ACADIA Pharmaceuticals Reports Second Quarter 2020 Financial Results

August 5, 2020

- 2Q20 Net Sales of $110.1 Million, a 32% Increase Over 2Q19

- FDA filed the supplemental NDA for pimavanserin for the treatment of dementia-related psychosis with a PDUFA action date set for April 3, 2021

- Initiated ADVANCE-2, a Phase 3 study evaluating pimavanserin for the treatment of the negative symptoms of schizophrenia

SAN DIEGO--(BUSINESS WIRE)--Aug. 5, 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 second quarter ended June 30, 2020.

"In the first half of 2020 we drove robust growth of NUPLAZID®. With the FDA filing of our sNDA for dementia-related psychosis we are one step closer to potentially delivering the first and only approved treatment for this devastating condition," said Steve Davis, ACADIA's Chief Executive Officer. "Building upon the successful development of our PDP and DRP programs, our clinical team is focused on advancing our innovative early- and late-stage pipeline."

Company Updates

- The U.S. Food and Drug Administration (FDA) filed the supplemental NDA for pimavanserin for the treatment of the hallucinations and delusions associated with dementia-related psychosis (DRP). The FDA has assigned a PDUFA (Prescription Drug User Fee Act) action date of April 3, 2021.
- ACADIA announced top-line results from the Phase 3 CLARITY study of pimavanserin for adjunctive treatment in patients with major depressive disorder. The study did not achieve statistical significance on the primary endpoint which was the 17-item Hamilton Depression Rating Scale (HAMD-17) total score.
- ACADIA initiated its second pivotal study, ADVANCE-2, a 26-week, placebo-controlled, 386 patient Phase 3 study designed to evaluate the efficacy and safety of the 34 mg dose of pimavanserin for the treatment of the negative symptoms of schizophrenia.
- ACADIA presented important clinical data at recent virtual medical congresses:
    - In May, at the 2020 American Society of Clinical Psychopharmacology virtual annual meeting, ACADIA presented six posters and an oral presentation on the positive pivotal ADVANCE study results, titled *ADVANCE: Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of Adjunctive Pimavanserin in Patients with Negative Symptoms of Schizophrenia*.
    - In July, at the 2020 Alzheimer's Association International Conference virtual event, ACADIA presented nine posters and an oral presentation on the positive findings from the open-label portion of the HARMONY study, titled *HARMONY: Response to Pimavanserin in the 12-Week, Open-label Treatment Phase*.
- ACADIA appointed Mark Schneyer as Senior Vice President, Business Development and Chief Business Officer and appointed Spyros Papapetropoulos, M.D., Ph.D., as Senior Vice President, Head of Clinical Development.

Financial Results

Revenue

Net sales of NUPLAZID (pimavanserin) were $110.1 million for the three months ended June 30, 2020, an increase of 32% as compared to $83.2 million reported for the three months ended June 30, 2019. For the six months ended June 30, 2020 and 2019, ACADIA reported net product sales of $200.2 million and $146.2 million, respectively.

Research and Development

Research and development expenses for the three months ended June 30, 2020 were $64.3 million, compared to $67.3 million for the same period of 2019. The decrease in the three month period ending June 2020 compared to June 2019 was primarily due to lower development costs for pimavanserin in schizophrenia and DRP. For the six months ended June 30, 2020 and 2019, research and development expenses were $136.9 million and $120.2 million, respectively. The increase during the six month period ending June 2020 compared to June 2019 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, offset by decreased development costs for pimavanserin in schizophrenia and DRP.

Selling, General and Administrative

Selling, general and administrative expenses for the three months ended June 30, 2020 were $84.3 million, compared to $68.0 million for the same period of 2019. For the six months ended June 30, 2020 and 2019, selling, general and administrative expenses were $186.3 million and $161.1 million, respectively. The increase during the 2020 periods as compared to 2019 was primarily due to increased advertising and promotional costs as well as an increase in personnel and related costs.

Net Loss

For the three months ended June 30, 2020, ACADIA reported a net loss of $42.1 million, or $0.27 per common share, compared to a net loss of $54.9 million, or $0.38 per common share, for the same period in 2019. The net losses for the three months ended June 30, 2020 and 2019 included $19.5 million and $20.4 million, respectively, of non-cash stock-based compensation expense. For the six months ended June 30, 2020, ACADIA reported a net loss of $130.2 million, or $0.83 per common share, compared to a net loss of $140.2 million, or $0.97 per common share, for the same period in 2019. The net losses for the six months ended June 30, 2020 and 2019 included $41.9 million and $40.3 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments

At June 30, 2020, ACADIA's cash, cash equivalents, and investment securities totaled $658.6 million, compared to $697.4 million at December 31, 2019.

2020 Financial Guidance

- NUPLAZID net sales guidance is updated to $430 to $450 million from the previous range of $420 to $450 million.
- GAAP R&D guidance is decreased to $265 to $280 million from the previous range of $270 to $285 million.
- GAAP SG&A guidance is decreased to $400 to $420 million from the previous range of $425 to $445 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 is expected to be $570 to $590 million from a previous range of $470 to $500 million.

Conference Call and Webcast Information

ACADIA management will review its second 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 9828845). A telephone replay of the conference call may be accessed through August 19, 2020 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 9828845). 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 September 2, 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 any other neuropsychiatric disorders. 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's development efforts are focused on pimavanserin for additional neuropsychiatric conditions, trofinetide for Rett syndrome, and an early-stage muscarinic receptor program. 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 June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues				
Product sales, net	$ 110,103	$ 83,205	$ 200,171	$ 146,164
Total revenues	110,103	83,205	200,171	146,164
Operating expenses				
Cost of product sales, license fees and royalties [1]	5,474	4,995	10,448	9,575
Research and development [1]	64,295	67,320	136,931	120,243
Selling, general and administrative [1]	84,344	67,981	186,317	161,071
Total operating expenses	154,113	140,296	333,696	290,889
Loss from operations	(44,010)	(57,091)	(133,525)	(144,725)
Interest income, net	1,825	2,527	4,814	5,461
Other income (expense)	437	(12)	(1,060)	(241)
Loss before income taxes	(41,748)	(54,576)	(129,771)	(139,505)
Income tax expense	393	365	393	740
Net loss	$ (42,141)	$ (54,941)	$ (130,164)	$ (140,245)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.38)	$ (0.83)	$ (0.97)
Weighted average common shares outstanding, basic and diluted	156,535	144,314	155,951	144,148

[1] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 743	$ 803	$ 1,592	$ 1,798
Research and development	$ 7,235	$ 7,901	$ 15,692	$ 15,781

Selling, general and administrative	$ 11,529	$ 11,718	$ 24,571	$ 22,726

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2020	**December 31, 2019**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 658,551	$ 697,429
Accounts receivable, net	43,785	35,781
Interest and other receivables	2,343	2,093
Inventory	6,210	6,341
Prepaid expenses	24,846	18,606
Total current assets	735,735	760,250
Property and equipment, net	6,687	3,180
Operating lease right-of-use assets	7,880	9,524
Intangible assets, net	1,846	2,585
Restricted cash	5,770	4,787
Other assets	1,731	2,857
Total assets	$ 759,649	$ 783,183
Liabilities and stockholders' equity		
Accounts payable	$ 6,466	$ 7,222
Accrued liabilities	79,956	67,604
Total current liabilities	86,422	74,826
Operating lease liabilities	5,669	6,361
Other long-term liabilities	4,545	2,861
Total liabilities	96,636	84,048

Total stockholders' equity	663,013	699,135
Total liabilities and stockholders' equity	$ 759,649	$ 783,183

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