ADAMAS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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Address	1900 POWELL ST., SUITE 750 EMERYVILLE, CA 94608
Telephone	510-450-3554
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): August 8, 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 August 8, 2017 , Adamas Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 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.

By: /s/ Alfred G. Merriweather

Dated: August 8, 2017

Alfred G. Merriweather
Chief Financial Officer

INDEX TO EXHIBITS

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

Exhibit 99.1

Adamas Reports Recent Achievements and Second Quarter 2017 Financial Results

EMERYVILLE, Calif., August 8, 2017 – Adamas Pharmaceuticals, Inc. (Nasdaq: ADMS) today reported recent achievements and financial results for the second quarter ended June 30, 2017 .

“This is a very exciting time for Adamas, as we are potentially at the cusp of transitioning from a company focused on product development to a commercial entity marketing its own medicines,” stated Gregory T. Went, Ph.D., Chairman and Chief Executive Officer of Adamas Pharmaceuticals, Inc. “We look forward to hearing from the FDA regarding the potential approval of ADS-5102 for the treatment of levodopa-induced dyskinesia in people with Parkinson’s disease. If approved, ADS-5102 will be the first and only approved medicine for this indication.” The New Drug Application for ADS-5102 has a PDUFA date of August 24, 2017.

Recent Achievements

- Presented expanded analysis from the ADS-5102 (amantadine extended release capsules) open-label study at the 21st International Congress of Parkinson's Disease and Movement Disorders (MDS) meeting showing tolerability and durability out to 88 weeks. The new subgroup analyses also showed that patients previously treated with immediate-release amantadine, who switched directly to ADS-5102, experienced a statistically significant benefit from ADS-5102 comparable to patients not previously treated with ADS-5102.
- Published ADS-5102 Phase 3 EASE LID clinical trial data in JAMA Neurology online. The data demonstrated that ADS-5102 significantly reduced both dyskinesia and OFF time at six months in Parkinson's disease patients with levodopa-induced dyskinesia.
- Presented positive Phase 1a clinical trial data in a podium presentation at the 14th Antiepileptic Drug and Device Trials Conference for ADS-4101 (lacosamide modified release capsules). The Phase 1 results showed that treatment with ADS-4101 resulted in reduced adverse events (including dizziness) compared to an equivalent dose of VIMPAT ® (lacosamide) immediate-release tablets in healthy volunteers.
- Initiated ADS-4101 Phase 1b steady-state study to evaluate the tolerability and pharmacodynamic profile of three ascending doses of ADS-4101 administered once daily at bedtime compared to ascending doses of twice daily VIMPAT (lacosamide) tablets. Announcement of topline data from the trial is expected in the third quarter of 2017.
- Signed $100 million royalty-backed note agreement with HealthCare Royalty Partners.
- Appointed Alfred G. Merriweather as Chief Financial Officer.

Second Quarter 2017 Financial Results

Adamas reported a net loss of $20.7 million , or $0.93 per share, basic and diluted, for the second quarter of 2017 , compared to a net loss of $16.9 million , or $0.78 per share, basic and diluted, for the second quarter of 2016 . The net losses for the second quarter s of 2017 and 2016 included $3.8 million and $2.6 million , respectively, in non-cash stock-based compensation expense.

Research and development expenses were $7.2 million for the second quarter of 2017 , including $0.9 million in stock-based compensation expense, compared to $9.2 million for the comparable quarter of 2016 , including $0.7 million in stock-based compensation expense. The 22 percent decrease was mainly attributable to the completion of two Phase 3 clinical trials of ADS-5102 for the treatment of levodopa-induced dyskinesia in people with Parkinson’s disease, in addition to decreased level of pre-commercial manufacturing activities. The decrease was offset in part by increased activity and expense related to clinical work associated with ADS-4101 for the treatment of partial onset seizures in patients with epilepsy.

General and administrative expenses for the second quarter ended June 30, 2017 , were $13.1 million , including $2.9 million in stock-based compensation expense, compared to $8.1 million for the quarter ended June 30, 2016 , which included $1.9 million in stock-based compensation expense. The 62 percent increase in general and administrative expenses was primarily due to growth in commercial headcount-related expenses and marketing expenses in preparation for the potential commercial launch of ADS-5102 for the treatment of levodopa-induced dyskinesia in people with Parkinson’s disease, pending regulatory approval.

Six-month 2017 Financial Results
Adamas reported a net loss for the six months ended June 30, 2017 , of $36.8 million , or $1.65 per share, basic and diluted, compared with a net loss for the same period in 2016 of $30.7 million , or $1.43 per share, basic and diluted. Research and development expenses for the six months ended June 30, 2017, were $14.3 million , including $1.7 million in stock-based compensation expense, compared to $16.7 million for the six months ended June 30, 2016 , which included $1.4 million in stock-based compensation expense. General and administrative expenses for the six months ended June 30, 2017 , were $22.3 million , including $4.9 million in stock-based compensation expense, compared to $14.7 million for the six months ended June 30, 2016 , which included $3.8 million in stock-based compensation expense.

Cash Position
Adamas ended the quarter with $144.9 million of cash, cash equivalents, and available-for-sale securities, compared to $135.9 million at December 31, 2016. This includes $35 million in funding from HealthCare Royalty Partners received at the initial closing of the $100 million royalty-backed loan financing.

Investor Conference Call and Webcast
Adamas will host a conference call and webcast today, August 8, 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 September 8, 2017.

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 timing patterns. 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 unique understanding of time-dependent biological processes informs our every innovation, targeting advancement in treatment of chronic neurologic disorders. Our proprietary portfolio includes ADS-5102, a high-dose amantadine therapy taken once-daily at bedtime, in development for the treatment of levodopa-induced dyskinesia in people with Parkinson's disease as well as walking impairment in people with multiple sclerosis, and ADS-4101, a high-dose lacosamide therapy taken once-daily at bedtime, in development for the treatment of partial onset seizures in patients with epilepsy. The NDA for ADS-5102 is currently under review by the U.S. Food and Drug Administration with a PDUFA date of August 24, 2017. Additionally, Adamas' licensed assets are currently marketed by Allergan under the brand names NAMENDA XR ® and NAMZARIC ®, 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 .

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

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 of ADS-5102 for the treatment of levodopa-induced dyskinesia in patients with Parkinson's disease. Words such as "potentially" 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 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.

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Contact:
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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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	$ 2	$ 222	$ 2	$ 397
Operating expenses				
Research and development	7,176	9,224	14,264	16,746
General and administrative, net	13,115	8,058	22,259	14,699
Total operating expenses	20,291	17,282	36,523	31,445
Loss from operations	(20,289)	(17,060)	(36,521)	(31,048)
Interest and other income, net	222	184	426	344
Interest expense	(729)	—	(729)	—
Loss before income taxes	(20,796)	(16,876)	(36,824)	(30,704)
Benefit for income taxes	(51)	—	(51)	—
Net loss	$ (20,745)	$ (16,876)	$ (36,773)	$ (30,704)
Net loss per share, basic and diluted	$ (0.93)	$ (0.78)	$ (1.65)	$ (1.43)
Weighted average shares used in computing net loss per share, basic and diluted	22,392	21,650	22,300	21,452

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

	June 30, 2017	December 31, 2016
Cash, cash equivalents, and available-for-sale securities	$ 144,929	$ 135,944
Total assets	149,922	142,473
Total current liabilities	11,049	9,743
Long-term debt	33,768	—
Total liabilities	46,018	10,290
Total stockholders' equity	103,904	132,183