ADAMAS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 11/02/17 for the Period Ending 11/02/17

Address	1900 POWELL ST., SUITE 750
	EMERYVILLE, CA, 94608
Telephone	510-450-3554
CIK	0001328143
Symbol	ADMS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): November 2, 2017

ADAMAS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36399**	**42-1560076**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1900 Powell Street, Suite 750 **Emeryville, CA**	**94608**
(Address of principal executive offices)	(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 November 2, 2017 , Adamas Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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

Exhibit No.	Description
99.1	Press Release dated November 2, 2017.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated August 8, 2017.

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: November 2, 2017

By: /s/ Alfred G. Merriweather

Alfred G. Merriweather

Chief Financial Officer

Exhibit 99.1

Adamas Reports Recent Achievements and Third Quarter 2017 Financial Results

EMERYVILLE, Calif., November 2, 2017 – Adamas Pharmaceuticals, Inc. (Nasdaq: ADMS) today reported recent achievements and financial results for the third quarter ended September 30, 2017 .

"We are thrilled that GOCOVRI (amantadine) extended release capsules is approved for Parkinson's disease patients with dyskinesia receiving levodopa-based therapy and now available for physician and patient use," stated Gregory T. Went, Ph.D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. "This is a momentous milestone for Adamas, as significantly improving patient lives with our approved medicines is the primary driver of our time-dependent biology approach to science, discovery and clinical development."

Recent Achievements

GOCOVRI ™

- Received approval by the U.S. Food and Drug Administration (FDA) for GOCOVRI (amantadine) extended release capsules (previously ADS-5102) for treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications, on August 24, 2017. GOCOVRI is the first and only medicine approved by the FDA for this indication.
- Earned seven-years of orphan drug exclusivity from the FDA for GOCOVRI, which will continue through August 24, 2024.
- Provided access to GOCOVRI for physicians and patients through its distribution network and GOCOVRI Onboard, Adamas' patient services support program.
- Hired six regional sales leaders to manage its planned 59 neurology account specialist sales force.
- Published GOCOVRI (ADS-5102) Phase 3 EASE LID 2 open-label clinical trial data in the *Journal of Parkinson's Disease* . The data demonstrated tolerability and durability out to 88 weeks and a subgroup analysis showed that patients previously having undergone Deep Brain Stimulation also received benefit from ADS-5102.
- Published GOCOVRI (ADS-5102) Phase 3 EASE LID 3 clinical trial data in *Movement Disorders* . The data demonstrated that ADS-5102 significantly reduced both dyskinesia and OFF time at three months in Parkinson's disease patients with dyskinesia on levodopa-based therapy and confirmed the results from the EASE LID study, as published in *JAMA Neurology,* which showed the significant reduction in dyskinesia and OFF time for 6 months.

ADS-4101

- Completed ADS-4101 (lacosamide) modified release capsules Phase 1b steady-state pharmacokinetic study. ADS-4101 is in development for the treatment of partial onset seizures in patients with epilepsy. The study demonstrated that a 600 mg dose of ADS-4101, taken once-nightly, provided a 1.5-2.5 fold increase in average lacosamide concentrations throughout the day compared to the maximum approved daily dose of 400 mg, taken as 200 mg twice-daily, of VIMPAT ® (lacosamide) immediate release tablets in healthy volunteers, with comparable tolerability. These Phase 1 data are scheduled to be presented at the American Epilepsy Society Annual Meeting in December 2017.

Corporate

- Appointed Mardi C. Dier, Chief Financial Officer of Portola Pharmaceuticals, Inc., to the Adamas Board of Directors.

Third Quarter 2017 Financial Results

Adamas reported a net loss of $23.4 million , or $1.04 per share, basic and diluted, for the third quarter of 2017 , compared to a net loss of $14.4 million , or $0.66 per share, basic and diluted, for the third quarter of 2016 . The net losses for the third quarter s of 2017 and 2016 included $3.3 million and $2.6 million , respectively, in non-cash stock-based compensation expense.

Research and development expenses were $6.5 million for the third quarter of 2017 , including $0.8 million in stock-based compensation expense, compared to $7.4 million for the comparable quarter of 2016 , including $0.7 million in stock-based compensation expense. In the third quarter of 2016, Adamas was focused on pre-commercial manufacturing activities and the completion of the Phase 3 clinical program for now approved GOCOVRI. In the third quarter of 2017, research and development activities were primarily the ongoing open-label safety study for

GOCOVRI, building of pre-FDA approval inventory, and development work for ADS-4101 and ADS-5102 (GOCOVRI) for the treatment of walking impairment in patients with multiple sclerosis.

Selling, general and administrative expenses for the third quarter ended September 30, 2017 , were $16.1 million , including $2.4 million in stock-based compensation expense, compared to $7.3 million for the quarter ended September 30, 2016 , which included $1.9 million in stock-based compensation expense. The increase in selling, general and administrative expenses was primarily due to growth in commercial and administrative expenses in preparation for the commercial launch of GOCOVRI.

Nine-month 2017 Financial Results
Adamas reported a net loss for the nine months ended September 30, 2017 , of $60.1 million , or $2.69 per share, basic and diluted, compared with a net loss for the same period in 2016 of $45.1 million , or $2.09 per share, basic and diluted. Research and development expenses for the nine months ended September 30, 2017 , were $20.7 million , including $2.6 million in stock-based compensation expense, compared to $24.2 million for the nine months ended September 30, 2016 , which included $2.1 million in stock-based compensation expense. Selling, general and administrative expenses for the nine months ended September 30, 2017 , were $38.3 million , including $7.4 million in stock-based compensation expense, compared to $22.0 million for the nine months ended September 30, 2016 , which included $5.6 million in stock-based compensation expense.

Cash Position
Adamas ended the quarter with $130.7 million of cash, cash equivalents, and available-for-sale securities, compared to $135.9 million at December 31, 2016. The company expects to receive $65 million in funding from HealthCare Royalty Partners (HCRP) in the fourth quarter of 2017, as part of the $100 million royalty-backed note the company signed in May 2017.

“With the $65 million proceeds from HCRP, together with our current available cash, cash equivalents and investments of $130.7 million as of September 30, 2017 , we believe we will be sufficiently capitalized to launch and commercialize GOCOVRI, complete the Phase 3 studies of ADS-5102 in multiple sclerosis patients with walking impairment and initiate a Phase 3 study of ADS-4101 in epilepsy patients with partial onset seizures,” stated Alfred G. Merriweather, Chief Financial Officer of Adamas Pharmaceuticals, Inc.

Investor Conference Call and Webcast
Adamas will host a conference call and webcast today, November 2, 2017 , 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 December 2, 2017.

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.
At Adamas, we believe in the power and the promise of medicines derived from a deep understanding of time-dependent biology. Our expertise lies in uncovering and mapping the relationship between disease and drug activity. From there, we strive to create medicines with therapeutic profiles that match the pattern of disease to drive a more significant and durable clinical effect. This understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our portfolio includes: 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 receiving levodopa-based therapy, with or without concomitant dopaminergic medications; ADS-5102 in development for the treatment of multiple sclerosis walking impairment and additional indications in Parkinson’s disease; and ADS-4101, a high-dose, modified release

lacosamide in development for the treatment of partial onset seizures in patients with epilepsy. For more information, please visit www.adamaspharma.com .

VIMPAT ® is a trademark of UCB.

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 Adamas' expectation of receiving $65 million in funding from HealthCare Royalty Partners in the fourth quarter of 2017, and its belief with respect to the sufficiency of its financial resources in Mr. Merriweather's quote. Words such as "expects," "believe" 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 2, 2017 , 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.

# # #

Contact:
Ashleigh Barreto
Director, Corporate Communications & Investor Relations
Adamas Pharmaceuticals, Inc.
510-450-3567
ir@adamaspharma.com

— Financial Tables Attached —

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
License and grant revenue	$ 1	$ 138	$ 3	$ 535
Operating expenses				
Research and development	6,459	7,437	20,723	24,183
Selling, general and administrative, net	16,064	7,344	38,323	22,043
Total operating expenses	22,523	14,781	59,046	46,226
Loss from operations	(22,522)	(14,643)	(59,043)	(45,691)
Interest and other income, net	839	249	1,265	593
Interest expense	(1,677)	—	(2,406)	—
Loss before income taxes	(23,360)	(14,394)	(60,184)	(45,098)
Benefit for income taxes	—	—	(51)	—
Net loss	$ (23,360)	$ (14,394)	$ (60,133)	$ (45,098)
Net loss per share, basic and diluted	$ (1.04)	$ (0.66)	$ (2.69)	$ (2.09)
Weighted average shares used in computing net loss per share, basic and diluted	22,569	21,941	22,390	21,616

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

	September 30, 2017	December 31, 2016
Cash, cash equivalents, and available-for-sale securities	$ 130,730	$ 135,944
Total assets	137,112	142,473
Total current liabilities	15,211	9,743
Long-term debt	35,408	—
Total liabilities	51,234	10,290
Total stockholders' equity	85,878	132,183