Pfenex Inc. (PFNX)

Continued Execution on Development of Lead Biosimilar Candidate and Diversified Pipeline

MARKET OUTPERFORM | Price: $8.36 | Target Price: $15.00

MARKET DATA

Price	$8.36
52-Week Range:	$5.28 - $8.50
Shares Out. (M):	20.5
Market Cap ($M):	$171.4
Average Daily Vol. (000):	22.0
Cash (M):	$52
Cash/Share:	$2.51
Enterprise Value (M):	$83
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

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	--
	FY	**$11.9**	**$11.1**	**$9.0**
EPS	1Q	--	($0.18)A	--
	2Q	--	($1.67)A	--
	3Q	--	($0.16)A	--
	4Q	--	($0.16)	--
	FY	**($0.37)**	**($2.18)**	**($1.05)**
	P/E	NM	NM	NM
	Previous FY	NC	($0.92)	($1.26)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

PF582 Phase 3 is on track to initiate in mid-2015; reiterate Market Outperform rating and $15 price target on Pfenex. Pfenex reported 3Q14 earnings results ahead of our and consensus estimates due to lower than expected operating expenses. The company ended the quarter with cash of $52M, which we project is sufficient to fund operations into 2016. The company has now completed enrollment in the Phase 1b/2a safety and tolerability trial for PF582, its biosimilar candidate to Lucentis. Results from this trial are expected in 1Q15, with the Phase 3 trial still on-track to begin in mid-2015. The company also announced the addition of Dr. Hubert Chen as its Chief Medical Officer who brings extensive clinical development experience, including at Aileron Therapeutics, Regulus, Amylin, and Amgen. Our $15 price target is derived through an NPV analysis of global PF582 sales, with pipeline programs and the platform representing upside potential.

PF582 Phase 3 trial remains on-track for mid-2015. Management reiterated its timeline for PF582, with enrollment now complete for the Phase 1b/2a trial. This is a randomized trial comparing PF582 to Lucentis in 25 wet-AMD patients (including the sentinel patient), and we await interim safety and tolerability data in 1Q15. We note that these data are not gating to the initiation of the Phase 3 trial, which remains on-track to initiate in mid-2015. Phase 3 results are projected to read out in 2017, which should enable worldwide approvals in timing with Lucentis patent expirations in key geographies.

Additional pipeline updates. Pfenex plans to initiate a Phase 1 trial of PF530, its biosimilar candidate to Betaseron, in early 2015. The company is also slated to file IND's for both its recombinant anthrax vaccine and recombinant malaria vaccine programs by YE2014. Recall that Pfenex announced in 3Q14 that it entered into a collaboration agreement with PATH, a global health non-profit organization, on a multi-product vaccine research program intended to enhance the production of vaccines.

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FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

3Q14 FINANCIAL SUMMARY

Pfenex reported 3Q14 earnings of ($0.16), ahead of both our estimate and consensus of ($0.26), due to lower than expected operating expenses. Revenue came in at $2.8M, slightly above our estimate of $2.5M, and above consensus of $2.1M. Total operating expenses were $3.7M, lower than our estimate of $5.8M, driven by both lower than expected SG&A and R&D costs. R&D expenses were $1.3M vs. our estimate of $2.2M, and SG&A expenses were $2.4M compared to our estimate of $3.6M. Cash, cash equivalents, and short-term investments, excluding restricted cash, were $51.5M as of September 30, 2014.

We have revised our model to include 3Q14 financial results, as summarized in Figure 1.

FIGURE 1. 3Q14 Earnings Summary and Changes to Our Model

PFNX	3Q14			2014 est			2015 est		
	JMP old	Cons	Actual	JMP old	Cons	JMP new	JMP old	Cons	JMP new
Revenue	**2.5**	**2.1**	**2.8**	**10.1**	**9.3**	**11.1**	**9.0**	**8.4**	**9.0**
R&D	2.2		1.3	7.8		4.5	15.6		13.6
SG&A	3.6		2.4	9.9		8.0	12.4		10.5
Total operating expense	5.8		3.7	17.7		12.6	28.0		24.1
Net income (loss)	**(5.2)**	**(5.1)**	**(2.5)**	**(15.2)**	**(14.8)**	**(10.3)**	**(25.7)**	**(23.6)**	**(21.8)**
Shares outstanding (diluted)	20.0		15.3	15.5		12.0	20.5		20.8
EPS (diluted)	**($0.26)**	**($0.26)**	**($0.16)**	**($0.92)**	**($0.86)**	**($2.18)**	**($1.26)**	**($1.19)**	**($1.05)**

Source: JMP Securities LLC and Company Reports

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

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.

JMP FACTS AND DISCLOSURES

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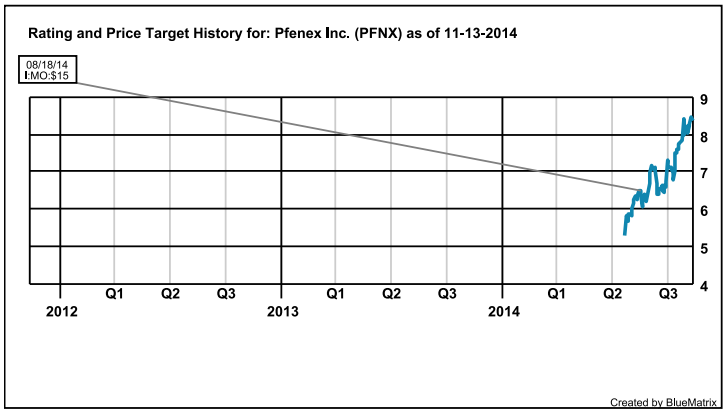
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	286	*61.11%*	Buy	286	*61.11%*	103	*36.01%*
MARKET PERFORM	Hold	141	*30.13%*	Hold	141	*30.13%*	15	*10.64%*
MARKET UNDERPERFORM	Sell	2	*0.43%*	Sell	2	*0.43%*	0	*0%*
COVERAGE IN TRANSITION		36	*7.69%*		36	*7.69%*	0	*0%*
TOTAL:		468	*100%*		468	*100%*	120	*25.64%*

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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