Acadia Pharmaceuticals Reports Third Quarter 2020 Financial Results

November 4, 2020

- 3Q20 Net Sales of $120.6 Million, a 27% Increase Over 3Q19

SAN DIEGO--(BUSINESS WIRE)--Nov. 4, 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 third quarter ended September 30, 2020.

"This quarter we drove strong performance through the continued growth of new prescribers with more patients benefitting from NUPLAZID® treatment for their Parkinson's disease psychosis and remain on-track with our supplemental NDA for the treatment of dementia-related psychosis with a PDUFA date of April 3, 2021," said Steve Davis, Acadia's Chief Executive Officer. "We continue to advance our late-stage programs and invest in new opportunities through business development, highlighted by our recent acquisition of CerSci Therapeutics which expands our clinical pipeline with an innovative first-in-class, non-opioid, acute and chronic pain program."

Company Updates

- New clinical analyses across multiple studies of pimavanserin are being presented at this week's 13th Clinical Trials on Alzheimer's Disease (CTAD) meeting, including:
  - Oral presentation by Dr. Clive Ballard, University of Exeter Medical School: *"Impact of Pimavanserin on Cognitive Measures in Patients with Neurodegenerative Disease: Results from 4 Placebo-Controlled Clinical Studies."*
  - Poster presentation by Dr. Daniel Weintraub, Perelman School of Medicine at the University of Pennsylvania: *"Impact of Pimavanserin Treatment on Motor Function in Patients with Neurodegenerative Disease: Results from 3 Clinical Studies."*
- In October, Acadia announced a partnership with The Lewy Body Dementia Association (LBDA) on the release of a disease education adaptation of the new documentary *Robin's Wish*©. The film is titled, "*SPARK - Robin Williams and his Battle with Lewy Body Dementia*©," and will be available to academic research institutions and universities as part of educational programming for healthcare professionals.
- In October, Acadia presented a poster titled "*Healthcare Resource Utilization and Associated Costs for Dementia Patients with Psychosis: A Medicare Database Study,*" at the Academy of Managed Care Pharmacy's (AMCP) Nexus conference, and received a Silver ribbon based on its relevance, originality, quality, bias and clarity of results.
- In August, Acadia acquired CerSci Therapeutics, a clinical-stage biotechnology company with worldwide rights to a portfolio of novel compounds for neurological conditions, including non-opioid therapies for acute and chronic pain. Acadia plans to initiate a Phase 2 program with the lead compound, ACP-044, in the first half of 2021.
- Appointed Dr. Gudarz Davar as Executive Vice President and Head of Research and Development, reporting to Serge Stankovic, M.D., M.S.P.H., President of Acadia.
- Elizabeth (Betsy) Garofalo, M.D. was appointed to the Acadia Board of Directors.

Financial Results

Revenue
Net sales of NUPLAZID (pimavanserin) were $120.6 million for the three months ended September 30, 2020, an increase of 27% as compared to $94.6 million reported for the three months ended September 30, 2019. For the nine months ended September 30, 2020 and 2019, Acadia reported net product sales of $320.7 million and $240.8 million, respectively.

Research and Development
Research and development expenses for the three months ended September 30, 2020 were $120.1 million, compared to $62.6 million for the same period of 2019. This increase was primarily due to $52.8 million in upfront consideration and transaction expenses related to the acquisition of CerSci Therapeutics. For the nine months ended September 30, 2020 and 2019, research and development expenses were $257.0 million and $182.9 million, respectively. This increase was primarily due to the acquisition of CerSci Therapeutics and the upfront payment to Vanderbilt University for the M1 PAM program.

Selling, General and Administrative
Selling, general and administrative expenses for the three months ended September 30, 2020 were $81.6 million, compared to $72.7 million for the same period of 2019. For the nine months ended September 30, 2020 and 2019, selling, general and administrative expenses were $267.9 million and $233.8 million, respectively. This increase 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 September 30, 2020, Acadia reported a net loss of $84.7 million, or $0.54 per common share, compared to a net loss of $42.0 million, or $0.29 per common share, for the same period in 2019. The net losses for the three months ended September 30, 2020 and 2019 included $21.4 million and $22.0 million, respectively, of non-cash stock-based compensation expense. For the nine months ended September 30, 2020, Acadia reported a net loss of $214.8 million, or $1.37 per common share, compared to a net loss of $182.2 million, or $1.26 per common share, for the same period in 2019. The net losses for the nine months ended September 30, 2020 and 2019 included $63.2 million and $62.5 million, respectively, of non-cash stock-based compensation expense.

Cash and Investments
At September 30, 2020, Acadia's cash, cash equivalents, and investment securities totaled $644.4 million, compared to $697.4 million at December 31, 2019.

2020 Financial Guidance

- Acadia reiterates its NUPLAZID net sales guidance of $430 to $450 million.
- GAAP R&D guidance is increased to $325 to $340 million from the previous range of $265 to $280 million, primarily as a result of the $52.8 million upfront and transaction expenses associated with the acquisition of CerSci Therapeutics.
- GAAP SG&A guidance is decreased to $385 to $400 million from the previous range of $400 to $420 million.
- Non-cash stock-based compensation expense guidance is decreased to $80 to $90 million from the previous range of $90 to $100 million.
- 2020 year-end cash, cash equivalents, and investment securities guidance of $570 to $590 million is unchanged.

Conference Call and Webcast Information
Acadia management will review its third 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 6266016). A telephone replay of the conference call may be accessed through November 18, 2020 by dialing 855-859-2056 for callers in the United States or Canada and 404-537-3406 for international callers (reference passcode 6266016). 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 December 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 trailblazing breakthroughs in neuroscience to elevate life through science. For more than 25 years we have been working at the forefront of healthcare to bring vital solutions to people who need them most. We developed and commercialized the first and only approved therapy for hallucinations and delusions associated with Parkinson's disease psychosis. Our late-stage development efforts are focused on dementia-related psychosis, negative symptoms of schizophrenia and Rett syndrome, and in early-stage clinical research we are exploring novel approaches to pain management, cognition and neuropsychiatric symptoms in central nervous system disorders. For more information, visit us at www.acadia-pharm.com and follow us on LinkedIn.

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, ACP-044 and the M1 PAM program; 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues				
Product sales, net	$ 120,577	$ 94,586	$ 320,748	$ 240,750
Total revenues	120,577	94,586	320,748	240,750
Operating expenses				
Cost of product sales, license fees and royalties [(1)]	4,801	4,689	15,249	14,264
Research and development [(1)]	120,083	62,622	257,014	182,865
Selling, general and administrative [(1)]	81,592	72,696	267,909	233,767
Total operating expenses	206,476	140,007	540,172	430,896
Loss from operations	(85,899)	(45,421)	(219,424)	(190,146)
Interest income, net	1,242	2,432	6,056	7,893
Other (expense) income	(202)	747	(1,262)	506
Loss before income taxes	(84,859)	(42,242)	(214,630)	(181,747)
Income tax expense	(199)	(264)	194	476
Net loss	$ (84,660)	$ (41,978)	$ (214,824)	$ (182,223)
Net loss per common share, basic and diluted	$ (0.54)	$ (0.29)	$ (1.37)	$ (1.26)
Weighted average common shares outstanding, basic and diluted	158,129	145,906	156,683	144,741

[(1)] Includes the following stock-based compensation expense

Cost of product sales, license fees and royalties	$ 495	$ 372	$ 2,087	$ 2,344

Research and development	$ 7,953	$ 8,680	$ 23,645	$ 24,461
Selling, general and administrative	$ 12,924	$ 12,971	$ 37,495	$ 35,697

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2020	**December 31, 2019**
	(unaudited)	
Assets		
Cash, cash equivalents and investment securities	$ 644,441	$ 697,429
Accounts receivable, net	46,344	35,781
Interest and other receivables	1,440	2,093
Inventory	7,979	6,341
Prepaid expenses	30,009	18,606
Total current assets	730,213	760,250
Property and equipment, net	8,427	3,180
Operating lease right-of-use assets	48,232	9,524
Intangible assets, net	1,477	2,585
Restricted cash	5,770	4,787
Other assets	1,545	2,857
Total assets	$ 795,664	$ 783,183
Liabilities and stockholders' equity		
Accounts payable	$ 3,471	$ 7,222
Accrued liabilities	88,385	67,604
Total current liabilities	91,856	74,826
Operating lease liabilities	45,343	6,361

Other long-term liabilities	3,598	2,861
Total liabilities	140,797	84,048
Total stockholders' equity	654,867	699,135
Total liabilities and stockholders' equity	$ 795,664	$ 783,183

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