

ADAMAS PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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**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): February 22, 2018

ADAMAS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36399
(Commission File Number)

42-1560076
(IRS Employer Identification No.)

**1900 Powell Street, Suite 750
Emeryville, CA**
(Address of principal executive offices)

94608
(Zip Code)

Registrant's telephone number, including area code: **(510) 450-3500**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- 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))

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 February 22, 2018, Adamas Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2017. A copy of the press release is furnished as Exhibit 99.1 to this report.

The information in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this current report shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this current report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	99.1 Press Release dated February 22, 2018.

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.

Adamas Pharmaceuticals, Inc.

Dated: February 22, 2018

By: /s/ Alfred G. Merriweather

Alfred G. Merriweather

Chief Financial Officer

Adamas Reports Recent Achievements and Financial Results for the Fourth Quarter and Full-Year 2017

EMERYVILLE, Calif., February 22, 2018 -- Adamas Pharmaceuticals, Inc. (Nasdaq: ADMS) today reported recent achievements and financial results for the fourth quarter and full-year ended December 31, 2017 .

“I’m very proud of the accomplishments made by the Adamas team in 2017, especially the approval and commercial availability of GOCOVRI™, the first and only FDA-approved treatment for dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy,” said Gregory T. Went, Ph.D., Founder, Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. “Parkinson’s disease is a particularly burdensome and costly disease, not only for patients, but also for their care partners and the healthcare system, which is why it was so important to bring to market a medicine that delivers substantial benefit in dyskinesia as well as a secondary benefit in OFF time. We are encouraged by the initial weeks of GOCOVRI’s full commercial launch and are pleased with the reaction we are receiving from physicians, patients, care partners and payers as we continue to educate them on the unique benefits of GOCOVRI.”

Dr. Went continued, “In addition, we are now capitalized to advance our clinical programs based upon our time-dependent biology approach and look forward to initiating the first Phase 3 study for ADS-5102 in multiple sclerosis patients with walking impairment early in the second quarter of 2018, and finalizing the clinical development pathway for ADS-4101 in epilepsy patients with partial onset seizures.”

Recent Achievements

GOCOVRI™ (amantadine) extended release capsules for the treatment of dyskinesia in patients with Parkinson’s disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications

- Commenced full U.S. commercial launch of GOCOVRI with 59 neurology account specialists in January 2018
- Received prescriptions for GOCOVRI from over 300 distinct prescribers as of February 16, 2018, up from 100 distinct prescribers as of December 31, 2017
- Published GOCOVRI open-label subgroup analysis in *Movement Disorders Clinical Practice* and presented two posters at scientific conferences
- Received approval of a supplemental New Drug Application for manufacturing GOCOVRI at a second commercial site

ADS-5102 (amantadine) extended release capsules in development for the treatment of walking impairment in patients with multiple sclerosis

- Published Phase 2 proof-of-concept data in *Multiple Sclerosis Journal*

ADS-4101 (lacosamide) modified release capsules in development for the treatment of partial onset seizures in patients with epilepsy

- Presented ADS-4101 Phase 1a and Phase 1b clinical data, as well as pre-clinical rotarod data at the American Epilepsy Society Annual Meeting in December 2017
- Scheduled a meeting with the FDA to discuss development program

Corporate

- Concluded 2017 with \$176.4 million in cash and investments, which includes \$65 million in funding from HealthCare Royalty Partners in the fourth quarter of 2017, as part of the \$100 million royalty-backed debt agreement executed in May 2017
- Raised \$134.1 million, net of underwriting discounts, commissions, and transaction costs, through a public offering of 3,450,000 shares of common stock at a price of \$41.50 per share in January 2018

Anticipated Milestones in the First Half of 2018

- Initiate the first Phase 3 study for ADS-5102 (GOCOVRI) in multiple sclerosis patients with walking impairment
 - Present GOCOVRI and ADS-4101 clinical data at the American Academy of Neurology (AAN) Annual Meeting
 - Report topline GOCOVRI data from EASE LID 2 long-term Phase 3 open-label study
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- Review ADS-4101 development program with the FDA
- Report first full quarter of revenues for GOCOVRI

Fourth Quarter and Full-Year 2017 Financial Results

Adamas recorded net product sales of GOCOVRI of \$0.6 million for both the fourth quarter and full-year ended December 31, 2017. GOCOVRI was made commercially available on October 20, 2017 and the full commercial launch occurred on January 8, 2018. The company recognizes revenue using a sell-in method when products are delivered to the specialty pharmacy. No product revenues were recorded in 2016.

Adamas reported a net loss of \$29.4 million, or \$1.27 per share, basic and diluted, for the fourth quarter of 2017, compared to a net loss of \$15.0 million, or \$0.68 per share, basic and diluted, for the fourth quarter of 2016. For the year ended December 31, 2017, Adamas reported a net loss of \$89.5 million, or \$3.97 per share, basic and diluted, compared to a net loss of \$60.1 million, or \$2.77 per share, basic and diluted, for the year ended 2016.

Research and development (R&D) expenses for the fourth quarter ended December 31, 2017, were \$6.4 million, including \$1.0 million in stock-based compensation expense, compared to \$7.0 million for the fourth quarter ended December 31, 2016, which included \$0.7 million in stock-based compensation expense. For the full-year 2017, R&D expenses were \$27.2 million, including \$3.6 million in stock-based compensation expense, compared to \$31.2 million for the full-year 2016, which included \$2.9 million in stock-based compensation expense. R&D expenses for the full-year were primarily for the ongoing open-label safety study for GOCOVRI, pre-approval manufacturing costs, and development work for ADS-5102 (GOCOVRI) in development for the treatment of walking impairment in patients with multiple sclerosis and for ADS-4101 in development for the treatment of partial onset seizures in patients with epilepsy.

Selling, general and administrative (SG&A) expenses for the fourth quarter ended December 31, 2017, were \$23.0 million, including \$2.4 million in stock-based compensation expense, compared to \$8.3 million for the same quarter in the prior year, which included \$2.1 million in stock-based compensation expense. In the full-year 2017, SG&A expenses were \$61.3 million, including \$9.8 million in stock-based compensation expense, compared to \$30.3 million, including \$7.7 million in stock-based compensation expense, incurred during the full-year 2016. The increase in SG&A expenses for the fourth quarter and full-year was primarily due to growth in commercial and administrative expenses in preparation for the commercial launch of GOCOVRI.

On December 31, 2017, Adamas had \$176.4 million of cash, cash equivalents and available-for-sale securities, which includes \$65 million in funding the company received from HealthCare Royalty Partners (HCR) in the fourth quarter of 2017 as part of the \$100 million royalty-backed debt agreement the company executed in May 2017. In January 2018, the company raised \$134.1 million net proceeds in a public offering.

2018 Guidance

For 2018, Adamas expects full-year R&D expenses to be between \$45 million and \$50 million, reflecting the completion of the GOCOVRI open-label study, initiation of the ADS-5102 Phase 3 trials in multiple sclerosis patients with walking impairment as well as preparation work for the ADS-4101 Phase 3 trial in epilepsy patients with partial onset seizures. Additionally, the company expects full-year SG&A expenses to be between \$115 million and \$125 million, in support of GOCOVRI commercialization.

Investor Conference Call and Webcast

Adamas will host a conference call and webcast today, February 22, 2018, at 4:30 p.m. Eastern Time. The conference call may be accessed by dialing 844-215-3280 for participants in the U.S. or Canada and 484-747-6383 for international callers. The webcast can be accessed live via the investor section of the Adamas website at <http://ir.adamaspharma.com/events.cfm> and will be available for replay until March 22, 2018.

About GOCOVRI

GOCOVRI (amantadine) extended release capsules is the first and only medicine approved by the FDA for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications. GOCOVRI is a high-dose 274 mg amantadine taken once-daily at bedtime, which delivers consistently high levels of amantadine in the morning and throughout the day when dyskinesia is most prevalent.

For more information about GOCOVRI, including important safety information and full U.S. Prescribing Information, please call 1-844-GOCOVRI (1-844-462-6874) or visit www.GOCOVRI.com.

About Adamas Pharmaceuticals, Inc.

Adamas is using its deep understanding of time-dependent biology to redefine the treatment experience for patients suffering from chronic neurological diseases. The company is building upon the commercial launch of GOCOVRI™ (amantadine) extended release capsules (previously ADS-5102), the first and only FDA-approved medicine for the treatment of dyskinesia in patients with Parkinson’s disease, with a pipeline of differentiated investigational programs, which includes: ADS-5102 in development for the treatment of multiple sclerosis walking impairment; and ADS-4101, a high-dose, modified release lacosamide in development for the treatment of partial onset seizures in patients with epilepsy. Adamas’ goal is to create and commercialize a new generation of neurological medicines intended to lessen the burden of disease on patients, caregivers and society. For more information about Adamas and its unique approach to developing medicines based on time-dependent biology, please visit www.adamaspharma.com.

Forward-looking Statements

Statements contained in this press release regarding matters that relate to future events, conditions, or circumstances are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, statements contained in this press release regarding the timing of initiating the first Phase 3 study for ADS-5102 in multiple sclerosis patients with walking impairment, and finalizing the clinical development pathway for ADS-4101 in epilepsy patients with partial onset seizures, and the statements under the captions “Anticipated Milestones in the First Half of 2018” and “2018 Guidance.” Words such as “look forward,” “expects,” and other words or expressions referencing future events, conditions, or circumstances are intended to identify forward-looking statements. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. For a description of risks and uncertainties that could cause actual results to differ from those expressed in forward-looking statements, including risks relating to Adamas’ research, clinical, development, and commercial activities relating to GOCOVRI, ADS-5102 and ADS-4101, the regulatory and competitive environment and Adamas’ business in general, see Adamas’ Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 22, 2018, particularly under the caption “Risk Factors.” Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Adamas undertakes no obligation to update any forward-looking statement in this press release.

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— Financial Tables Attached —

Adamas Pharmaceuticals, Inc.
Unaudited Condensed Consolidated Statements of Operations
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	\$ 568	\$ —	\$ 568	\$ —
License and grant revenue	—	37	3	572
Total net revenues	568	37	571	572
Costs and operating expenses:				
Cost of product sales	17	—	17	—
Research and development	6,445	7,047	27,168	31,230
Selling, general and administrative, net	22,989	8,283	61,312	30,326
Total costs and operating expenses	29,451	15,330	88,497	61,556
Loss from operations	(28,883)	(15,293)	(87,926)	(60,984)
Interest and other income, net	86	218	1,351	811
Interest expense	(2,239)	—	(4,645)	—
Loss before income taxes	(31,036)	(15,075)	(91,220)	(60,173)
Benefit for income taxes	(1,679)	(115)	(1,730)	(115)
Net loss	\$ (29,357)	\$ (14,960)	\$ (89,490)	\$ (60,058)
Net loss per share, basic and diluted	\$ (1.27)	\$ (0.68)	\$ (3.97)	\$ (2.77)
Weighted average shares used in computing net loss per share, basic and diluted	23,056	21,992	22,558	21,711

Adamas Pharmaceuticals, Inc.
Unaudited Consolidated Balance Sheet Data
(in thousands)

	December 31, 2017	December 31, 2016
Cash, cash equivalents, and available-for-sale securities	\$ 176,433	\$ 135,944
Total assets	186,176	142,473
Total current liabilities	16,607	9,743
Long-term debt	102,647	—
Total liabilities	120,050	10,290
Total stockholders' equity	66,126	132,183