern Time. The conference call may be accessed by dialing 855-638-4820 for participants in the United States or Canada and 443-877-4067 for international callers (reference passcode 1974276). A telephone replay of the conference call may be accessed through May 21, 2020 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 1974276). 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 until June 4, 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, major depressive disorder, the negative symptoms of schizophrenia, 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; unanticipated 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. 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, 2019 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 March 31,	
	2020	**2019**
Revenues		
Product sales, net	$ 90,068	$ 62,959

Total revenues	90,068	62,959
Operating expenses		
Cost of product sales, license fees and royalties [1]	4,974	4,580
Research and development [1]	72,636	52,923
Selling, general and administrative [1]	101,973	93,090
Total operating expenses	179,583	150,593
Loss from operations	(89,515)	(87,634)
Interest income, net	2,989	2,934
Other expense	(1,497)	(229)
Loss before income taxes	(88,023)	(84,929)
Income tax expense	—	375
Net loss	$ (88,023)	$ (85,304)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.59)
Weighted average common shares outstanding, basic and diluted	155,368	143,981

[1] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 849	$ 995
Research and development	$ 8,457	$ 7,880
Selling, general and administrative	$ 13,042	$ 11,008

ACADIA PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	March 31, 2020	**December 31, 2019**
	(unaudited)	
Assets		

Cash, cash equivalents and investment securities	$ 651,406	$ 697,429
Accounts receivable, net	41,636	35,781
Interest and other receivables	2,935	2,093
Inventory	6,318	6,341
Prepaid expenses	22,126	18,606
Total current assets	724,421	760,250
Property and equipment, net	5,089	3,180
Operating lease right-of-use assets	8,613	9,524
Intangible assets, net	2,215	2,585
Restricted cash	5,770	4,787
Other assets	1,342	2,857
Total assets	$ 747,450	$ 783,183
Liabilities and stockholders' equity		
Accounts payable	$ 6,623	$ 7,222
Accrued liabilities	93,118	67,604
Total current liabilities	99,741	74,826
Operating lease liabilities	6,090	6,361
Other long-term liabilities	3,237	2,861
Total liabilities	109,068	84,048
Total stockholders' equity	638,382	699,135
Total liabilities and stockholders' equity	$ 747,450	$ 783,183

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Media Contact:
ACADIA Pharmaceuticals Inc.
Stephanie Fagan
(858) 212-0534
media@acadia-pharm.com

Investor Contact:
ACADIA Pharmaceuticals Inc.
Mark Johnson, CFA
(858) 261-2771

ir@acadia-pharm.com

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