# Pfenex Inc. (PFNX)

Biosimilar Progress Continues to Drive Value

**MARKET DATA**

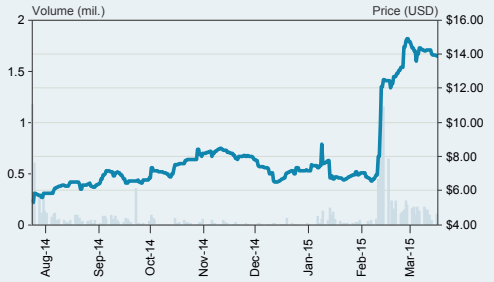
| | |
|---|---|
| Price | $13.75 |
| 52-Week Range: | $5.28 - $15.19 |
| Shares Out. (M): | 20.5 |
| Market Cap ($M): | $281.9 |
| Average Daily Vol. (000): | 101.0 |
| Cash (M): | $46 |
| Cash/Share: | $2.22 |
| Enterprise Value (M): | $83 |
| LT Debt (M): | $0 |

Source: Thomson Reuters and JMP Securities LLC

| FY DEC | | 2014A | 2015E | 2016E |
|---|---|---|---|---|
| Revenue ($M) | 1Q | $2.6 | $1.8 | -- |
| | 2Q | $3.3 | $1.8 | -- |
| | 3Q | $2.8 | $1.8 | -- |
| | 4Q | $2.0 | $1.8 | -- |
| | **FY** | **$10.6** | **$7.0** | **$6.0** |
| EPS | 1Q | ($0.18) | ($0.23) | -- |
| | 2Q | ($1.67) | ($0.28) | -- |
| | 3Q | ($0.16) | ($0.33) | -- |
| | 4Q | ($0.18) | ($0.40) | -- |
| | **FY** | **($2.19)** | **($1.24)** | **($1.24)** |
| | P/E | NM | NM | NM |
| | Previous FY | ($2.18) | ($1.05) | ($1.08) |

Source: Company reports and JMP Securities LLC

**STOCK PRICE PERFORMANCE**




**MARKET OUTPERFORM** | Price: $13.75 | Target Price: $15.00

## INVESTMENT HIGHLIGHTS

**Continued progress with biosimilar programs; we reiterate our Market Outperform rating and $15 price target on Pfenex.** The company reported 4Q14 earnings results largely in line with our and consensus estimates. Pfenex ended the quarter with cash of $46M, not including the $51M the company will receive from Hospira in ~March 2015 when the collaboration is finalized. In addition to the progress with PF582, the company's biosimilar candidate to Lucentis now partnered with Hospira/ Pfizer, we expect catalysts in 2015 from Pfenex's advancing pipeline, including PF530, a biosimilar candidate to Betaseron, the generic candidate to Forteo, and the anthrax and malaria vaccines. Our $15 price target is derived through an NPV analysis of global PF582 sales, with pipeline programs and the platform representing upside potential.

**The recent Hospira partnership provided important platform validation.** The partnership with Hospira, which has agreed to be acquired by Pfizer, is expected to be completed this month following anti-trust approval. Once the partnership is finalized, transfer for the manufacturing technology of PF582 to Hospira's manufacturing site is expected to occur in 2015, and we anticipate that the Phase 3 PF582 trial will begin in 2016. We view it as unlikely that Hospira will release results from the open-label proof-of-concept trial; however, we believe that its diligence of the bioanalytical validation and available data for PF582 provides clear validation of this program, and more broadly, Pfenex's protein expression platform.

**Focus on wholly owned pipeline candidates.** Key new information announced in the earnings release, and discussed on the conference call, was that Pfenex has notified partner Strides Acrolab that it was removing several of the candidates from the joint development and license agreement. These programs are PF530 (biosimilar candidate to Betaseron), PF726 (peginterferon beta 1B), and PF529 (biosimilar candidate to Neulasta), and the company now intends to advance these programs as wholly owned products. We note that there was no cost to Pfenex in removing these programs from the collaboration and Strides retains no options or economic interest in them. We view this as a positive step for Pfenex, leveraging increased cash resources resulting from the Hospira partnership, and increasing upside potential from its pipeline.

**Pipeline catalysts anticipated in 2015.** Pfenex remains on track to initiate a Phase 1 trial of PF530 (a biosimilar candidate to Betaseron) in 1Q14 with results expected in 2H15. It also intends to initiate a Phase 1 PK trial for PF708 (generic to Forteo) in 2H15. Additionally, we expect Pfenex to initiate Phase 1 trials for its recombinant anthrax and malaria vaccines in 2015.

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## 4Q14 FINANCIAL SUMMARY

Pfenex reported a 4Q14 EPS loss of ($0.18), largely in line with our estimate of ($0.16) and consensus of ($0.20). Revenue of $2.0M was slightly below our estimate of $2.5M and consensus of $2.1M, and we expect that contract service revenue will decline in coming quarters as the company focuses resources on its proprietary development programs. Total operating expenses were $4.4M, slightly ahead of our estimate of $3.8M, including R&D expenses of $1.3M, vs. our estimate of $1.8M, and SG&A expenses of $3.0M, vs. our $2.1M estimate.

We have updated our model to reflect 4Q14 financial results, as summarized in Figure 1. We note that while we are increasing our estimate for R&D expenses in 2015, under the terms of the Hospira partnership, the Phase 3 costs for the PF582 program are capped at $20M, with $10M deferred until commercialization, and therefore, cash burn assumptions for this program have been reduced.

**FIGURE 1. 4Q14 Financial Summary**

| PFNX | 4Q14 | | | 2014 est | | | 2015 est | | |
|---|---|---|---|---|---|---|---|---|---|
| | JMP old | Cons | Actual | JMP old | Cons | JMP new | JMP old | Cons | JMP new |
| **Revenue** | **2.5** | **2.1** | **2.0** | **11.1** | **10.5** | **10.6** | **9.0** | **8.5** | **7.0** |
| R&D | 1.8 | | 1.3 | 4.5 | | 4.1 | 13.6 | | 15.0 |
| SG&A | 2.1 | | 3.0 | 8.0 | | 9.0 | 10.5 | | 12.8 |
| Total operating expense | 3.8 | | 4.4 | 12.6 | | 13.1 | 24.1 | | 27.7 |
| **Net income (loss)** | **(3.2)** | | **(3.6)** | **(10.3)** | | **(10.7)** | **(21.8)** | | **(26.0)** |
| Shares outstanding (diluted) | 20.4 | | 20.4 | 12.0 | | 12.0 | 20.8 | | 20.9 |
| **EPS (diluted)** | **($0.16)** | **($0.20)** | **($0.18)** | **($2.18)** | **($2.06)** | **($2.19)** | **($1.05)** | **($0.15)** | **($1.24)** |

*Source: Company reports and JMP Securities LLC*

## Company Description

Pfenex is a clinical-stage biotechnology company engaged in the development of difficult-tomanufacture and high-value proteins, focused on biosimilars. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab). Lucentis, marketed by Roche Ltd. and Novartis AG, for the treatment of retinal diseases, achieved approximately $4.3 billion in global product sales in 2013. PF582 is currently undergoing a Phase 1b/2a trial in patients with wet-AMD (age-related macular degeneration), with data expected in 4Q14. Initiation of a Phase 3 trial is anticipated in mid- 2015 with data expected in 2017. Additional pipeline candidates include PF530, a biosimilar candidate to Betaseron (interferon beta-1b, multiple sclerosis), vaccine development programs for anthrax and malaria, and next-generation biologics further leveraging the protein production platform.

## Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial and competitive factors.

**Clinical risk.** Pfenex may not be successful in the full development and launch of its product candidates. There may be enrollment, dosing, efficacy, or safety issues that would preclude development. It is a possibility that the drug candidates may fail to reach endpoints in their respective clinical trials or an improved version of the reference drugs, Lucentis or Betaseron, may be developed. Any of the aforementioned issues would cause a delay, or discontinuation of development. If the product candidates do make it through clinical trials, the company may yet encounter manufacturing issues, including challenges with the scale-up to commercial quantities. All of the above circumstances should be taken into consideration when assessing clinical risk.

**Regulatory risk.** To date, there have been no FDA approved biosimilars; however, we expect the 351(k) regulatory pathway to be validated prior to the review of PF582. The company's drug candidates still may not receive approval from the FDA or from ex-U.S. agencies. They may request additional preclinical or clinical trials to provide validation for approval, which would delay approval timelines and increase expenses. If approval is granted, the regulatory agency may impose restrictions on the label, or require a REMS program for a drug candidate. This may limit commercial uptake and delay commercial progress.

**Market risk.** We assume that the market dynamic and share for Lucentis remains stable vs. current conditions. We note that this could be impacted by changes in the competitive landscape with drugs available today (e.g., Eyelea, Avastin) or those in development. The market opportunity for products may not accurately reflect current estimates and there may be challenges with market adoption. This would impact the ability to reach revenue and profitability projections. The company must obtain and protect its intellectual property rights in order to effectively compete in the marketplace. Pfenex could get involved in patent lawsuits, which would be time consuming and expensive.

**Financial risk.** Pfenex has no commercial products generating revenue, thus it has not been and is not yet profitable. It has incurred losses each year since inception due to research and development expenses. These expenses are expected to increase in the near future as product candidates advance through the pipeline. The company will likely need to raise additional capital to fund these trials and continue operations. If there are any issues with acquiring needed financing, commercializing its product candidates, and achieving sales revenue, the company may not reach profitability, which may jeopardize the business.

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

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.
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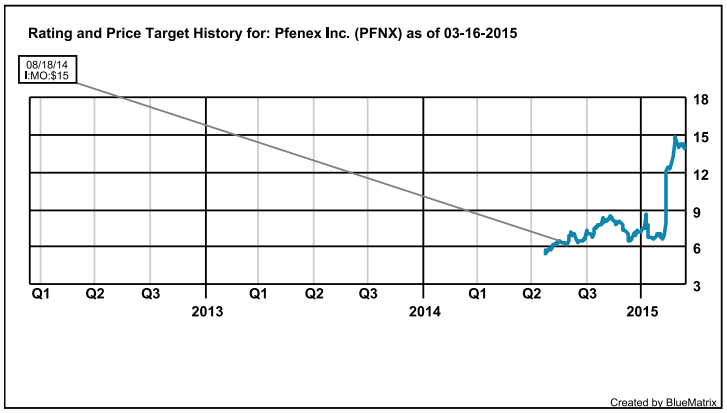
**JMP Securities Research Ratings and Investment Banking Services:** (as of March 17, 2015)

| 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 | 285 | *63.62%* | Buy | 285 | *63.62%* | 88 | *30.88%* |
| MARKET PERFORM | Hold | 153 | *34.15%* | Hold | 153 | *34.15%* | 23 | *15.03%* |
| MARKET UNDERPERFORM | Sell | 8 | *1.79%* | Sell | 8 | *1.79%* | 0 | *0%* |
| COVERAGE IN TRANSITION | | 1 | *0.22%* | | 1 | *0.22%* | 0 | *0%* |
| TOTAL: | | 448 | *100%* | | 448 | *100%* | 111 | *24.78%* |

**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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