

Trevena, Inc. (TRVN)

TRV130 Phase II Trial Reports Pain Reduction Over Morphine

Key Takeaway

TRVN reports positive data from its Phase IIa/b trial testing TRV130, a treatment for post-surgical pain, in 333 patients undergoing a bunionectomy. On the primary endpt of pain reduction over 48 hours vs placebo, TRV130 2 and 3 mg achieved significance over placebo. TRV130 3 mg also exhibited pain reduction over 48 hours vs morphine. The data along w/ an ongoing P2 trial in abdominal surgery could support PIII trial initiation in 2016.

TRVN Executes On First Clinical Trial Post-IPO: The company reports positive PII data from a PIIa/b trial enrolling 333 patients undergoing bunionectomy procedure (vs original projections of 400 patients), and on a more expedited timeline (vs original projection of 1H '15). TRVN observed a stat sig reduction in pain reduction vs placebo at 48 hours w/ the 2 mg dose (mean difference of 1.4 points; $p = 0.0024$) and 3 mg dose (mean difference of 2.4 points; $p < 0.0001$). The mean baseline pain rating of 7 points in a 10-point scale, and indicative of severe pain. More importantly, TRVN reported significant analgesia differences btwn TRV130 and morphine. TRV130 3 mg observed a significant reduction on the 10-point NRS scale vs morphine (mean difference of 1.0 points; $p = 0.014$). TRV130 2 and 3 mg doses also observed greater reduction in pain intensity in the first 3 hours after surgery compared to morphine. The data are striking given TRV130 2 mg and 3 mg doses observed a 1.2 point change and 1.8 point difference vs morphine respectively. Pain intensity reductions were observed within the first 5 minutes of dosing for both doses. Early PI trials reported similar onset of pain relief w/ the evoke pain model observing analgesic activity 10 minutes after dosing. TRVN allowed for the use of rescue medications such as acetaminophen and ketorolac, however, did not disclose the % of patients that received these therapies in either arm. TRVN reported similar incidence of adverse events across TRV130 and morphine arms, however, the severity of adverse events was not disclosed.

Second PII TRV130 Trial Expected To Commence This Quarter: TRVN will be proceeding to the next PII trial which will start this quarter and will evaluate flexible, as-needed, dosing. TRV130 (n=80), morphine (n=80), or pbo (n=40) will be administered as an initial loading dose followed by delivery of on-demand doses via a PCA device to pts who have undergone uncomplicated, elective abdominoplasty surgery. The 1 EP will be efficacy v. pbo over 24 hrs, and data may help inform PIII design. Topline data from this trial are expected in Q2 '15 w/ PIII initiation expected in 2016. We currently apply a 65% discount rate to our TRV130 revenue estimates, and currently estimate risk-adjusted U.S. peak sales of \$205 million.

BUY

Price target \$11.00

Price \$5.66

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Company Description

Trevena Inc. a clinical stage biopharmaceutical company, headquartered in King of Prussia, PA, and is the leader in the discovery and development of G-protein coupled receptors (GPCR) biased ligands. Trevena's lead pipeline program, TRV-027, is currently in Phase IIb trials in acute heart failure. Trevena is also developing novel therapeutics for pain with TRV-130 in Phase II trials in patients with post-surgical pain.

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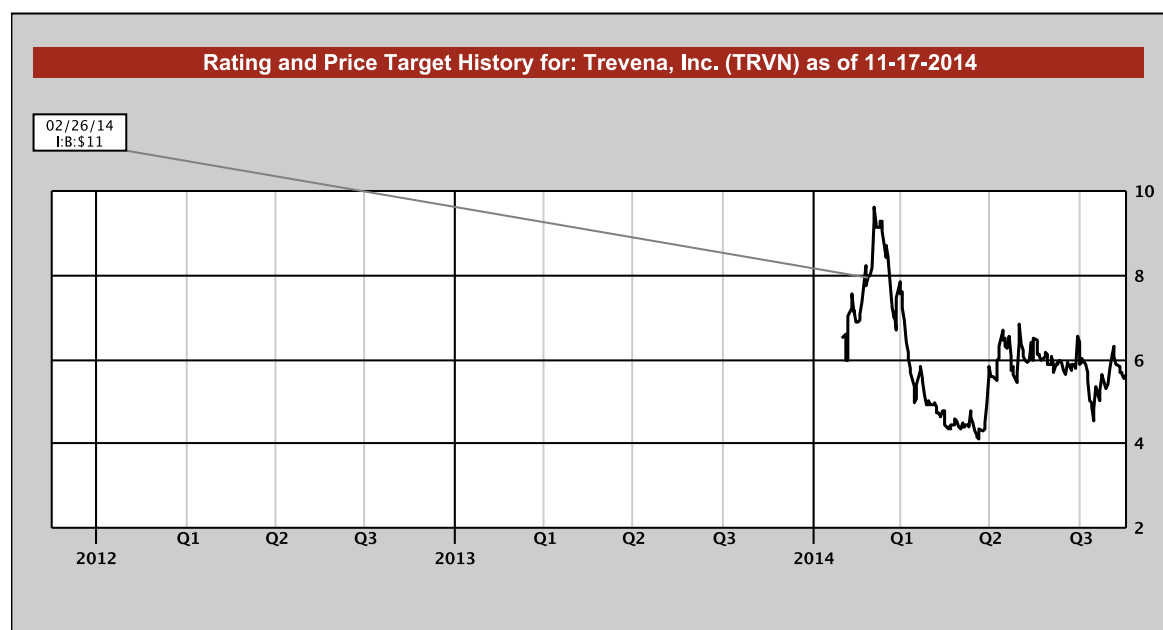
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Other Companies Mentioned in This Report

- Trevena, Inc. (TRVN: \$5.66, BUY)



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			Count	Percent
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