

Trevena, Inc. (TRVN)

TRV130 PII Bunionectomy Trial Enrolled Ahead of Schedule; Data Expected In Q4

Key Takeaway

TRVN announced that the PIIa/b trial for TRV130 for post-op bunionectomy pain has fully enrolled ahead of schedule. Topline data is now expected this qtr (v. prev Q1'15). Based on supportive early data in which TRV130 showed superior analgesia v. morphine while observing lower rates of AEs, we have a positive outlook for TRV130. Positive data will not only enable PIII development, but also further validate the GPCR biased ligand platform.

PIIa/b Study for TRV130 Enrolled Ahead of Schedule; Data Expected in Q4: This morning, TRVN announced that the PIIa/b trial for TRV130 for post-operative bunionectomy pain has completed enrollment ahead of schedule. Topline data is now expected this qtr (v. prev guidance of Q1'15), and assuming positive data the study will enable PIII development. The trial enrolled ~350 pts and has an adaptive dose-selection design. Part A of the study evaluated TRV130 at 1, 2, 3, and 4 mg q4h v. morphine at 4 mg q4h and pbo (n=25 each). After seeing early signs of analgesic efficacy, TRVN initiated Part B of the study ahead of schedule, and evaluated doses (starting w/ two adaptive regimens) in 250 pts (10 cohorts) to optimize performance characteristics based on the results from Part A. The topline data this qtr (including data from Parts A and B) will include results on efficacy, tolerability, and safety measures of TRV130 v. morphine and pbo. Based on supportive PI/preclinical data in which TRV130 showed superior analgesia compared to high-dose morphine while observing lower rates of adverse events, we have a positive outlook for TRV130 in this study.

Positive Data for TRV130 Will Help Further Validate the GPCR Biased Ligand Platform: TRVN is also moving forward with oral TRV734, the follow-on program for TRV130, for moderate-to-severe acute and chronic pain. Thus, positive data from the PII bunionectomy trial for TRV130 will help validate the GPCR biased ligand platform and support the outlook for TRV734. Top-line data from the multiple ascending dose PI study is expected H1'15. For TRV027, dosing of the first patient in the PIIb BLAST trial in acute heart failure (AHF) occurred in Jan. It is a 500-pt trial and will evaluate effects of three dose levels of TRV027: 1.0 mg/hr, 5.0 mg/hr, and 25 mg/hr on a composite of clinically relevant outcomes: mortality, worsening heart failure, hospital readmission rate, dyspnea, and length of hospital stay. Recruitment is ongoing and topline data is expected in Q4'15.

BUY

Price target \$11.00

Price \$5.89

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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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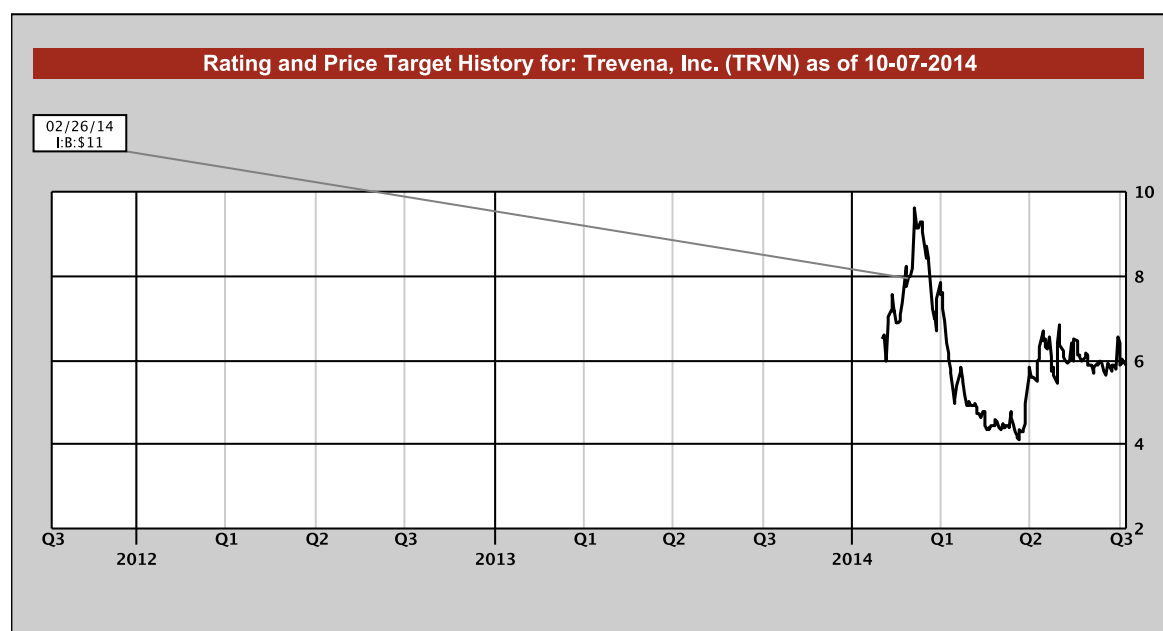
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