

Pfenex Inc.

Biosimilar Theme Continues; Pfenex Receives Capital Infusion From PF582 Deal With Hospira

Before the open on Tuesday, February 10, Pfenex announced a collaboration agreement with Hospira (HSP \$87.50) to exclusively develop and commercialize PF582, a biosimilar candidate to Roche's (RHHBY \$32.97) Lucentis. We believe the collaboration echoes our view that biosimilars will play an increasing role in the healthcare space and provides further validation to Pfenex's technology platform. We share our thoughts on the development below.

- **We view the collaboration, which involves a \$51 million nondilutive up-front payment to Pfenex, decreases the company's capital risk.** Under the terms of the agreement, Pfenex is entitled to receive up to a total of \$342 million in development and commercial milestones, as well as tiered double-digit royalty on future net sales of PF582. In addition, Pfenex will share with Hospira the costs associated with Phase III clinical development of PF582. **Pfenex's financial responsibility for the Phase III study is capped at \$20 million, with \$10 million deferred until commercialization.**
- **We highlight Pfizer's (PFE \$33.94) announcement last week regarding its proposal to acquire Hospira as an illustration of the growing importance of biosimilars in the healthcare sector.** Continuing the theme of biosimilars, we believe that today's collaboration agreement further validates Pfenex's differentiated expression platform technology. Behind PF582 is a portfolio of wholly owned and partnered development initiatives with three compounds entering clinical trials in the next 3-6 months. We view the coming year as extremely formative for Pfenex, with the potential for clinical data from multiple products and additional corporate and government collaborations, which could infuse additional nondilutive capital into the company as well as material increases in the level of awareness of the biosimilar commercial opportunity. We highlight PF530, a biosimilar form of Betaseron for the treatment of multiple sclerosis, which is expected to advance into clinical studies early this year, with Phase I data expected in the second half. We believe the activity surrounding the company's portfolio will present significant catalysts over the next two years, which we summarize in exhibit 1.
- **We believe there will be significant headlines regarding the biosimilar space in the coming months.** In our opinion, the recent lawsuit Amgen (AMGN \$150.77, Market Perform) filed against Novartis's (NVS \$102.03) subsidiary Sandoz in regard to the new drug application of biosimilar Neupogen will clarify the approval pathway for biosimilar drugs. The results of this lawsuit could provide Pfenex and its partner Hospira with clarity into a legal framework for gaining regulatory approval in the biosimilar space. Of note, we see potential for the regulatory approval of several biosimilar drugs in 2015, which should provide a tailwind to the biosimilars industry. We summarize a list of biosimilar compounds currently under FDA review in exhibit 2, on the following page.

Pfenex is a San Diego-based biotechnology company focused on biosimilars and difficult-to-manufacture protein-based therapeutics. The lead product candidate, PF582, a biosimilar to Lucentis (ranibizumab), is in Phase I/II study with data expected later this year.

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Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**

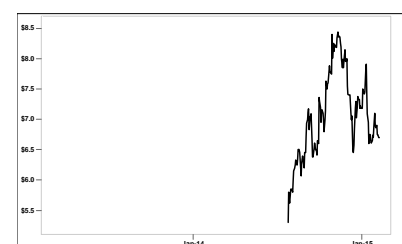
Symbol: PFNX (NYSE)
Price: \$8.42 (52-Wk.: \$5-\$9)
Market Value (mil.): \$163
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS FY	\$-3.76	\$-3.35	\$-1.01
CY		\$-3.35	\$-1.01
Sales (mil.)	12	10	8
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	15
Float (mil.)	10
Average Daily Volume	30,148

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	3.1
Return on Equity (TTM)	-19.6

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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- **At this time we maintain our current financial projections pending additional guidance from management and year-end results.** We anticipate management to provide additional guidance regarding the deal's impact on Pfenex's R&D spending. Accordingly, we will update our financial model along with the quarterly and yearly update. Pfenex ended the third quarter 2014 with ~\$50 million in cash, which combined with today's \$51 million up-front payment should provide at least two years of cash.

**Exhibit 1
Pfenex Inc.
Timeline**

Date	Product	Event
2015	PF530 (biosimilar Betaseron)	Phase I trial initiation in relapsing forms of MS (1H).
	PF530 (biosimilar Betaseron)	Phase I trial results in relapsing forms of multiple sclerosis (2H).
	PF582 (biosimilar Lucentis)	Phase Ib/IIa trial interim results in wet age-related macular degeneration (1Q).
	PF582 (biosimilar Lucentis)	Phase III equivalence trial in wet age-related macular degeneration (3Q).
	PF708 (generic Forteo)	ANDA-enabling pharmacokinetic bioequivalence trial initiation in osteoporosis (2H).
	Recombinant Malaria Vaccine	Phase I trial results in malaria.
2016	PF688 (biosimilar Cimzia)	Phase I trial initiation in Crohn's disease and rheumatoid arthritis.
	Recombinant Anthrax Vaccine	Phase Ia trial results in anthrax (3Q).
2017	PF582 (biosimilar Lucentis)	Phase III trial results in age-related macular degeneration.

ANDA = abbreviated new drug application.

Sources: Pfenex reports.

**Exhibit 2
Pfenex Inc.
Biosimilar Candidates Currently under FDA Regulatory Review**

Sponsor	Filing Date	Generic Name	Branded Name	Biosimilar Branded Name
Sandoz (Novartis)*	7/24/2014	Filgrastim	Neupogen	Zarzio
Celltrion*	8/11/2014	Infliximab	Remicade	Remsima
Hospira	12/16/2014	Epoetin alfa	Epogen/Procrit	Retacrit
Apotex	12/17/2014	Pegfilgrastim	Neulasta	

*Approved in Europe

Valuation

Pfenex is trading around \$8 with a market cap of \$163 million, and we believe the stock represents an attractive value at current price levels. Given the breadth of the clinical pipeline and an active news calendar in the next two years, we see significant room for upside potential in Pfenex shares.

Risks

While we view Pfenex as a well-capitalized company with a modest clinical risk profile, given the company's product candidates are biosimilars of commercialized drugs, numerous risks remain, including clinical, capital, and regulatory risk. The clinical risk is the emergence of unexpected adverse events from compounds generated from Pfenex's proprietary manufacturing platform. The major capital risk is that additional infusions of funding are needed before the company can reach profitability, which may include further equity fundraising. The major regulatory risk is that PF582 could face scrutiny before approval. However, given the comprehensive bioanalytical testing completed by Pfenex, we believe the asset is de-risked and we remain optimistic about the compound's path forward.

William Blair & Company, L.L.C.

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William Blair is a market maker in the security of Pfenex Inc.

William Blair intends to seek investment banking compensation in the next three months from Pfenex Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Pfenex Inc.

Additional information is available upon request.

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DOW JONES: 17,729.21

S&P 500: 2,046.74

NASDAQ: 4,726.01



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	16
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

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