

COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

August 12, 2014

Jefferies

Trevena, Inc. (TRVN) Q2: TRVN Rich in Data Catalysts over the Next 12-18 Months

Key Takeaway

TRVN continues to make progress on its clinical pipeline of GPCR biased ligands. TRVN has initiated Part B of the 400-pt PIIa/b bunionectomy trial for TRV130 with an adaptive design, with top-line data expected in Q1'15. The PIIb BLAST trial for TRV027 for acute heart failure is on-track to have data in Q4'15. For oral TRV734, top-line data from the multiple ascending dose PI study is expected H1'15.

TRV130 and TRV734 for Pain Management Continue to Advance: TRVN continues to move forward with the PIIa/b bunionectomy trial for TRV130, which will enroll ~400 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). TRVN has seen early signs of analgesic efficacy and has now initiated Part B of the study, which will evaluate doses (starting w/ two adaptive regimens) in 250 pts (10 cohorts) to optimize performance characteristics based on the results from Part A. Top-line data from both Part A and B are expected in Q1'15 (data may potentially be out b/f in YE'14). TRVN is also moving forward with oral TRV734 for moderate-to-severe acute and chronic pain, and top-line data from the multiple ascending dose PI study is expected H1'15.

Top-line Data for PIIb BLAST Trial for TRV027 Expected in Q4'15: TRVN reported dosing of the first patient in the PIIb BLAST trial in acute heart failure (AHF) 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 (v. prev H2'15). We believe promising PIIa data supports a favorable outlook for TRV027 in AHF.

Q2 Financials: TRVN reported Q2 EPS of \$(0.44) (v. JEF: \$(0.35) and cons: \$(0.39)). Cash and equivs were \$81.6M at end Q2, and TRVN believes should be sufficient to fund operations through to end of '15.

Valuation/Risks

Our \$11 PT is DCF-based. Risks to our thesis include clinical trial failure, regulatory approval risks, and commercial launch risks.

USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	0.1	--	0.0	--	0.0	--	42.3
EV/Rev		NM						1.8x
EPS								
Mar	--	(0.23)	--	(0.59)A	--	--	--	--
Jun	--	(0.30)	(0.35)	(0.44)A	--	--	--	--
Sep	--	(0.64)	(0.36)	(0.39)	--	--	--	--
Dec	--	(0.42)	(0.37)	(0.41)	--	--	--	--
FY Dec	--	(1.60)	(1.68)	(1.82)	(1.66)	(1.79)	0.20	0.06
FY P/E		NM		NM		NM		NM

BUY

Price target \$11.00

Price \$6.01

Financial Summary

Net Debt (MM):	(\$81.6)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$81.6
Cash/Share:	\$3.11
Cash (MM):	\$81.6

Market Data

52 Week Range:	\$9.95 - \$4.07
Total Entprs. Value (MM):	\$75.9
Market Cap. (MM):	\$157.5
Shares Out. (MM):	26.2
Float (MM):	12.4
Avg. Daily Vol.:	85,856

Biren Amin *

Equity Analyst

(212) 284-8162 bamin@jefferies.com

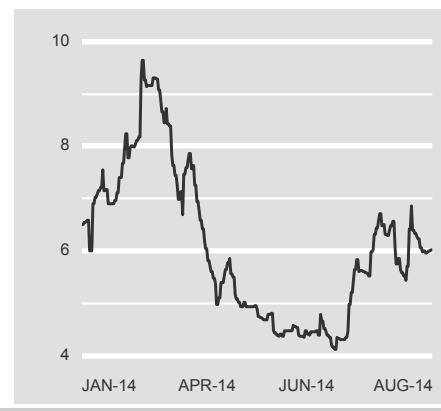
Hugo Ong, Ph.D. *

Equity Associate

(212) 323-3364 hong@jefferies.com

* Jefferies LLC

Price Performance



Valuation

We arrive at our \$11 price target based on a DCF valuation model, which assumes a 14% WACC and outstanding shares of 26.2 million, driven by royalties from TRV027 and revenues from TRV130. We expect U.S. approval for TRV027 in 2020, reaching revenues of \$612 million by 2030 on an unadjusted-basis. Applying a 65% risk discount, we believe TRV027 will have U.S. revenues of \$214 million by 2030, translating to royalty revenue of \$41 million. We also expect ex-U.S. revenues of \$126 million at peak on a risk-adjusted basis (65%), translating to royalty revenue of \$24 million. For TRV130, we estimate approval in 2019 and total peak net sales for in- and out-patient surgical patients at \$585 million in 2031 on an unadjusted-basis (\$562 million for in-patient and \$22 million for out-patient). Applying a 65% discount rate to reflect the risk associated with this early stage asset, we estimate risk-adjusted peak sales of \$205 million by 2031. We expect TRVN to partner TRV130 for commercialization ex-U.S. and estimate royalty revenue of \$82 million by 2031. We do not yet model TRV734 for pain management or TRVN's delta opioid program, both of which represent upside to our estimates.

Exhibit 1: DCF sensitivity analysis

Discount rate	Equity value	Price/Share
10.0%	\$404.1	\$15.35
12.0%	\$333.4	\$12.66
14.0%	\$276.7	\$10.51
16.0%	\$231.0	\$8.77
18.0%	\$193.8	\$7.36

Source: Jefferies estimates

Risks

Clinical Failure: As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

Regulatory Failure: The FDA could determine the Biologic Licensing Application is inadequate for one or more of TRVN's programs and could delay approval. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

Commercial Failure: We currently project \$214 million (risk-adjusted) in U.S. sales for TRV027 in 2030, translating to royalty revenue of \$41 million. We also project \$205 million (risk-adjusted) in U.S. sales for TRV130 in 2031. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

Financing Risks: We expect TRVN to have adequate cash until 2016, and may need additional financing from 2014 to 2016 to fund its R&D programs, and a sales and marketing infrastructure for a potential commercial launch of TRV130 (if approved). However, the company may partner ex-U.S. licensing rights and/or other pipeline candidates to offset the need for equity financing.

Exhibit 2: Key Upcoming Milestones.

Product	Indication	Event	Date
TRV027	Acute Heart Failure (AHF)	Enrollment completion of Phase II BLAST-AHF	H1 2015
		Topline data for Phase II BLAST-AHF	Q4 2015
		FDA AdComm Panel for Novartis' serelaxin in AHF	Mar 27, 2014
		Forest Laboratories' exercise of license option (JEF est)	H2 2015
		Initiation of pivotal Phase III trial	H2 2016
		Topline data for pivotal Phase III trial	2019
		U.S. approval of TRV027	2020
		EU/ROW approval of TRV027	2020
TRV130	Post-operative pain	Full data of Phase Ib trial at American Pain Society	May 2014
		Initiation of Phase II trial (bunionectomy model)	Q2 2014
		Topline data for Phase II trial (bunionectomy model) - Part A and B	Q1 2015
		Initiation of separate Phase II trial (alternative pain model)	Q4 2014
		Initiation of pivotal Phase III trial	H2 2015
		Topline data for pivotal Phase III trial	2018
		U.S. approval of TRV130	2019
		EU/ROW approval of TRV130	2020
TRV734	Moderate-to-Severe Pain	Initiation of Phase I trial for TRV734 in healthy subjects	Feb 2014
		Data for Phase I trial for TRV734 on oral bioavailability	Mid-2014
		Topline data for MAD PI study	H1 2015
Delta Opioid Program	Parkinson's Disease, Pain, Depression	Candidate selection for Parkinson's Disease	2014
		IND filing	Q1 2015
		Initiation of Phase I trial	2015

Source: Company estimates, Jefferies.

Exhibit 3: TRVN Income Statement

Trevena, Inc.

Quarterly Income Statement

(All values in \$MM except EPS and average shares)

	2012A	2013A	2014E					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY	FY	1QA	2QA	3QE	4QA	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																		
TRV027 US Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.6	6.3	12.5	17.3	23.9	26.6
TRV027 EU Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.6	4.5	7.2	9.2	11.5	12.6
TRV027 ROW Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	1.0	1.6	2.0	2.5	2.8
TRV130 US Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.3	52.6	94.0	122.3	143.3	156.3	159.6
TRV130 EU/ROW Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	4.1	7.1	9.0	10.2	11.0
Grant and collaboration revenues	0.8	0.1	0.0	0.0	0.0	0.0	0.0	0.0	42.3	1.0	0.0	17.5	35.0	0.0	17.5	0.0	17.5	0.0
Total revenue, net	0.8	0.1	0.0	0.0	0.0	0.0	0.0	0.0	42.3	1.0	0.0	24.8	95.0	109.8	168.2	180.8	221.9	222.5
Costs and expenses:																		
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7	5.3	9.4	12.2	14.3	15.6	17.0
Research & development	13.3	18.8	7.6	9.0	8.2	8.6	33.5	35.0	32.0	30.0	19.0	15.0	5.8	16.5	17.4	18.2	19.0	19.5
Selling, general & administrative	3.1	4.7	2.0	2.5	2.0	2.2	8.7	8.0	8.2	8.6	9.0	20.0	21.8	23.3	24.5	25.7	26.7	27.5
Total operating expenses	16.4	23.5	9.7	11.5	10.2	10.8	42.2	43.0	40.2	38.6	28.0	35.7	42.8	49.3	54.1	58.3	61.3	64.0
Income (loss) from operations	(15.6)	(23.3)	(9.7)	(11.5)	(10.2)	(10.8)	(42.2)	(43.0)	2.1	(37.6)	(28.0)	(10.9)	52.2	60.5	114.1	122.5	160.6	158.4
Other income (expense):																		
Change in fair value of warrant liability		0.2	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Miscellaneous (expense) income	(0.0)	0.0	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest income	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest expense	-	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (loss) before income taxes	(15.6)	(23.3)	(9.4)	(11.5)	(10.2)	(10.8)	(41.8)	(43.0)	2.1	(37.6)	(28.0)	(10.9)	52.2	60.5	114.1	122.5	160.6	158.4
Income tax expense (benefit)									0.0	0.0	0.0	5.2	6.1	11.4	42.9	56.2	55.5	
Income tax (%)									0.0%	0.0%	0.0%	10.0%	10.0%	10.0%	35.0%	35.0%	35.0%	
Net Income (GAAP)	(15.6)	(23.3)	(9.4)	(11.5)	(10.2)	(10.8)	(41.8)	(43.0)	2.1	(37.6)	(28.0)	(10.9)	47.0	54.5	102.7	79.7	104.4	103.0
EPS, GAAP																		
Basic	(150)	(160)	(0.59)	(0.44)	(0.39)	(0.41)	(182)	(179)	0.06	(109)	(0.80)	(0.31)	132	151	2.83	2.17	2.82	2.75
Diluted	\$ (1.50)	\$ (1.60)	\$ (0.59)	\$ (0.44)	\$ (0.39)	\$ (0.41)	\$ (1.82)	\$ (1.79)	\$ 0.06	\$ (1.09)	\$ (0.80)	\$ (0.31)	\$ 1.32	\$ 1.51	\$ 2.83	\$ 2.17	\$ 2.82	\$ 2.75
Weighted average share- Basic	10.4	14.5	15.0	26.3	26.3	26.3	23.8	24.0	34.2	34.6	34.9	35.3	35.6	36.0	36.3	36.7	37.1	37.4
Weighted average share- Diluted	10.4	14.5	15.0	26.3	26.3	26.3	23.8	24.0	34.2	34.6	34.9	35.3	35.6	36.0	36.3	36.7	37.1	37.4

Source: Jefferies estimates, company data

Exhibit 4: TRVN DCF Analysis**Trevena, Inc.****Discounted Cash Flow Analysis**

<i>(All values in \$MM)</i>	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Sales	0.1	0.0	0.0	42.3	1.0	0.0	24.8	95.0	109.8	168.2	180.8	221.9	222.5
Operating Expenses	23.5	42.2	43.0	40.2	38.6	28.0	35.7	42.8	49.3	54.1	58.3	61.3	64.0
EBIT	(23.3)	(42.2)	(43.0)	2.1	(37.6)	(28.0)	(10.9)	52.2	60.5	114.1	122.5	160.6	158.4
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.2	6.1	11.4	42.9	56.2	55.5
EBIAT	(23.3)	(42.2)	(43.0)	2.1	(37.6)	(28.0)	(10.9)	47.0	54.5	102.7	79.7	104.4	103.0
(+): Depreciation	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.0	0.0
(+): FAS-123 Options	0.0	0.3	0.5	0.5	0.5	0.5	0.5	0.7	0.7	0.7	1.0	1.0	1.0
Unlevered free cash flow	(22.8)	(41.3)	(42.0)	3.1	(36.6)	(27.0)	(9.9)	48.3	55.7	103.9	81.2	105.4	104.0

Source: Jefferies estimates, company data

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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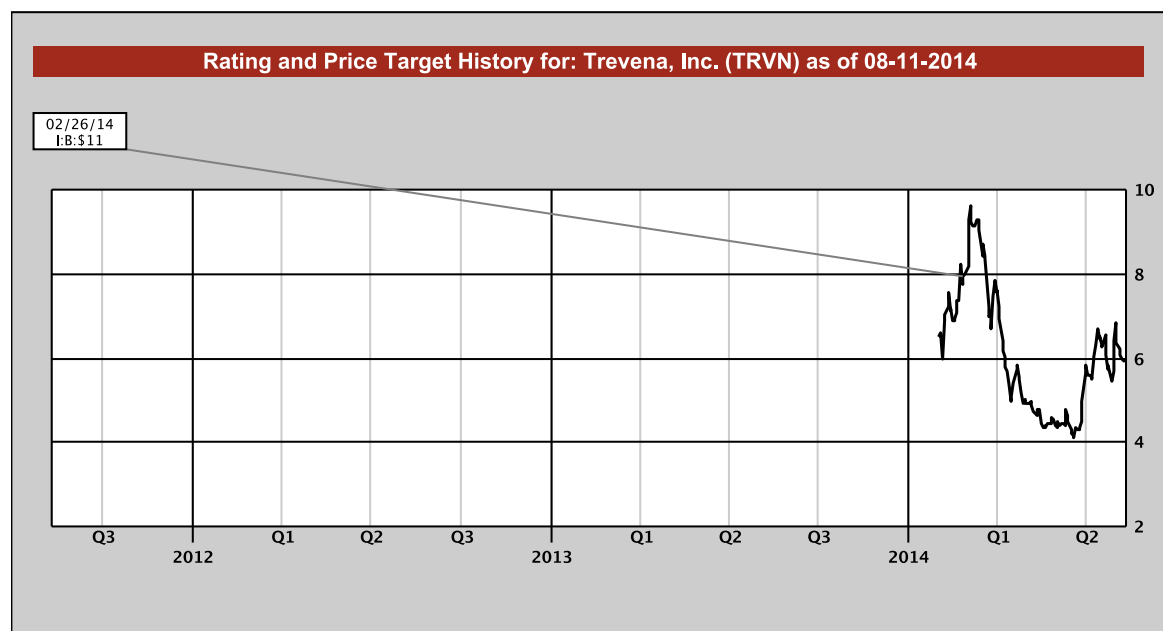
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