William Blair

Pfenex Inc.

March 06, 2015

FDA's First Biosimilar Approval Paves Path for Regulatory and Commercial Clarity for Pfenex

Before the open on Friday, March 6, the FDA announced the approval of Novartis's/Sandoz's (NVS $97.62) Zarxio (filgrastim-sndz), the first biosimilar product approved in the United States. We continue to believe this year will be particularly formative for biosimilar sponsors, as regulatory- and intellectual property-related issues will likely be clarified leading to additional visibility. We share our thoughts on the development below.

- **Friday's FDA approval signals the beginning of an era for biosimilars.** Given Novartis/Sandoz already markets biosimilar filgrastim in Europe (Zarzio), the unanimous support during the January advisory committee (14-0 vote in favor of its approval), and the positive Phase III PIONEER trial comparing the efficacy and safety between Zarxio and Amgen's Neupogen, we view Friday's positive decision as in line with our expectation. *In addition, Zarxio received complete label extrapolation (the demonstration of clinical similar attributes of the biosimilar enables its approval in all disease settings indicated for the reference product) of Neupogen by the FDA as was expected because of its extensive marketing experience in Europe.*

- **We view the next hurdle in the field of biosimilars will likely be the lawsuit between Amgen (AMGN $154.49; Market Perform) and Novartis regarding intellectual property issues over Zarxio.** Accordingly, Novartis/Sandoz had previously agreed to delay Zarxio's launch until the earlier date between April 10 and the court decision on Amgen's request for a preliminary injection. In our opinion, the Amgen lawsuit should provide clarify the path to market for biosimilar drugs and could provide Pfenex and its partner Hospira with additional visibility into a legal framework for gaining commercial rights 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 1, on the following page.

- **We expect interchangeability, "naming," and extrapolation to continue to be key issues.** We believe FDA's view on label extrapolation will continue be an open question going forward and will likely be made on a case-by-case basis. We also highlight the difference between "biosimilar" and "interchangeable" as an important issue because establishing "interchangeability" allows patients to switch from a reference product without new prescriptions. While the FDA agrees with Zarxio's status as a biosimilar, it is not "interchangeable" with Neupogen. Regarding the proprietary name, the FDA has temporarily added the "-sndz" suffix to denote its biosimilar status, and we look forward to gaining additional insight from the agency in the near future. Consistent with our stance, we believe the path to approval for Novartis's/Sandoz's biosimilar filgrastim will likely set precedent for future biosimilars to follow.

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:	$14.29 (52-Wk.: $5-$15)
Market Value (mil.):	$286
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	92,022

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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- **In light of recent business development activities in the biosimilar space (Pfizer's [PFE $34.02] acquisition of Hospira [HSP $87.90] and Hospira's collaboration agreement with Pfenex), we believe Pfenex offers investors the opportunity to own a stake in a well-managed company with a proprietary and disruptive platform that enables the participation in a diverse array of therapeutic markets.** Pfenex is in possession of a proprietary expression platform technology that enables the company to cost effectively produce biologics, and coupled with its expertise in bioanalytics offer differentiated profile and competitive advantage in the biosimilar market. The lead candidate, PF582, is a biosimilar form of Roche's (RHHBY $33.15) Lucentis, which is being co-developed with Hospira, and we anticipate Phase Ib/IIa results this quarter. Behind PF582 is a portfolio of wholly owned and partnered development initiatives with three compounds entering clinical trials in the next three to six 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 2.

Exhibit 1
Pfenex Inc.
Biosimliar Candidates Currently under FDA Regulatory Review

Sponsor	FDA Acceptance Date	Generic Name	Reference Product Branded Name	Biosimilar Product Branded Name
Sandoz (Novartis)*	7/24/2014	Filgrastim	Neupogen	Zarxio
Celltrion*	8/8/2014**	Infliximab	Remicade	Remsima
Hospira*	12/16/2014**	Epoetin alfa	Epogen/Procrit	Retacrit
Apotex	12/17/2014	Pegfilgrastim	Neulasta	
Apotex	2/13/2015	Filgrastim	Neupogen	Grastofil

*Approved in Europe
**Filing date

Exhibit 2
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.

Valuation
Pfenex is trading at $14.22 with a market cap of $286 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 that 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 remain optimistic about the compound's path forward.

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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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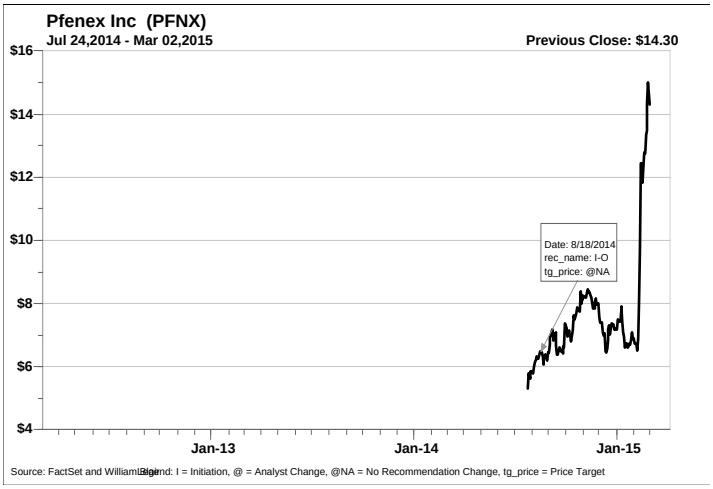
DOW JONES: 18,135.72
S&P 500: 2,101.04
NASDAQ: 4,982.81



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Market Perform (Hold)	32	Market Perform (Hold)	2
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