**COMPANY NOTE**

Estimate Change

USA | Healthcare | Biotechnology

November 11, 2014

Jefferies

# Trevena, Inc. (TRVN)

## Q3 Update: Topline PII Data for TRV130 Expected in Next Few Weeks

**BUY**

Price target $11.00

Price $5.85

EQUITY RESEARCH AMERICAS

### Key Takeaway

**TRVN continues to advance its clinical pipeline of GPCR biased ligands. Topline data for the PIIa/b bunionectomy trial for TRV130 is expected in the next few wks, and TRVN is set to begin its next PII trial this qtr evaluating flexible as-needed dosing via IV PCA in pts who have undergone abdominoplasty surgery. TRVN believes the study is more reflective of the real-world, and will complement the bunionectomy study in informing PIII development.**

**TRV130 and TRV734 for Pain Management Continue to Advance:** As announced in Oct, enrollment for the PIIa/b trial for TRV130 for post-operative bunionectomy pain has completed early and topline data is expected within the next few wks, and will include results on efficacy, tolerability, and safety measures of TRV130 v. morphine and pbo (including data from Parts A and B). TRVN also announced the next PII trial that will be initiated this qtr 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 initial loading dose has not been disclosed, but may be informed by the PII bunionectomy trial. The 1 EP will be efficacy v. pbo over 24 hrs, and data may help inform PIII design. TRVN is also moving forward with oral TRV734 for mod-to-severe acute and chronic pain, w/ enrollment complete for the PI multiple ascending dose trial in healthy volunteers. Topline data including safety, tolerability, and PK/PD data is expected in Q1'15 (v. H1'15 prev).

**Topline Data for PIIb BLAST Trial for TRV027 Expected in Q4'15:** The PIIb BLAST trial in acute heart failure (AHF) continues to enroll well w/ >200 pts as of Oct 31 (target enrollment: 500 pts, expected to be achieved in Q3'15). The study 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. Topline data is expected in Q4'15.

**Q3 Financials:** TRVN reported Q3 EPS of $(0.59) [v. JEF: $(0.39) and cons: $(0.43)] on higher R&D expenses. Cash and equivs were $72.2M at end-Q3, and TRVN believes should be sufficient to fund operations through to end of '15.

### Valuation/Risks

Our $11 PT is DCF-based (Exh4). Risks to our thesis include clinical trial failure, regulatory approval risks, and commercial launch risks.

| Financial Summary | |
|---|---|
| Net Debt (MM): | ($72.2) |
| Long-Term Debt (MM): | $0.0 |
| Cash & ST Invest. (MM): | $72.2 |
| Cash/Share: | $2.73 |
| Cash (MM): | $72.2 |

| Market Data | |
|---|---|
| 52 Week Range: | $9.95 - $4.01 |
| Total Entprs. Value (MM): | $81.1 |
| Market Cap. (MM): | $153.3 |
| Shares Out. (MM): | 26.2 |
| Float (MM): | 12.4 |
| Avg. Daily Vol.: | 55,485 |

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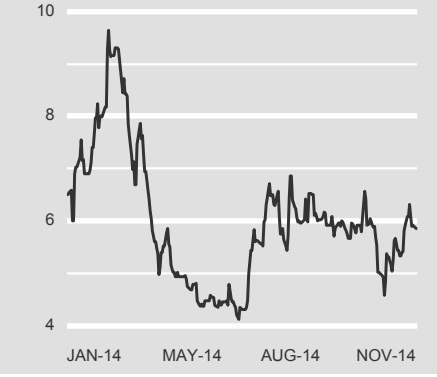
| USD | Prev. | 2013A | Prev. | 2014E | Prev. | 2015E | Prev. | 2016E |
|---|---|---|---|---|---|---|---|---|
| Rev. (MM) | -- | 0.1 | -- | 0.0 | -- | 0.0 | -- | 42.3 |
| EV/Rev | | NM | | | | | | 1.9x |
| **EPS** | | | | | | | | |
| Mar | -- | (0.23) | -- | (0.59)A | -- | -- | -- | -- |
| Jun | -- | (0.30) | -- | (0.44)A | -- | -- | -- | -- |
| Sep | -- | (0.64) | *(0.39)* | (0.59)A | -- | -- | -- | -- |
| Dec | -- | (0.42) | *(0.41)* | (0.47) | -- | -- | -- | -- |
| FY Dec | -- | (1.60) | *(1.82)* | (2.08) | *(1.79)* | (1.81) | *0.06* | 0.05 |
| FY P/E | | NM | | NM | | NM | | NM |

**Price Performance**



# Trevena, Inc.

## Buy: $11 Price Target

THE LONG VIEW

### Scenarios

**Target Investment Thesis**

- Positive outcomes in TRV027's Phase II BLAST-AHF and Phase III trial, with US and EU approval in 2020. Assume Forest Labs exercises license option in H2 2015
- Expect TRVN to receive royalty revenue of $41M in the U.S. and $24M in EU/ROW for TRV027 at peak
- Positive outcome in TRV130's clinical trials and U.S. approval in 2019, with peak net sales of $205M (risk-adjusted)
- DCF-based PT: $11

**Upside Scenario**

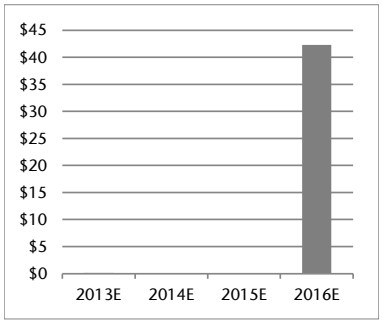
- Positive outcome in TRV734 clinical program for chronic pain
- Positive outcome in delta opioid program in CNS disorders
- DCF-based PT: $24

**Downside Scenario**

- Negative outcome in TRV027 clinical program , DCF-based PT: $5
- Negative outcome in TRV130 clinical program, DCF-based PT: $4
- On all clinical failure, including TRV734 and delta opioid program, cash-based PT: $2.50

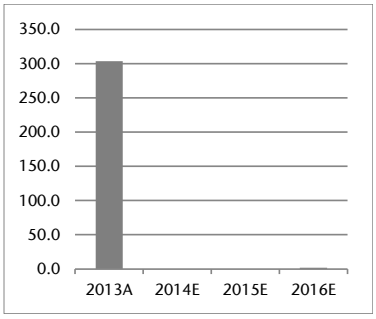
### Long Term Analysis

**Revenue (millions)**




Source: Company data; Jefferies estimates

**Enterprise Value (EV)/Sales**



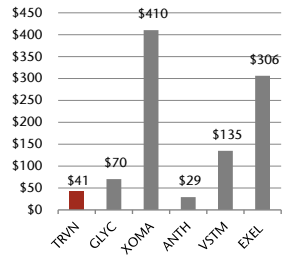

Source: Company data; Jefferies estimates

**Other Considerations**

We consider small-cap and mid-cap biotech companies with late-stage programs to continue to be attractive targets for partnering or M&A partnering with large-cap biotech and pharma companies, which we believe will be a driving factor for performance in the biotech sector 2014-2015.

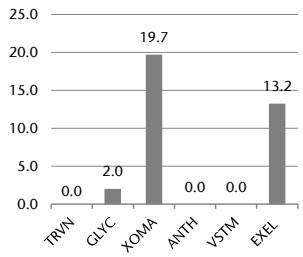
### Peer Group

**Group EV**




Source: Factset, Jefferies estimates

**Group EV/2014E Sales**




Source: Factset, Jefferies estimates

**Recommendation / Price Target**

| Ticker | Rec. | PT |
|---|---|---|
| **TRVN** | **Buy** | **$11** |
| GLYC | Buy | $19 |
| XOMA | Buy | $9 |
| ANTH | Buy | $18 |
| VSTM | Buy | $21 |
| EXEL | Hold | $2 |

### Catalysts

- Topline data for Phase II bunionectomy trial for TRV130 in mid-/late Nov
- Initiation of Phase II soft-tissue trial for TRV130 in Q4 2014
- Topline data for Phase I trial for TRV734 in Q1 2015
- Topline data for Phase II (BLAST-AHF) for TRV027 in Q4 2015

### Company Description

Trevena is a biopharmaceutical company based in King of Prussia, PA, dedicated to the development of G-protein coupled receptor (GPCR) biased ligands. Trevena's lead product is TRV027, a β-arrestin2 biased ligand which is in Phase II evaluation for treatment of acute heart failure. Trevenas' pipeline also includes TRV130; a biased μ-opioid receptor ligand that will soon undergo Phase II clinical evaluation in post-operative pain, TRV734; a μ-opioid receptor ligand in pre-clinical trials for acute and chronic pain and Delta BL program which involves biased ∂-opioid receptor ligands for treating pain, depression and neurological disorders like Parkinson's disease.



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## 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% | $405.2 | $15.37 |
| 12.0% | $333.9 | $12.66 |
| **14.0%** | **$276.8** | **$10.50** |
| 16.0% | $230.7 | $8.75 |
| 18.0% | $193.3 | $7.33 |

**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.



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**Exhibit 2: Key Upcoming Milestones.**

| Product | Indication | Event | Date |
|---|---|---|---|
| **TRV027** | **Acute Heart Failure (AHF)** | Enrollment completion of Phase II BLAST-AHF | Q3 2015 |
| | | Topline data for Phase II BLAST-AHF | Q4 2015 |
| | | 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* |
| | | *Enrollment completion of Phase II (bunionectomy model)* | *October 8, 2014* |
| | | Topline data for Phase II trial (bunionectomy model), Parts A and B | Q4 2014 |
| | | Initiation of separate Phase II trial (uncomplicated, elective abdominoplasty surgery) | 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 | Q1 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.**



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**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 | 3QA | 4QE | 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 | 169.6 |
| 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 | 13.0 | 10.0 | 39.7 | 35.0 | 32.0 | 30.0 | 19.0 | 15.0 | 15.8 | 16.5 | 17.2 | 17.7 | 18.2 | 18.8 |
| Selling, general & administrative | 3.1 | 4.7 | 2.0 | 2.5 | 2.5 | 2.3 | 9.3 | 8.4 | 8.6 | 8.9 | 9.3 | 20.1 | 21.9 | 23.4 | 24.4 | 25.3 | 26.1 | 26.6 |
| **Total operating expenses** | **16.4** | **23.5** | **9.7** | **11.5** | **15.5** | **12.3** | **49.0** | **43.4** | **40.6** | **38.9** | **28.3** | **35.8** | **42.9** | **49.4** | **53.8** | **57.4** | **60.0** | **62.4** |
| **Income (loss) from operations** | **(15.6)** | **(23.3)** | **(9.7)** | **(11.5)** | **(15.5)** | **(12.3)** | **(49.0)** | **(43.4)** | **1.7** | **(37.9)** | **(28.3)** | **(11.0)** | **52.1** | **60.4** | **114.4** | **123.4** | **162.0** | **160.1** |
| **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 | 0.01 | 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)** | **(15.5)** | **(12.3)** | **(48.7)** | **(43.4)** | **1.7** | **(37.9)** | **(28.3)** | **(11.0)** | **52.1** | **60.4** | **114.4** | **123.4** | **162.0** | **160.1** |
| Income tax expense (benefit) | | | | | | | | | | 0.0 | 0.0 | 0.0 | 5.2 | 6.0 | 11.4 | 43.2 | 56.7 | 56.0 |
| *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)** | **(15.5)** | **(12.3)** | **(48.7)** | **(43.4)** | **1.7** | **(37.9)** | **(28.3)** | **(11.0)** | **46.9** | **54.4** | **102.9** | **80.2** | **105.3** | **104.1** |
| **EPS, GAAP** | | | | | | | | | | | | | | | | | | |
| Basic | (1.50) | (1.60) | (0.59) | (0.44) | (0.59) | (0.47) | (2.08) | (1.81) | 0.05 | (1.10) | (0.81) | (0.31) | 1.32 | 1.51 | 2.83 | 2.19 | 2.84 | 2.78 |
| **Diluted** | **$ (1.50)** | **$ (1.60)** | **$ (0.59)** | **$ (0.44)** | **$ (0.59)** | **$ (0.47)** | **$ (2.08)** | **$ (1.81)** | **$ 0.05** | **$ (1.10)** | **$ (0.81)** | **$ (0.31)** | **$ 1.32** | **$ 1.51** | **$ 2.83** | **$ 2.19** | **$ 2.84** | **$ 2.78** |
| Weighted average share- Basic | 10.4 | 14.5 | 16.0 | 26.3 | 26.4 | 26.4 | 23.8 | 24.0 | 34.2 | 34.6 | 34.9 | 35.3 | 35.6 | 36.0 | 36.4 | 36.7 | 37.1 | 37.5 |
| Weighted average share- Diluted | 10.4 | 14.5 | 16.0 | 26.3 | 26.4 | 26.4 | 23.8 | 24.0 | 34.2 | 34.6 | 34.9 | 35.3 | 35.6 | 36.0 | 36.4 | 36.7 | 37.1 | 37.5 |

**Source: Jefferies estimates, company data**



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**Exhibit 4: TRVN DCF Analysis**

## Trevena, Inc.

### Discounted Cash Flow Analysis

| *(All values in $MM)* | 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 | 49.0 | 43.4 | 40.6 | 38.9 | 28.3 | 35.8 | 42.9 | 49.4 | 53.8 | 57.4 | 60.0 | 62.4 |
| EBIT | (23.3) | (49.0) | (43.4) | 1.7 | (37.9) | (28.3) | (11.0) | 52.1 | 60.4 | 114.4 | 123.4 | 162.0 | 160.1 |
| (-): Taxes | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 5.2 | 6.0 | 11.4 | 43.2 | 56.7 | 56.0 |
| EBIAT | (23.3) | (49.0) | (43.4) | 1.7 | (37.9) | (28.3) | (11.0) | 46.9 | 54.4 | 102.9 | 80.2 | 105.3 | 104.1 |
| (+):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 | 0.3 | 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)*** | ***(48.2)*** | ***(42.4)*** | ***2.7*** | ***(36.9)*** | ***(27.3)*** | ***(10.0)*** | ***48.2*** | ***55.6*** | ***104.2*** | ***81.8*** | ***106.3*** | ***105.1*** |

**Source: Jefferies estimates, company data**



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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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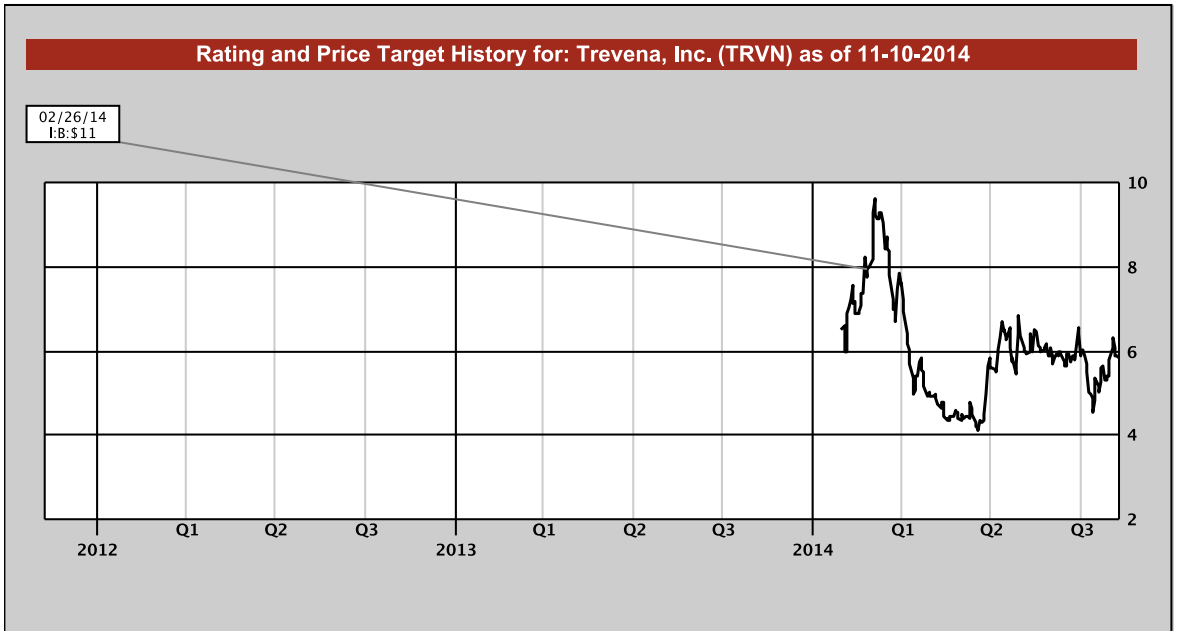
## Other Companies Mentioned in This Report

- Anthera (ANTH: $1.84, BUY)
- Exelixis, Inc. (EXEL: $1.79, HOLD)
- GlycoMimetics, Inc. (GLYC: $7.99, BUY)
- Verastem Inc. (VSTM: $9.08, BUY)
- XOMA Ltd. (XOMA: $3.90, BUY)




## Distribution of Ratings

| Rating | Count | Percent | IB Serv./Past 12 Mos. Count | IB Serv./Past 12 Mos. Percent |
|---|---|---|---|---|
| BUY | 1014 | 52.16% | 267 | 26.33% |
| HOLD | 790 | 40.64% | 142 | 17.97% |
| UNDERPERFORM | 140 | 7.20% | 5 | 3.57% |



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