

Adamas Pharmaceuticals Inc
Form 8-K
December 24, 2015

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): **December 23, 2015**

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**

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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))
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Item 8.01 Other Events.

On December 23, 2015, Adamas Pharmaceuticals, Inc. (the Company) announced positive top-line results from its Phase 3 EASE LID clinical trial of ADS-5102 (amantadine hydrochloride) for the treatment of levodopa-induced dyskinesia (LID) associated with Parkinson's disease. This study met its primary endpoint, a reduction of LID ($p = 0.0009$) at 12 weeks for patients who received ADS-5102 versus placebo as assessed by the Unified Dyskinesia Rating Scale (UDysRS). This represents a 23% reduction in LID for ADS-5102-treated patients compared to placebo. The reduction in LID was maintained at 24 weeks ($p = 0.0008$), a key secondary analysis. In this study, there were four additional key secondary analyses based on patient diary data. All achieved statistical significance. Notably, at week 12, ADS-5102 significantly increased ON time without troublesome dyskinesia by 2.7 hours versus placebo and reduced OFF time by 0.9 hours. These effects were maintained at week 24.

The reported adverse events associated with ADS-5102 were consistent with the known safety profile of amantadine as well as the safety results from our earlier placebo-controlled trial. The most common adverse events (occurring in greater than five percent of ADS-5102-treated patients) were: hallucinations, peripheral edema, dizziness, dry mouth, constipation, falls, urinary tract infections, anxiety, contusion, livedo reticularis, abnormal dreams, depression and headaches. Four subjects discontinued treatment due to adverse events in the placebo group versus 13 in the ADS-5102 group. There were 17 subjects who experienced severe adverse events, four in the placebo group and 13 in the ADS-5102 group. Of these, one subject in the placebo group and three subjects in the ADS-5102 group had an event assessed to be study drug related. There were 10 subjects who experienced serious adverse events, three subjects in the placebo group and seven subjects in the ADS-5102 group. None of the serious adverse events were assessed to be study drug related.

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: December 23, 2015

By: */s/ Gregory Went*
Gregory Went, Ph.D.
Chief Executive Officer