

COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

March 20, 2014

Jefferies

Trevena, Inc. (TRVN) Q4: Biased-Ligand Platform Advancing

Key Takeaway

TRVN continues to make progress on its clinical pipeline of GPCR biased ligands. The CRDAC panel for Novartis' serelaxin for AHF is scheduled for Thurs, Mar 27, which we believe may help guide TRV027's development. TRV130 is also making progress with a PII bunionectomy trial set to begin in Q2'14, and an additional PII trial in a soft tissue pain model to begin in Q4'14.

Serelaxin CRDAC Meeting on Mar 27 May Help Guide TRV027's Development:

The FDA Cardiovascular and Renal Drugs Advisory Committee Panel meeting for Novartis' (NOVN VX, CHF71.60, Hold) serelaxin for acute heart failure (AHF) is scheduled for Thurs, Mar 27, '14, which we believe will help guide TRVN/FRX (\$96.00, Buy) on the pivotal PIII design for TRV027 and may begin in H2'16. We expect the panel to discuss key issues on RELAX-AHF's trial design/dataset and relevance of dyspnea in AHF. As a reminder, we believe promising PIIa data supports a favorable outlook for TRV027 in AHF as it begins its PIIb trial (topline data expected in H2'15). Assuming a positive outcome on the pivotal PIII trial, we believe TRV027 can generate WW royalty revenue for TRVN of \$65M at peak by 2030 (\$41M in U.S.) (risk-adjusted).

TRV130 and TRV734 for Pain Management are Advancing: TRV130 is a biased ligand against the μ -opioid receptor for acute post-operative pain, which may exhibit more effective analgesia while reducing adverse events commonly associated with opioids. PI and preclinical data have been supportive where TRV130 showed superior analgesia v. morphine, while causing less respiratory depression, nausea, and vomiting. TRV130 remains on-track to begin a PII bunionectomy trial in Q2'14, which should enroll ~400 pts and have an adaptive dose-selection design. Assuming positive data expected Q1'15 and in the subsequent pivotal PIII trial, we estimate TRV130 approval in 2019 and anticipate U.S. revenues of \$205M by 2031 (risk-adjusted). TRVN also anticipates an additional PII trial in soft-tissue-surgery in Q4'14. The PI trial for oral TRV734 was initiated in Feb '14 for moderate-to-severe acute and chronic pain, and data is expected in Q3'14.

Q4 Financials: TRVN reported FY'13 EPS of (\$29.71) v. FY'12 of (\$23.70). Cash and equivs were \$38.0M at end Q4, and including the net proceeds of \$59.6M from the IPO in Jan '14, 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						3.1x
EPS								
Mar	--	(0.23)	(0.33)	(0.31)	--	--	--	--
Jun	--	(0.30)	(0.35)	(0.34)	--	--	--	--
Sep	--	(0.64)	(0.37)	(0.36)	--	--	--	--
Dec	(0.56)	(0.42)	(0.38)	(0.37)	--	--	--	--
FY Dec	(1.76)	(1.60)	(1.44)	(1.37)	(1.64)	(1.50)	0.11	0.19
FY P/E		NM		NM		NM		44.3x

BUY

Price target \$11.00

Price \$8.42

Financial Summary

Net Debt (MM):	(\$90.6)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$90.6
Cash/Share:	\$3.46
Cash (MM):	\$90.6

Market Data

52 Week Range:	\$9.95 - \$6.35
Total Entprs. Value (MM):	\$130.0
Market Cap. (MM):	\$220.6
Shares Out. (MM):	26.2
Float (MM):	8.0
Avg. Daily Vol.:	NA

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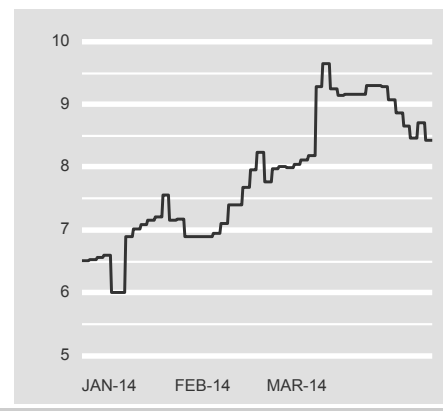
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Price Performance



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%	\$405.5	\$15.48
12.0%	\$332.8	\$12.70
14.0%	\$275.3	\$10.51
16.0%	\$229.7	\$8.77
18.0%	\$193.2	\$7.37

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	H2 2015
		FDA AdComm Panel for Novartis' serelaxin in AHF	Mar 27, 2014
		PDUFA date for Novartis' serelaxin in AHF	Q2 2014
		EMA decision for conditional approval of Novartis' serelaxin in AHF	Q2 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)	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	IND filing	Q1 2014
		<i>Initiation of Phase I trial for TRV734 in healthy subjects</i>	<i>Feb 2014</i>
		Data for Phase I trial for TRV734	Q3 2014
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	1Q	2Q	3Q	4Q	FY	1Q	2Q	3Q	4Q	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	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	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	0.0	0.0	0.0	0.0	0.6	1.0	1.6	2.0	2.5	2.8
TRV030 US Sales	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	7.3	52.6	94.0	122.3	143.3	156.3	159.6
TRV030 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	0.0	0.0	0.0	0.0	0.6	4.1	7.1	9.0	10.2	11.0
Grant and collaboration revenues	0.8	0.0	0.1	0.0	0.0	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	0.0	0.1	0.0	0.0	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	0.0	0.0	0.0	0.0	0.7	5.3	9.4	12.2	14.3	15.6	17.0
Research & development	13.3	2.3	3.2	6.6	6.6	18.8	7.1	7.7	8.2	8.6	31.6	35.0	32.0	30.0	19.0	15.0	15.8	15.5	17.4	15.2	19.1	19.7
Selling, general & administrative	3.1	0.7	0.9	1.2	1.9	4.7	0.9	1.1	1.2	1.0	4.2	4.7	3.4	3.7	4.0	14.7	15.0	17.4	18.6	19.5	20.5	21.1
Total operating expenses	16.4	3.0	4.1	7.8	8.5	23.5	8.0	8.8	9.4	9.6	35.8	39.7	35.4	33.7	23.0	30.4	37.0	43.4	48.1	52.0	55.2	57.7
Income (loss) from operations	(15.6)	(3.0)	(4.0)	(7.8)	(8.5)	(23.3)	(8.0)	(8.8)	(9.4)	(9.6)	(35.8)	(39.7)	6.9	(32.7)	(23.0)	(5.6)	58.0	66.4	120.0	128.8	166.7	164.7
Other income (expense):																						
Change in fair value of warrant liability		0.0	0.0	0.0	0.2	0.2	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
Miscellaneous (expense) income	(0.0)	(0.2)	(0.2)	(0.9)	1.4	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 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	0.0	0.0	0.0	0.0
Interest expense	-	0.0	0.0	0.0	(0.2)	(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)	(3.2)	(4.2)	(8.8)	(7.1)	(23.3)	(8.0)	(8.8)	(9.4)	(9.6)	(35.8)	(39.7)	6.9	(32.7)	(23.0)	(5.6)	58.0	66.4	120.0	128.8	166.7	164.7
Income tax expense (benefit)													0.0	0.0	0.0	0.0	5.8	6.6	12.0	45.1	58.3	57.7
Income tax (%)													0.0%	0.0%	0.0%	0.0%	10.0%	10.0%	10.0%	35.0%	35.0%	35.0%
Net Income (GAAP)	(15.6)	(3.2)	(4.2)	(8.8)	(7.1)	(23.3)	(8.0)	(8.8)	(9.4)	(9.6)	(35.8)	(39.7)	6.9	(32.7)	(23.0)	(5.6)	52.2	59.8	108.0	83.7	108.4	107.1
EPS, GAAP																						
Basic	(150)	(0.23)	(0.30)	(0.64)	(0.42)	(160)	(0.31)	(0.34)	(0.36)	(0.37)	(137)	(150)	0.19	(0.88)	(0.61)	(0.15)	137	155	2.77	2.13	2.72	2.67
Diluted	\$ (150)	\$ (0.23)	\$ (0.30)	\$ (0.64)	\$ (0.42)	\$ (160)	\$ (0.31)	\$ (0.34)	\$ (0.36)	\$ (0.37)	\$ (137)	\$ (150)	\$ 0.19	\$ (0.88)	\$ (0.61)	\$ (0.15)	\$ 137	\$ 155	\$ 2.77	\$ 2.13	\$ 2.72	\$ 2.67
Weighted average share- Basic	10.4	13.8	13.8	13.8	16.7	14.5	26.2	26.2	26.2	26.2	26.2	26.5	36.7	37.1	37.5	37.8	38.2	38.6	39.0	39.4	39.8	40.2
Weighted average share- Diluted	10.4	13.8	13.8	13.8	16.7	14.5	26.2	26.2	26.2	26.2	26.2	26.5	36.7	37.1	37.5	37.8	38.2	38.6	39.0	39.4	39.8	40.2

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	35.8	39.7	35.4	33.7	23.0	30.4	37.0	43.4	48.1	52.0	55.2	57.7
EBIT	(23.3)	(35.8)	(39.7)	6.9	(32.7)	(23.0)	(5.6)	58.0	66.4	120.0	128.8	166.7	164.7
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.8	6.6	12.0	45.1	58.3	57.7
EBIAT	(23.3)	(35.8)	(39.7)	6.9	(32.7)	(23.0)	(5.6)	52.2	59.8	108.0	83.7	108.4	107.1
(+): 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	0.4	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)	(34.9)	(38.7)	7.9	(31.6)	(21.9)	(4.5)	53.5	61.0	109.3	85.2	109.4	108.1

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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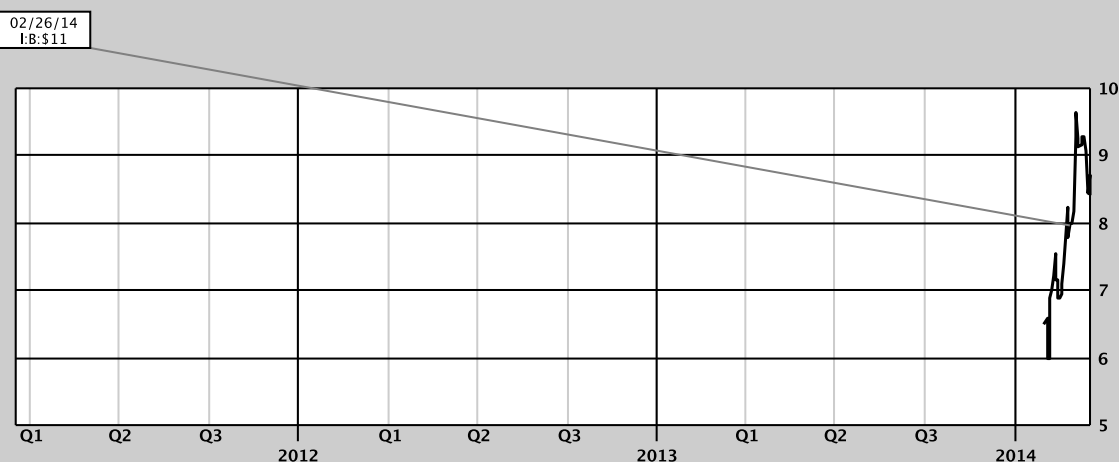
Risk which may impede the achievement of our Price Target

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Other Companies Mentioned in This Report

- Forest Laboratories, Inc. (FRX: \$96.00, BUY)
- Novartis AG (NOVN VX: CHF71.60, HOLD)
- Trevena, Inc. (TRVN: \$8.42, BUY)

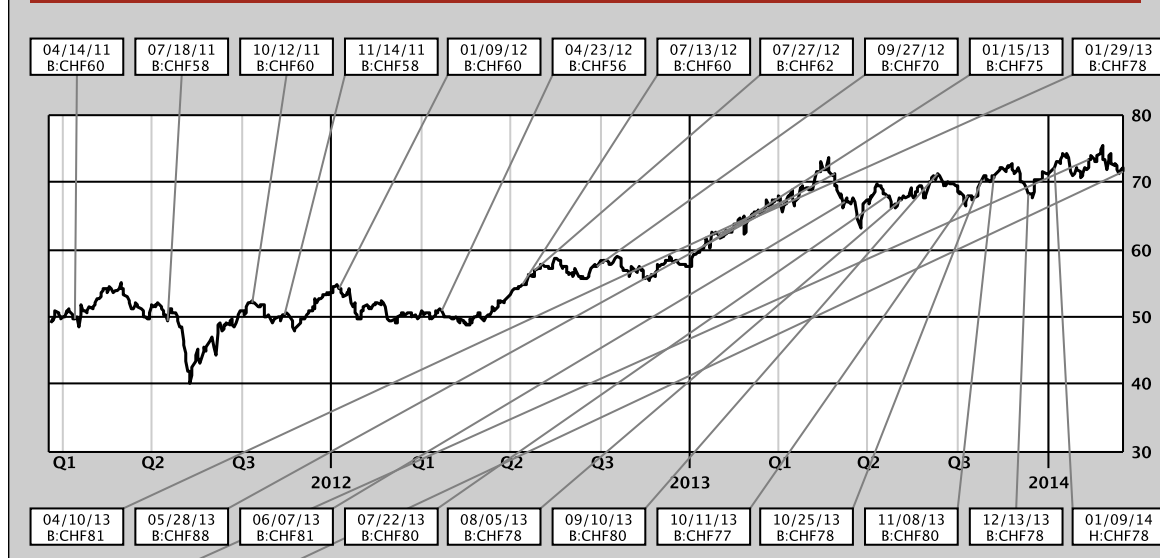
Rating and Price Target History for: Trevena, Inc. (TRVN) as of 03-19-2014



Rating and Price Target History for: Forest Laboratories, Inc. (FRX) as of 03-19-2014



Rating and Price Target History for: Novartis AG (NOVN VX) as of 03-19-2014



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Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
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