Adamas Pharmaceuticals, Inc. (ADMS) — Overweight

ADS-5102 Orphan Designation Reinforces Our Confidence in Asset Durability

CONCLUSION

This morning, Adamas announced that the FDA has granted orphan drug designation (ODD) to ADS-5102 in levodopa-induced dyskinesias (LID) associated with Parkinson's disease (PD). Recall that ADS-5102 is ADMS' extended-release (ER) form of amantadine that is currently in late-stage development (an NDA is likely next year). Though we have viewed the product as having strong visibility on a lengthy period of exclusivity, bearing in mind that there are nine issued patents surrounding the product that expire as late as 2030, the ODD, and potential orphan exclusivity, will at a minimum allay investor concerns about generic filings shortly after commercialization (as is typical for oral solids filed via 505(b)(2)). We continue to believe that peak U.S. sales potential of $200M+ for ADS-5102 in LID is realistic. We reiterate our Overweight rating and $37 PT.

- **ODD further reinforces our confidence in the durability of ADS-5102.** We would keep in mind that there are no products that are currently approved for LID (the immediate-release (IR) form of amantadine is approved for Parkinson's disease, broadly speaking, but is not indicated for LID). ADMS has estimated that around 30% of patients with advanced PD on levodopa/carbidopa (i.e., dopamine replacement) experience LID, translating into a U.S. addressable market of around 144,000 individuals. The potential for seven years of orphan drug exclusivity (ODE) is obviously attractive, and at a minimum, forestalls paragraph IV (PIV) filings until we get closer to the expiry date (and to be clear, for an ER oral solid, PIV filings are an inevitability). That said, the patent estate surrounding ADS-5102 is deep, with nine issued U.S. patents for amantadine-based ER/controlled-release products that expire as late as 2030 (ADMS also has 12 more patent applications pending).

- **Phase III results from ADS-5102 in LID should be ready before year-end.** Recall that ADMS has a total of three Phase III clinical trials ongoing for the treatment of LID. This includes an open-label safety study in PD patients, as well as two randomized, placebo-controlled efficacy studies that will enroll a total of 200 patients evaluating a daily dose of 340 mg (administered once daily at bedtime). The primary endpoint is the assessment of dyskinesias per changes in the Unified Dyskinesia Rating Scale (UDysRS).

- **Would not overlook potential market expansion opportunities for ADS-5012.** ADMS has previously made it clear that it will eventually evaluate ADS-5102 in other neurological diseases, and will focus on other movement disorders. Potential areas of study could include hyperkinetic disorders such as Huntington's chorea and tardive dyskinesia, as well as hypokinetic movement disorders such as stroke-induced walking deficits. ADMS eventually may also explore the development of ADS-5102 in certain neuropsychiatric diseases such as depression and Alzheimer's. We could very well see ADS-5102 gain ODD in other treatment settings (i.e., Huntington's chorea and tardive dyskinesia are both settings that have under 200,000 patients in the U.S.). ADMS plans to initiate up to two additional studies in these market expansion settings later this year.

COMPANY DESCRIPTION

Adamas is focused on treatments for diseases of the central nervous system.

PRICE: US$17.14
TARGET: US$37.00
15x 2020E EPS of $5.10, disc. 20%

David Amsellem
Sr. Research Analyst, Piper Jaffray & Co.
212 284-9455, david.a.amsellem@pjc.com

Traver A. Davis, CFA
Research Analyst, Piper Jaffray & Co.
212 284-5031, traver.a.davis@pjc.com

Michael C. Chang
Research Analyst, Piper Jaffray & Co.
michael.c.chang@pjc.com

Related Companies:	Share Price:
ADMS	17.14

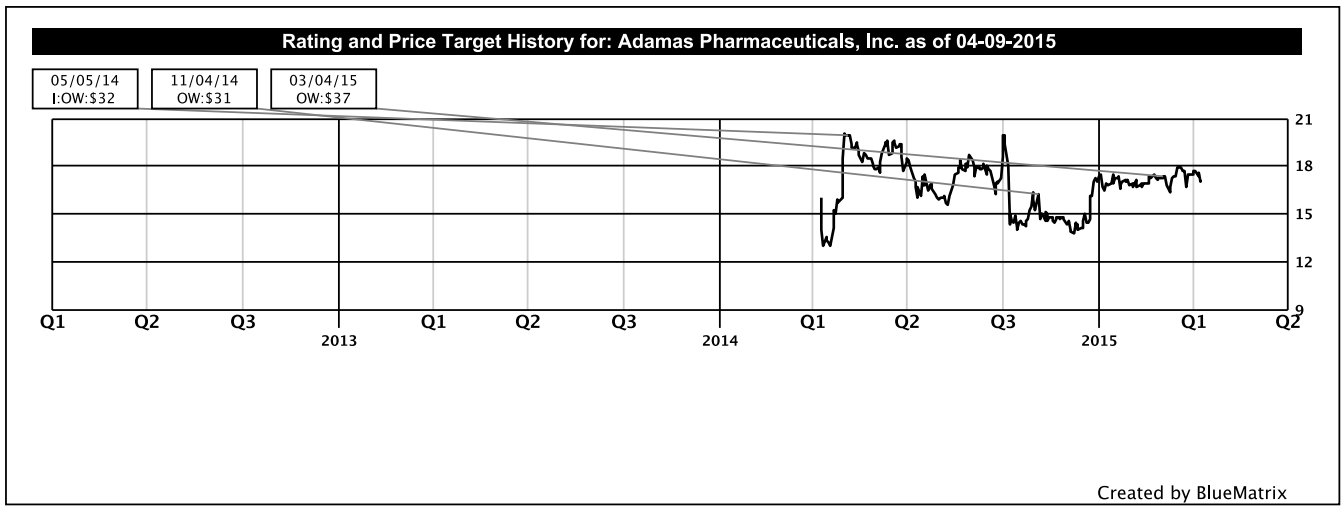
RISKS TO ACHIEVEMENT OF PRICE TARGET

Clinical setbacks for ADS-5102 and commercial risks for the Namenda line extensions.

Price Performance - 1 Year

Source: Bloomberg

IMPORTANT RESEARCH DISCLOSURES



Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

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R: Resuming Coverage
T: Transferring Coverage
D: Discontinuing Coverage
S: Suspending Coverage
OW: Overweight
N: Neutral
UW: Underweight
NA: Not Available
UR: Under Review

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Piper Jaffray

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BUY [OW]	372	60.69	104	27.96
HOLD [N]	227	37.03	17	7.49
SELL [UW]	14	2.28	0	0.00

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Analyst Certification — David Amsellem, Sr. Research Analyst
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- **Underweight (UW):** Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

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