

Trevena, Inc. (TRVN)

Phase 2 Results Support Bias Toward a Better Opioid

MARKET DATA

Price	\$5.66
52-Week Range:	\$4.01 - \$9.95
Shares Out. (M):	26.2
Market Cap (\$M):	\$148.3
Average Daily Vol. (000):	15.0
Cash (M):	\$72
Cash/Share:	\$2.74
Enterprise Value (M):	\$76
LT Debt (M):	\$2

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$5.66 | Target Price: \$21.00

INVESTMENT HIGHLIGHTS

Phase 2 results for TRV130 demonstrate superior efficacy to morphine, and support advancement into later stage development; reiterate Market Outperform rating on Trevena shares, and increase price target to \$21 from \$18. Yesterday afternoon, Trevena announced positive results from a Phase 2a/b trial demonstrating that TRV130, a novel drug candidate for the treatment of pain, achieved significantly superior pain relief to IV morphine with a favorable safety profile. We believe these data support the potential for TRV130 as a highly effective, differentiated IV treatment option with an improved therapeutic window vs. current opioids. The company intends to initiate a second Phase 2 trial, in patients who have undergone soft tissue surgery, later in 4Q14. We increase our probability of success for TRV130 to 60% from 50%, and therefore, increase our price target to \$21, which remains derived through a sum-of-the-parts analysis for TRV130 and TRV027.

TRV130 efficacy robustly superior to morphine. The Phase 2a/b trial evaluated TRV130 over a range of doses in patients following bunionectomy procedure. The trial met its primary endpoint, demonstrating greater pain reduction than placebo over 48 hours for the TRV130 2mg ($p=0.0024$) and 3mg ($p<0.0001$) doses. Furthermore, TRV130 (3mg) demonstrated significantly superior analgesic efficacy vs. morphine ($p=0.0023$). An additional analysis performed three hours after the first dose, when baseline pain intensity was the most severe, showed greater differentiation vs. morphine, with both the 2mg ($p=0.0029$) and 3mg ($p<0.0001$) achieving superior analgesia. We believe these results de-risk the Phase 3 program, and validate Trevena's development platform. We look to additional analyses when the data are presented and published in peer review forums.

Safety and tolerability similar to morphine benchmark. We believe the results from this trial support that TRV130 has a more favorable therapeutic index vs. morphine as the drug was able to achieve superior efficacy with a similar safety and tolerability profile. The company stated that tolerability for 2 mg and 3 mg TRV130 over the full 48 hours of dosing was similar to morphine. There were no serious adverse events reported in the trial, and both TRV130 and morphine were associated with opioid-related adverse events, including dizziness, headache, somnolence, nausea, vomiting, flushing, and itching.

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	--	\$0.0A	--
	2Q	--	\$0.0A	--
	3Q	--	\$0.0A	--
	4Q	--	\$0.0	--
	FY	\$0.1	\$0.0	\$0.0
EPS	1Q	--	(\$0.59)A	--
	2Q	--	(\$0.44)A	--
	3Q	--	(\$0.59)A	--
	4Q	--	(\$0.62)	--
	FY	(\$29.71)	(\$2.23)	(\$2.42)
	P/E	NM	NM	NM
	Previous FY	NC	(\$2.02)	(\$2.01)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



Initiating TRV130 Phase 2 abdominoplasty trial in 4Q14. Trevena intends to initiate a second Phase 2 trial for TRV130 later in 4Q14 to evaluate as-needed, dosing in patients following soft tissue surgery (abdominoplasty). The primary endpoint will be the efficacy of TRV130 compared to placebo over 24 hours, an endpoint that may be used as a registration endpoint in Phase 3 trials. The study is designed to enroll ~200 patients with ~40 receiving placebo, 80 receiving TRV130, and 80 receiving morphine. An initial loading dose will be followed by delivery of on-demand doses via a patient controlled analgesia (PCA) device. Results are expected in 2Q15, and in our view, should further inform the design of a Phase 3 program that can reinforce the differentiated clinical benefit of TRV130.

TRV130 PHASE 2A/B TRIAL DESIGN AND RESULTS

Doses of 2 mg and 3 mg of TRV130 at three-hour intervals achieved a statistically significant reduction in pain intensity difference from placebo over 48 hours, measured as the time-weighted average change in pain score (TWA0-48). At 2 mg, TRV130 reduced average pain score (LS mean change in TWA0-48) by 1.4 points ($p=0.0024$ vs. placebo; all p -values 1-sided). At 3 mg, TRV130 reduced LS mean TWA0-48 by 2.4 points ($p<0.0001$ vs. placebo) (Figure 1). Over 48 hours, 3 mg of TRV130 at three-hour intervals achieved a statistically significant reduction in pain intensity difference from 4 mg morphine at four-hour intervals, reducing average pain score (LS mean change in TWA0-48) by 1.0 point vs. morphine ($p=0.014$). Morphine reduced LS mean change in TWA0-48 by 1.3 points vs. placebo ($p = 0.0023$). Baseline pain rating was ~7 out of 10, or severe pain.

FIGURE 1. TRV130 Phase 2a/b: Statistically Significant Results on Primary Endpoint

Success on primary endpoint:
pain relief vs. placebo over 48 hours (TWA0-48)

Additionally: TRV130 3 mg demonstrated pain relief superior to morphine

Stage B data

Dose (mg)	Interval (hr)	Patients (n)	LS mean Δ TWA 0-48	p (vs. Placebo)	p (vs. Morphine)
Placebo	3 or 4	28	-	-	-
TRV130 (0.5 mg)	3	20	-0.5	0.18	0.95
TRV130 (1 mg)	3	38	-0.3	0.23	0.99
TRV130 (2 mg)	3	36	-1.4	0.0024*	0.48
TRV130 (3 mg)	3	31	-2.4	<0.0001*	0.014**
Morphine (4 mg)	4	39	-1.3	0.0023*	-

**statistically significant vs. placebo*

***statistically significant vs. morphine*

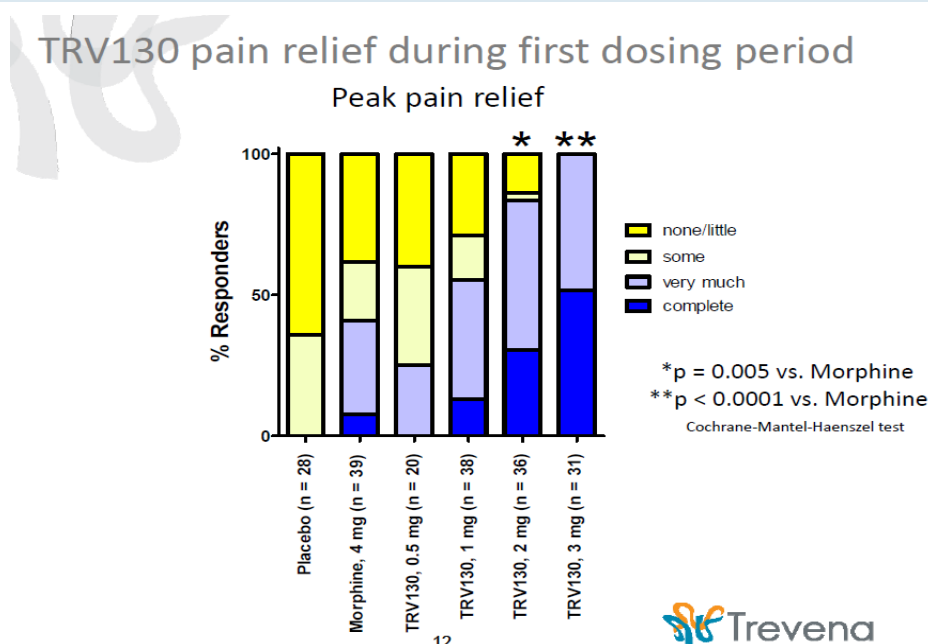
1 sided p values

TWA0-48 = time weighted average pain intensity difference from 0 to 48 hours

Source: Company reports

Importantly, TRV130 achieved a reduction in mean pain intensity of up to ~6 points, with notable efficacy at five minutes, the first pain intensity assessment after dosing. Patients reported statistically greater peak pain relief during the first dosing period for 2 mg and 3 mg TRV130 compared to 4 mg morphine ($p = 0.005$ and $p < 0.0001$ for TRV130 2 mg and 3 mg vs. morphine, respectively), Figure 2. Complete pain relief during this period was reported in 13%, 31%, and 52% of patients receiving 1 mg, 2 mg, and 3 mg TRV130, respectively, compared to 0% and 8% for patients receiving placebo and 4 mg morphine, respectively.

FIGURE 2. TRV130 Pain Relief at First Dose



Source: Company reports

Additionally, the 2 mg and 3 mg doses of TRV130 demonstrated statistically superior analgesic efficacy compared to 4 mg morphine in the first three hours of dosing, when study pain was most severe. During the first three hours after the initial dose, TRV130 at 1 mg, 2 mg, and 3 mg showed a statistically significant reduction in pain (TWA0-3) vs. placebo (LS mean change -1.0, -2.4, and -3.0 respectively; $p = 0.021$, $p < 0.0001$, and $p < 0.0001$, respectively). For these doses, patients also reported maximum pain relief during the first dosing period that was statistically superior compared to morphine. TRV130 at 2 mg and 3 mg showed a statistically significant reduction in pain vs. 4 mg morphine during this time (LS mean change: TRV130 2 mg -1.2 vs. morphine, $p = 0.0029$; TRV130 3 mg -1.8 vs. morphine, $p < 0.0001$), Figure 3.

FIGURE 3. TRV130 Shows Superior Analgesia vs. Morphine

TRV130 analgesia superior to morphine
when pain is severe, at first dose (TWA0-3)

Stage B data

Dose (mg)	Patients (n)	LS mean Δ TWA 0-3	p (vs. Placebo)	p (vs. Morphine)
Placebo	28	-	-	-
TRV130 (0.5 mg)	20	-0.8	0.076	0.77
TRV130 (1 mg)	38	-1.0	0.021*	0.68
TRV130 (2 mg)	36	-2.4	<0.0001*	0.0029**
TRV130 (3 mg)	31	-3.0	<0.0001*	<0.0001**
Morphine (4 mg)	39	-1.2	0.0075*	-

*statistically significant vs. placebo

**statistically significant vs. morphine

1 sided p values

TWA0-3 = time weighted average pain intensity difference from 0 to 3 hours

Source: Company reports

KEY UPCOMING MILESTONES

- 4Q14E TRV130 Phase 2 initiation in soft tissue surgery
- 1Q15E TRV734 Phase 1 data read-out
- 2Q15E TRV130 Phase 2 results in soft tissue surgery
- 4Q15E Phase 2b BLAST-AHF top-line data

3Q14 FINANCIAL SUMMARY

Last week, Trevena reported a 3Q14 EPS loss of (\$0.59), below both our forecast of (\$0.49) and consensus of (\$0.43). The company reported no revenue, which was in line with our expectation, as well as consensus. Total operating expenses were \$15.5M, higher than our estimate of \$12.9M. R&D expenses were \$13.0M, compared to our estimate of \$10.4M. SG&A expenses were \$2.5M, in line with our estimate of \$2.5M. Cash and cash equivalents totaled \$72.2M as of September 30, 2014, which the company believes will be sufficient to fund operations through YE 2015.

We have updated our model (Figure 4) to reflect the 3Q14 financial results.

FIGURE 4. 3Q14 Earnings Summary and Changes to Our Model

TRVN	3Q14			2014 est		2015 est	
	JMP est	Cons	Actual	JMP old	JMP new	JMP old	JMP new
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0
R&D	10.4		13.0	38.0	43.3	42.6	53.4
SG&A	2.5		2.5	9.7	9.7	11.5	11.5
Total operating expense	12.9		15.5	47.6	53.0	54.1	64.9
Net income (loss)	(12.9)	(11.2)	(15.5)	(47.4)	(52.8)	(54.1)	(64.9)
Shares outstanding (diluted)	26.5		26.4	23.9	23.8	26.9	26.8
EPS (diluted)	(\$0.49)	(\$0.43)	(\$0.59)	(\$2.02)	(\$2.23)	(\$2.01)	(\$2.42)

Source: JMP Securities LLC, Company reports

Company Description

Trevena is a clinical-stage biopharmaceutical company based in King of Prussia, PA, focused on the discovery and development of small molecule and peptide G-protein coupled receptor (GPCR) biased ligands. The company was established in 2007 with the aim of translating groundbreaking academic research on GPCR signaling into a new generation of medicines. The company has two programs in clinical development: TRV027, currently in Phase 2 clinical testing for the treatment of acute heart failure, and TRV130, currently completing Phase 2 testing for the treatment of post-operative pain. In addition, Trevena has built an early stage portfolio of drug discovery programs currently in lead optimization, including TRV734, currently in preclinical testing for oral treatment of acute and chronic pain.

In January 2014, Trevena completed its initial public offering, raising net proceeds of approximately \$60MM through the sale of 9.25 million shares of common stock at a price of \$7 per share. The proceeds from the IPO are intended to fund the development of TRV027, TRV130, and TRV734, as well as additional preclinical programs and for general working capital and corporate purposes.

Investment Risks

Clinical risk. Trevena may not be successful in the full development and launch of its product candidates. There may be efficacy or safety issues related to product candidates undergoing clinical trials that would preclude continued development.

Regulatory risk. The FDA and/or other ex-U.S. regulatory agencies could reject any of the company's, or its partners', future regulatory filings or require additional studies prior to granting approval.

Industry risk. Given the competitive landscape in the biotechnology space, another company may come out with a more efficacious, less expensive product that could take significant market share away from Trevena's products, challenging the company's chances for success.

Balance sheet risk. The company has a history of losses and has not yet established a track record of consistent profitability. While we project that the company will not need to raise additional capital to maintain profitability, it may be necessary to do so to fund the business model.

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JMP Securities currently makes a market in the security of Trevena, Inc.

JMP Securities was manager or co-manager of a public offering of securities for Trevena, Inc. (TRVN) in the past 12 months, and received compensation for doing so.

JMP Securities expects to receive OR intends to seek compensation for investment banking services from Trevena, Inc. in the next 3 months.

JMP Securities Investment Opinion Definitions:

Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

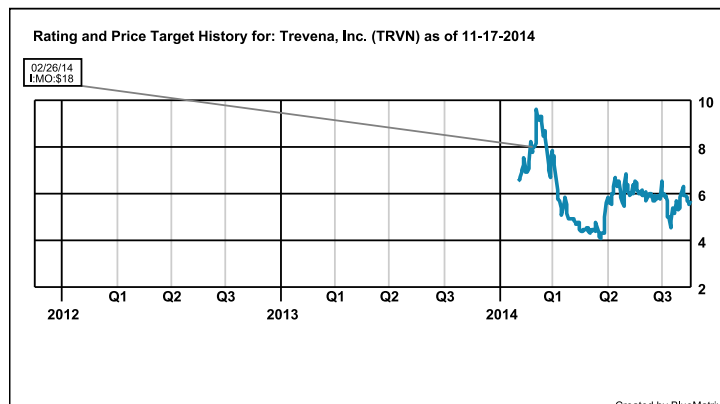
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of November 18, 2014)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	286	60.98%	Buy	286	60.98%	105	36.71%
MARKET PERFORM	Hold	143	30.49%	Hold	143	30.49%	15	10.49%
MARKET UNDERPERFORM	Sell	2	0.43%	Sell	2	0.43%	0	0%
COVERAGE IN TRANSITION		35	7.46%		35	7.46%	0	0%
TOTAL:		469	100%		469	100%	122	26.01%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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