BARCLAYS

Equity Research

Healthcare | U.S. Specialty Pharmaceuticals

26 June 2015

Pfenex

(A lot) more than biosimilars

Stock Rating	OVERWEIGHT Unchanged
Industry View	POSITIVE Unchanged
Price Target	USD 28.00 Unchanged

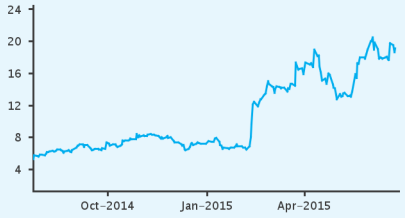
Price (25-Jun-2015)	USD 19.24
Potential Upside/Downside	+46%
Tickers	PFNX

Market Cap (USD mn)	445
Shares Outstanding (mn)	23.13
Free Float (%)	69.84
52 Wk Avg Daily Volume (mn)	0.1
52 Wk Avg Daily Value (USD mn)	N/A
Dividend Yield (%)	N/A
Return on Equity TTM (%)	N/A
Current BVPS (USD)	2.65

Source: Thomson Reuters

Price Performance — Exchange-NYSE

52 Week range — USD 21.01-5.28



Link to Barclays Live for interactive charting

U.S. Specialty Pharmaceuticals

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Introducing PFNX, the platform technology company formerly known as a biosimilar company. Many assume PFNX is "just another" biosimilar company; however, after hosting meetings with company managment, we believe PFNX is actually an innovative platform technology company. In addition to biosimilars, this platform can be applied for the manufacture of complex generics, such as LLY's Forteo, as well as vaccines, which PFNX is pursuing under a government contract. These opportunities come on top of what we'd characterize as a best-in-class biosimilars business, which makes PFNX one of our favorite small cap ideas.

Vaccines and complex generics. In particular, we came away encouraged about the prospects for PFNX's anthrax vaccine program and one which shareholders get for free since it isn't in our model and the costs are borne by the government. While the likelihood of a procurement program is difficult to handicap – perhaps the reason that many investors have given it little attention – we are encouraged by the U.S. government's commitment to stockpile approximately $300mn in a recombinant protein based anthrax vaccine beginning in 2017; PFNX is the only recombinant vaccine program under contract with the government.

PFNX's generic version of Forteo will benefit from the simpler ANDA pathway as well as potentially first-to-file exclusivity since, as a peptide of just 34 amino acids, still qualifies as a small molecule. In addition to this attractive opportunity, we expect eventually PFNX will pursue development of GLP-1's for the treatment of diabetes.

Best-in-class biosimilars. While some would argue it's difficult to differentiate among the different biosimilar players, we believe the value of PFNX's platform has been validated by the "best-in-class" terms that PFNX garnered for its partnership with HSP for its biosimilar candidate for Lucentis, which calls for higher royalties and milestone payments as well as "protection" if HSP pursues another anti-VEGF for the treatment of AMD, presumably Eylea, through a profit-share.

PFNX: Quarterly and Annual EPS (USD)

	2014	2015			2016			Change y/y	
FY Dec	Actual	Old	New	Cons	Old	New	Cons	2015	2016
Q1	-1.28A	-0.29A	-0.29A	-0.29A	-0.39E	-0.39E	-0.40E	77%	-34%
Q2	-1.67A	-0.35E	-0.35E	-0.39E	-0.46E	-0.46E	-0.43E	79%	-31%
Q3	-0.16A	-0.36E	-0.36E	-0.44E	-0.34E	-0.34E	-0.37E	N/A	6%
Q4	-0.18A	-0.36E	-0.36E	-0.49E	-0.38E	-0.38E	-0.38E	-100%	-6%
Year	-3.29A	-1.37E	-1.37E	-1.62E	-1.56E	-1.56E	-1.89E	58%	-14%
P/E	N/A		N/A			N/A			

Source: Barclays Research.
Consensus numbers are from Thomson Reuters

U.S. Specialty Pharmaceuticals — **Industry View: POSITIVE**

Pfenex (PFNX)

Stock Rating: OVERWEIGHT

Income statement ($mn)	2014A	2015E	2016E	2017E	CAGR
Revenue	11	10	12	11	-0.3%
EBITDA (adj)	-9	-31	-37	-40	N/A
EBIT (adj)	-10	-32	-38	-41	N/A
Pre-tax income (adj)	-10	-32	-38	-41	N/A
Net income (adj)	-11	-32	-38	-41	N/A
EPS (adj) ($)	-3.29	-1.37	-1.56	-1.58	N/A
Diluted shares (mn)	9.4	23.6	24.6	26.5	41.1%
DPS ($)	0.00	0.00	0.00	0.00	N/A

Margin and return data					Average
EBITDA (adj) margin (%)	-86.9	-299.4	-312.0	-377.7	-269.0
EBIT (adj) margin (%)	-91.3	-309.8	-322.2	-390.1	-278.3
Pre-tax (adj) margin (%)	-92.0	-310.4	-322.8	-390.8	-279.0
Net (adj) margin (%)	-100.3	-310.6	-322.8	-390.8	-281.1
ROIC (%)	N/A	-35.4	-38.2	-45.5	-39.7
ROA (%)	N/A	-33.2	-36.6	-43.6	-37.8
ROE (%)	-27.2	-74.5	-471.9	128.7	-111.2

Balance sheet and cash flow ($mn)					CAGR
Tangible fixed assets	2	3	3	4	18.3%
Intangible fixed assets	6	6	5	5	-9.0%
Cash and equivalents	46	98	60	77	19.1%
Total assets	71	124	86	103	13.2%
Short and long-term debt	4	0	0	0	-100.0%
Other long-term liabilities	3	3	3	3	0.0%
Total liabilities	11	8	8	7	-14.2%
Net debt/(funds)	-42	-98	-60	-77	N/A
Shareholders' equity	60	27	-11	-53	N/A
Change in working capital	38	56	-38	18	-21.8%
Cash flow from operations	-10	19	-37	-40	N/A
Capital expenditure	0	-1	-1	-1	N/A
Free cash flow	-10	18	-39	-42	N/A

Valuation and leverage metrics					Average
P/E (adj) (x)	N/A	N/A	N/A	N/A	N/A
EV/sales (x)	13.1	8.0	10.2	9.9	10.3
EV/EBITDA (adj) (x)	-15.1	-2.7	-3.3	-2.6	-5.9
FCF yield (%)	-5.7	4.0	-8.1	-8.2	-4.5
P/BV (x)	3.0	16.6	-42.7	-9.6	-8.2
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Total debt/capital (%)	6.0	0.0	0.0	0.0	1.5

Selected operating metrics					Average
SG&A/sales (%)	84.6	N/A	N/A	N/A	84.6
R&D/sales (%)	84.6	164.1	167.9	208.6	156.3
R&D growth (%)	-24.9	402.2	20.7	4.0	100.5
SG&A growth (%)	34.4	90.7	16.5	10.0	37.9

Source: Company data, Barclays Research
Note: FY End Dec

Price (25-Jun-2015) USD 19.24
Price Target USD 28.00

Why Overweight? We believe PFNX's propietary expression platform gives them meaningful competitive advantages in the development and commercialization of therapeutic biologics. PFNX has used its platform to develop a unique portfolio of biosimilar candidates. PFNX's technology was validated with its partnership with HSP on the development of a biosimilar to Lucentis.

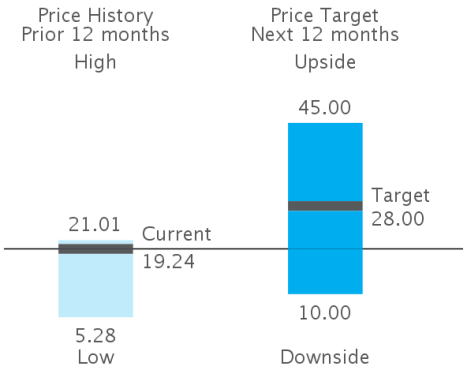
Upside case USD 45.00

We see upside from the opportunity for PFNX to accelerate the development of its wholly-owned biosimilar candidates to Betaseron and Neulasta. Abbreviated development pathways would improve sentiment and pull forward PFNX's revenue ramp.

Downside case USD 10.00

Downside would come from delays or unsuccessful clinical development work on PFNX's biosimilar candidates.

Upside/Downside scenarios



We still see PFNX as a differentiated brew

Many assume PFNX is "just another" biosimilar company; however, after hosting meetings with CEO Bert Liang and CFO Paul Wagner, it was striking to us how versatile the company's platform is. In addition to biosimilars, PFNX's expression platform can be applied for the manufacture of complex generics, such as LLY's Forteo, as well as vaccines, which PFNX is pursuing under a government contract. This diversification is important because it should make PFNX less dependent on shifts in investor sentiment regarding the prospects for biosimilars.

One pathway is not like the other

While many products in PFNX's pipeline are true biosimilar candidates, PF708 (Reference product: Forteo) is in fact a peptide. In February 2012, the FDA issued draft guidance to add "protein (except any chemically synthesized polypeptide)" to the definition of a biological product.[1] The guidance further specified a protein to be "any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size".[2] Eli Lilly's Forteo falls into the "peptide" bucket, as it is only 34 amino acids. The importance of this differentiation is that PFNX's PF708 will only require the ANDA pathway to gain approval, which should not only be faster but simpler in terms of establishing bioequivalence.

With PFNX initiating the ANDA-enabling PK study in 2H2015, the company is that much closer to disrupting the $1.2bn Forteo market. Management remained confident the pen would not be a blocking patent and appeared optimistic to launch Forteo in 2019 when the last blocking Orange book patent expires. The company believes this could a first-to-file opportunity, potentially offering 180-day of exclusivity, but that would be "upside" in our mind since even if another competitor reaches market first, generic Forteo will prove to be a durable long-term asset given the high likelihood of limited competition. We believe there is a very limited universe of generic manufacturers capable of making peptide products. Even with two other competitors, we believe Forteo has the potential to generate $200 million in revenue/year. PFNX does not have a development program in place currently, but, in time, we expect the company will begin development of a GLP-1 program.

Shareholders' free lunch?

One of the supposed truisms of economics is that there's no such thing as a free lunch, but we'd argue that PFNX's vaccine program might qualify (at least for company shareholders). To date, PFNX has received U.S. government funding for the development of Px563L, a recombinant protein-based anthrax vaccine after the Department of Homeland Security (DHS) determined anthrax to be a material threat to the US population. Under the Biomedical Advanced Research and Development Authority (BARDA) guidance, the US Government is obligated to fund the development of the next generation anthrax vaccine. The next generation vaccine, further defined as a recombinant protein, will be an alternative to Emergent Biosolutions' Biothrax vaccine, which is currently stockpiled by the US Government. However, Biothrax is plagued by costly storage, frequent dosing (6-7 doses) and poor compliance rates.

PFNX technology system offers a more stable vaccine, which reduces the cost burden of storage, with a longer shelf-life and production efficiencies; PFNX management estimated the company could fill the US Government's $300 million recombinant vaccine stockpile in only 6 weeks. Furthermore, it is worth noting that US Government funding not only covers the direct development costs associated with the Px563L program, but also covers a portion of the company's indirect overhead costs, so it actually subsidizes the company's biosimilar

[1] Kingham, Klasa et al. (2014) Key regulatory guidelines for the development of biologics in the united states and Europe.
[2] Kingham, Klasa et al. (2014).

and complex generics programs. Importantly, the government can procure PFNX's vaccine before FDA approval and so limited clinical testing would be required. PFNX awaits another contract which would advance development and, seemingly, meaningfully increase the chances, in our view, of an eventual procurement contract. Thus far, PFNX is the only drug maker that the government has funded for development of a recombinant vaccine.

In addition to the anthrax vaccine, PFNX is also developing Px533, a prophylactic malaria infection vaccine—an unmet need. The program is fully funded by Leidos through its Malaria Vaccine Production and Support Services contract with the National Institute of Allergy and Infectious Diseases (NIAID).

While the vaccines portfolio is not our primary interest in PFNX, a government anthrax stockpile contract worth $300 million at no cost is materially meaningful to PFNX, a company that presently has a market cap of approximately $400 million. Emergent Biosolutions carries a $1.2 billion market cap based almost wholly on its anthrax vaccine program.

Best-in-class terms

While the "Year of Biosimilars" may be upon us in terms of the first U.S. biosimilar launch, we cannot forget the plentiful partnerships we've seen leading to this year. The past few years has seen no shortage of powerful combinations in biosimilar development including Samsung-Biogen Idec, Pfizer-Biocon (since disbanded), Coherus-Baxter, Momenta-Baxter (since disbanded), and, as PFNX management was quick to boast, PFNX-Hospira.

The surge in partnerships begs examination into deal terms and when, or if, partnership is the most efficient route to market. Considering the deal terms upfront payment, milestone payments and royalty structure, and potential upside of partnering with Hospira/Pfizer on an Eylea biosimilar, we feel PFNX has executed one of the best biosimilar deals to date (Figure 1). This speaks volumes, in our view, regarding the value of Pfnex's development capabilities as well as the complexity of developing a biosimilar to Lucentis. We've heard some claim that Lucentis isn't that complex, and therefore not that hard to develop, although the economic value that PFNX has created would clearly suggest otherwise.

FIGURE 1
Notable biosimilar deal terms

	Pfenex (PFNX)	Coherus (CHRS)	Momenta (MNTA)
Reference Product	Lucentis	Enbrel	Humira
Reference Product Expiry	2020 (US)	2028 (US)	2016 (US)
Partner	Hospira	Baxter	Baxter
Negotiated Rights for Partner	Ex-US	Ex-US	N/A
Upfront Payment	$51mn	$30mn	$33mn
Milestone	$291mn	$210mn	$12mn*
Est. Starting Royalty	"double digits"	5%**	8%
Est. Market Opportunity	$4bn (US)	$8.7bn (WW)	$10.7bn (WW)
Biosimilar Competition	NO	YES	YES
No. of Biosimilar Competitors	0	12	10
Added Upside	Eylea biosimilar	BAX owns CHRS stock via private placement	N/A

MNTA-BAX collaboration discontinued in Feb 2015; remainder of planned milestone payments will be unrealized (~$400mn);
**Royalty based on mfg cost as % of net sales

Source: Barclays Research

The Opportunity Costs of the Courtroom

PFNX management was frequently asked for its perspectives on the legal pathway for biosimilars, in particular the pending Sandoz v. Amgen case. One interesting takeaway for us is that PFNX's use of an alternative expression system lets them avoid the risk of infringing manufacturing patents. The FDA's Purple Book, which lists all biological products and any biosimilar or interchangeable biologic products, *does not list* biologic patents or any manufacturing processes that are associated with the biologic. However, PFNX uses its patented (and proprietary) Pfenex Expression Technology System to develop its candidates; therefore, the company is not subject to the possibility of biologic manufacturing patent infringement. Therefore, PFNX can focus less time on courtroom litigation and more time taking biosimilar candidates from the bench to BLA filing.

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Primary Stocks (Ticker, Date, Price)

Pfenex (PFNX, 25-Jun-2015, USD 19.24), Overweight/Positive, A/C/D/J/L

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Pfenex (PFNX / PFNX)

Stock Rating	Industry View
OVERWEIGHT	**POSITIVE**

USD 19.24 (25-Jun-2015)

Rating and Price Target Chart - USD (as of 25-Jun-2015) **Currency=USD**

Date	Closing Price	Rating	Adjusted Price Target
18-May-2015	15.87	Overweight	28.00

Source: Thomson Reuters, Barclays Research

Historical stock prices and price targets may have been adjusted for stock splits and dividends.

Source: IDC, Barclays Research

Link to Barclays Live for interactive charting

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Valuation Methodology: Our $28 price target is based on 15x our FY20 EPS estimate of $5.90 discounted back to the present and applying a 65% probability of success.

Risks which May Impede the Achievement of the Barclays Research Price Target: PFNX's key products remain unapproved: Even though PFNX's focus on biosimilars reduces regulatory risk, the complexity of biologics could cause unexpected clinical outcomes, preventing FDA approval and commercial launch. PFNX faces many large competitors in the biosimilars market: The biosimilars market could prove highly competitive, resulting in meaningful price discounts which diminish the revenue opportunity for the company. Additionally, PFNX could be competing with companies with greater commercial resources, putting them at a discount in promoting products to physicians. Innovators could prevent or delay commercial launch of biosimilars. The branded products which PFNX is targeting for biosimilars are protected by patents which could delay or block timely commercial launch. Products opportunities could be diminished by innovation. The market opportunity for some of PFNX's biosimilar candidates could be diminished by new innovative therapies.

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