

# Pfenex Inc. (PFNX)

Transformational Biosimilar Partnership with Hospira/Pfizer

## MARKET DATA

Price	\$7.97
52-Week Range:	\$5.28 - \$9.00
Shares Out. (M):	20.5
Market Cap (\$M):	\$163.4
Average Daily Vol. (000):	441.0
Cash (M):	\$52
Cash/Share:	\$2.51
Enterprise Value (M):	\$83
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

**MARKET OUTPERFORM** | Price: \$7.97 | Target Price: \$15.00

## INVESTMENT HIGHLIGHTS

**Biosimilar Lucentis partnership with Hospira/Pfizer provides transformational validation of Pfenex's biosimilar platform; reiterate our Market Outperform rating and \$15 price target.** Yesterday, Pfenex announced that it had entered into a partnership with Hospira/Pfizer for the development and commercialization of PF582, the company's biosimilar candidate to Lucentis. We view this transaction as transformational for Pfenex, as it can maximize the commercial potential of PF582 and moreover provides clear validation of Pfenex's biosimilar and protein production platform. We have updated our model to reflect the partnership (assuming a 10-12% royalty rate and increasing our sales/probability of success assumptions). In addition to the progression of PF582 into Phase 3 development in mid-2015, we also anticipate initiation of a Phase 1 trial for PF530 (biosimilar betaseron) in early 2015, and catalysts for the generic teriparatide and anthrax/malaria vaccine programs. Our \$15 price target is derived through an NPV analysis of global PF582 sales, with pipeline programs and the platform representing upside potential.

**Partnership details and updates to our model.** Pfenex will receive an upfront payment of \$51MM and is entitled to receive development and sales milestones totaling an additional \$291MM. The company is also eligible to receive tiered double-digit royalties in net sales of the biosimilar Lucentis product. We have updated our model to include the partnership. In addition to incorporating the royalty rate, which we assume ramps from 10-12%, we have increased our market share assumptions and probability of success to reflect the established commercial infrastructure of Hospira/Pfizer. Lastly, we lowered our discount rate for the program from 15% to 10% to reflect lower capital requirements.

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$3.4	\$2.6A	--
	2Q	\$0.0	\$3.3A	--
	3Q	\$0.0	\$2.8A	--
	4Q	\$0.0	\$2.5	--
	<b>FY</b>	<b>\$11.9</b>	<b>\$11.1</b>	<b>\$9.0</b>
EPS	1Q	--	(\$0.18)A	--
	2Q	--	(\$1.67)A	--
	3Q	--	(\$0.16)A	--
	4Q	--	(\$0.16)	--
	<b>FY</b>	<b>(\$0.37)</b>	<b>(\$2.18)</b>	<b>(\$1.05)</b>
	P/E	NM	NM	NM

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



## Company Description

Pfenex is a clinical-stage biotechnology company engaged in the development of difficult-to-manufacture 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

**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 was manager or co-manager of a public offering of securities for Pfenex Inc. (PFNX) 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 Pfenex 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.

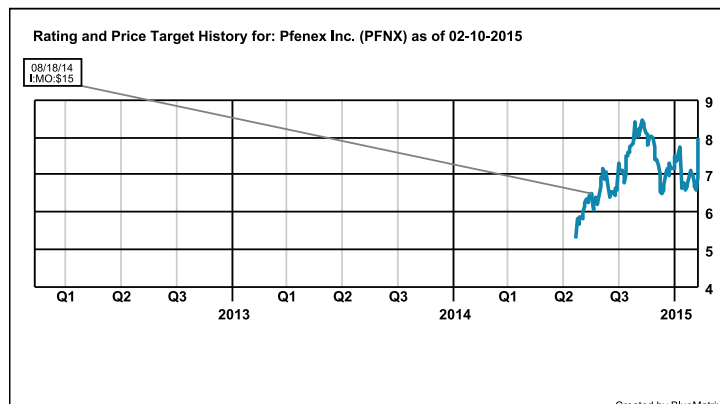
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

### JMP Securities Research Ratings and Investment Banking Services: (as of February 11, 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	283	63.17%	Buy	283	63.17%	91	32.16%
MARKET PERFORM	Hold	154	34.38%	Hold	154	34.38%	21	13.64%
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%	114	25.45%

### 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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