ADAMAS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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Address	1900 POWELL ST., SUITE 750
	EMERYVILLE, CA 94608
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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 28, 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))

Item 2.02 Results of Operations and Financial Condition.

On February 28, 2017, Adamas Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2016. 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	99.1 Press Release dated February 28, 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.

By: /s/ William J. Dawson

Dated: February 28, 2017

William J. Dawson
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit No.	Description
99.1	99.1 Press Release dated February 28, 2017.

Exhibit 99.1

Adamas Reports Recent Achievements and Financial Results for the Fourth Quarter and Full-Year 2016

EMERYVILLE, Calif., February 28, 2017 -- Adamas Pharmaceuticals, Inc. (Nasdaq: ADMS) today reported recent achievements and financial results for the fourth quarter and full-year ended December 31, 2016 .

“We expect 2017 to be a pivotal year as we transform from an R&D-focused company to a commercial organization as we anticipate FDA approval of ADS-5102 for the treatment of levodopa-induced dyskinesia. If approved, we expect to launch ADS-5102 in the second half of 2017, providing Parkinson’s patients with the first and only medicine indicated for the treatment of levodopa-induced dyskinesia,” said Gregory T. Went, Ph.D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. “In addition, we are continuing to develop ADS-5102 in additional indications, as well as to advance the clinical development of ADS-4101 for the treatment of partial onset seizures in patients with epilepsy, the fourth chrono-synchronous targeted therapy to emerge from our drug development platform.”

Recent Achievements

ADS-5102 (amantadine hydrochloride) extended release capsules

- Acceptance of the New Drug Application (NDA) for ADS-5102 for the treatment of levodopa-induced dyskinesia (LID) in patients with Parkinson’s disease by the U.S. Food and Drug Administration (FDA); the PDUFA date is August 24, 2017
- Presented an updated analysis from EASE LID 2, the open-label, long-term safety study of ADS-5102 in Parkinson’s disease patients with LID, at the First Pan American Parkinson’s Disease and Movement Disorders Congress. The updated analysis showed the safety and tolerability of ADS-5102 and treatment effect on LID and OFF time with ADS-5102 up to 64 weeks, as measured by Part IV (Motor Complications) of the Movement Disorder Society-Unified Parkinson’s Disease Rating Scale (MDS-UPDRS)
- Participated in a productive End-of-Phase 2 meeting with the FDA regarding the Phase 3 development pathway for ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis
- Presented data from a Phase 2 proof-of-concept study of ADS-5102 for the treatment of walking impairment in patients with multiple sclerosis at the American Committee for the Treatment and Research of Multiple Sclerosis (ACTRIMS), highlighting treatment effect in several performance measures in multiple sclerosis patients, warranting further development of ADS-5102

ADS-4101(lacosamide) capsules

- Initiated clinical development of ADS-4101, a potential once-daily, high-dose chrono-synchronous lacosamide therapy, for the treatment of partial onset seizures in patients with epilepsy; lacosamide is an anti-epilepsy active ingredient previously approved by the FDA and currently marketed as VIMPAT ® (lacosamide)
- Completed a single-dose Phase 1 trial of four formulations of ADS-4101, and plan to present the data at a medical meeting in 2017

Corporate

- Promoted Jennifer J. Rhodes to the position of Chief Business Officer in recognition of her contribution to Adamas and significant commercial experience in the pharmaceutical and biotech industry. She will continue to serve as General Counsel, Chief Compliance Officer, and Corporate Secretary
- Broadened the responsibilities of Rajiv Patni, M.D., Chief Medical Officer, to lead all Research and Development activities

Anticipated Milestones

- FDA approval of the NDA for ADS-5102 for the treatment of LID in patients with Parkinson’s disease
- Launch of ADS-5102 in the U.S. for the treatment of LID in patients with Parkinson’s disease, if approved, in the second half of 2017
- Evaluation of additional indications for ADS-5102 including Phase 3 development for the treatment of walking impairment in patients with multiple sclerosis and for the management of patients earlier in the Parkinson’s disease treatment journey
- Completion of Phase 1 clinical trials of ADS-4101 to select suitable formulations to advance into pivotal studies
- Presentation of clinical data at the American Academy of Neurology (AAN) Annual Meeting and other medical meetings throughout 2017

Fourth Quarter and Full-Year 2016 Financial Results
Adamas reported a net loss of $15.0 million , or $0.68 per share, basic and diluted, for the fourth quarter of 2016 , compared to a net loss of $10.7 million , or $0.58 per share, basic and diluted, for the fourth quarter of 2015 . For the year ended December 31, 2016 , Adamas reported a net loss of $60.1 million , or $2.77 per share, basic and diluted, compared to a net loss of $51.8 million , or $2.86 per share, basic and diluted, for 2015 .

For the quarter ended December 31, 2016 , Adamas recorded revenues of $37,000 compared to $0.5 million in the corresponding period of 2015 . Adamas recorded total revenues of $0.6 million for the full-year 2016 , compared to $1.9 million during the same period of 2015 . The decrease reflected the reduction in reimbursements for activities Adamas employees performed related to a license agreement with Allergan.

Research and development (R&D) expenses for the quarter ended December 31, 2016 , were $7.0 million , including $0.7 million in stock-based compensation expense, compared to $9.7 million for the quarter ended December 31, 2015 , which included $0.9 million in stock-based compensation expense. For the full-year 2016 , R&D expenses were $31.2 million , including $2.9 million in stock-based compensation expense, compared to $35.9 million for the full-year 2015 , which included $3.2 million in stock-based compensation expense. R&D expenses for the full-year declined over the prior period primarily due to the completion of Phase 3 clinical trials of ADS-5102 for LID in patients with Parkinson's disease.

General and administrative (G&A) expenses for the quarter ended December 31, 2016 , were $8.3 million , including $2.1 million in stock-based compensation expense, compared to $6.9 million for the same quarter in the prior year, which included $1.9 million in stock-based compensation expense. In the full-year 2016 , G&A expenses were $30.3 million , including $7.7 million in stock-based compensation expense, compared to $23.5 million , including $6.8 million in stock-based compensation expense, incurred during the full-year 2015 . The increase in G&A expenses for the fourth quarter and full-year was primarily due to increased investment in infrastructure to support the anticipated commercialization of ADS-5102 for LID in Parkinson's disease.

On December 31, 2016 , Adamas had $135.9 million of cash, cash equivalents and available-for-sale securities compared to $120.0 million at December 31, 2015 . On January 6, 2016, Adamas raised net proceeds of $61.8 million from the sale of 2,875,000 shares of common stock through a follow-on public offering.

About Adamas Pharmaceuticals, Inc.
Adamas develops new medicines to improve the daily lives of those affected by chronic neurologic disorders, including Parkinson's disease, multiple sclerosis, epilepsy and Alzheimer's disease. Adamas has pioneered a platform to develop medicines, called chrono-synchronous therapies, for chronic neurologic disorders based on an understanding of the time-dependent biologic processes responsible for disease activity and drug response to potentially achieve symptomatic relief without tolerability issues. The company's most advanced product candidate, ADS-5102, is in development for levodopa-induced dyskinesia (LID) in patients with Parkinson's disease and walking impairment. An NDA supporting ADS-5102 for the treatment of LID in patients with Parkinson's disease is under review by the FDA, with a PDUFA date of August 24, 2017. Adamas is exploring other indications for ADS-5102 for further development. Adamas is also investigating ADS-4101 for the treatment of partial onset seizures in patients with epilepsy. Additionally, Adamas' licensed assets, NAMENDA XR ® and NAMZARIC ® , are currently marketed by Allergan, and Adamas is eligible to receive royalties on sales of these medicines beginning in June 2018 and May 2020, respectively. For more information, please visit www.adamaspharma.com .

VIMPAT ® is a trademark of UCB. Namenda XR ® and Namzaric ® are trademarks of Merz Pharma GmbH & Co. KGaA.

Forward-looking Statements
Statements contained in this press release regarding matters that are not historical facts 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 potential approval and commercial launch of ADS-5102 for treatment of levodopa-induced dyskinesia in patients with Parkinson's disease, the potential for additional clinical development programs for ADS-5102 including walking impairment in multiple sclerosis and other indications, that 2017 will be a pivotal year as Adamas transforms from an R&D-focused company to a commercial organization, the advancement of ADS-4101 in clinical development, and the statements under the heading "Anticipated Milestones." Words such as "expect," "anticipate," and similar expressions (as well as 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 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 28, 2017. 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:
Martin Forrest
Vice President, Corporate Communications & Investor Relations
Adamas Pharmaceuticals, Inc.
510-450-3528
ir@adamaspharma.com

— Financial Tables Attached —

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
Revenue	$ 37	$ 524	$ 572	$ 1,916
Operating expenses				
Research and development	7,047	9,697	31,230	35,895
General and administrative, net	8,283	6,890	30,326	23,458
Total operating expenses	15,330	16,587	61,556	59,353
Loss from operations	(15,293)	(16,063)	(60,984)	(57,437)
Interest and other income, net	218	98	811	363
Loss before income taxes	(15,075)	(15,965)	(60,173)	(57,074)
Benefit for income taxes	(115)	(5,275)	(115)	(5,272)
Net loss	$ (14,960)	$ (10,690)	$ (60,058)	$ (51,802)
Net loss per share, basic and diluted	$ (0.68)	$ (0.58)	$ (2.77)	$ (2.86)
Weighted average shares used in computing net loss per share, basic and diluted	21,992	18,438	21,711	18,111

Adamas Pharmaceuticals, Inc.
Unaudited Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 23,735	$ 33,104
Available-for-sale securities	89,917	73,691
Accounts receivable	794	1,284
Prepaid expenses and other current assets	2,541	5,108
Total current assets	116,987	113,187
Property and equipment, net	3,156	2,353
Available-for-sale securities, non-current	22,292	13,165
Other assets	38	38
Total assets	$ 142,473	$ 128,743
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,589	$ 3,052
Accrued liabilities	5,867	8,457
Other current liabilities	287	298
Total current liabilities	9,743	11,807
Non-current liabilities	547	749
Total liabilities	10,290	12,556
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value — 5,000,000 shares authorized, and zero shares issued and outstanding at December 31, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value — 100,000,000 shares authorized, 22,013,644 and 18,505,462 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	27	23
Additional paid-in capital	254,558	178,473
Accumulated other comprehensive loss	(193)	(158)
Accumulated deficit	(122,209)	(62,151)
Total stockholders' equity	132,183	116,187
Total liabilities and stockholders' equity	$ 142,473	$ 128,743

Adamas Pharmaceuticals, Inc.
Unaudited Consolidated Statements of Cash Flows
(in thousands)

	Twelve Months Ended December 31,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (60,058)	$ (51,802)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	808	435
Stock-based compensation	10,571	9,956
Net accretion of discounts and amortization of premiums of available-for-sale securities	(301)	875
Changes in assets and liabilities		
Accrued interest of available-for-sale securities	(2)	110
Prepaid expenses and other assets	2,643	(4,416)
Accounts receivable	490	(760)
Accounts payable	502	(788)
Accrued liabilities and other liabilities	(2,721)	(820)
Net cash used in operating activities	(48,068)	(47,210)
Cash flows from investing activities		
Purchases of property and equipment	(1,624)	(1,399)
Purchases of available-for-sale securities	(103,528)	(59,828)
Maturities of available-for-sale securities	78,443	69,285
Net cash provided by (used in) investing activities	(26,709)	8,058
Cash flows from financing activities		
Proceeds from public offerings, net of offering costs	61,822	9,657
Proceeds from issuance of common stock upon exercise of stock options	2,966	746
Proceeds from employee stock purchase plan	620	407
Net cash provided by financing activities	65,408	10,810
Net decrease in cash and cash equivalents	(9,369)	(28,342)
Cash and cash equivalents at beginning of period	33,104	61,446
Cash and cash equivalents at end of period	$ 23,735	$ 33,104