

Pfenex Inc.

Third-Quarter Earnings Highlighted by Active Clinical Pipeline and Business Update

After the markets closed on Thursday, November 13, Pfenex reported its third-quarter financial results and provided an update on clinical programs. While the financial results were uneventful, the company updated the clinical development timeline, highlighted by a Phase III initiation and several new compounds entering into clinical testing within the next 12-18 months. Exhibit 1 provides a detailed variance analysis of the company's operating results compared to our financial estimates.

- **Pfenex's lead product candidate PF582 is a biosimilar form of the \$4.3 billion drug Lucentis and has an expanding development pipeline.** PF582 is the wholly owned, lead compound at Pfenex. We expect Phase Ib/IIa data in the first quarter of 2015 and project the company to advance the product candidate into a registration-enabling trial in the second half of 2015. We estimate that by 2018, roughly \$530 million in current sales volume of Lucentis will come off patent, and by 2020, we predict that figure will increase by an additional \$2.0 billion with patent expiry in the United States. In our view, the development timelines of the Phase III trial align nicely with the patent expiration schedule for Lucentis, which we believe is an attractive reference drug given the sizable market it addresses and challenging manufacturing profile.
- **Behind PF582 is a portfolio of wholly owned and partnered development initiatives with three compounds entering clinical trials in the next six to nine months.** We view the coming 12-18 months as extremely formative for Pfenex, with the potential for clinical data from multiple products and additional corporate and government collaborations, which could infuse 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 in early 2015, with Phase I data expected in the second half of 2015. We believe the activity surrounding the company's portfolio will present significant catalysts over the next two years, which we summarize in exhibit 3.
- **We believe there will be significant headlines regarding the biosimilar space in the coming months.** In our opinion, the recent lawsuit Amgen (AMGN \$160.85, Market Perform) filed against Novartis's (NVS \$94.38) subsidiary Sandoz regarding a new drug application will clarify the approval pathway for biosimilar drugs. The results of this lawsuit could provide Pfenex and other biosimilar manufacturers with clarity into a legal framework for gaining regulatory approval in the biosimilar space. We see potential for the regulatory approval of several biosimilar drugs in 2015, which should provide a tailwind to the biosimilars industry.

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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November 13, 2014

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

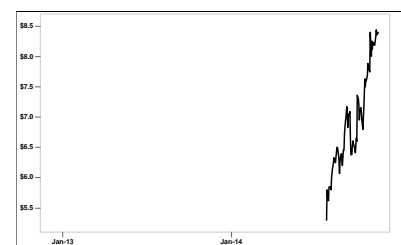
Symbol: PFNX (NYSE)
Price: \$8.36 (52-Wk.: \$5-\$9)
Market Value (mil.): \$170
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

		2013A	2014E	2015E
Estimates				
EPS	Q1	\$-0.94	A\$-1.28	\$-0.24
	Q2	\$-0.94	A\$-1.67	\$-0.25
	Q3	\$-0.94	A\$-0.16	\$-0.25
	Q4	\$-0.94	\$-0.23	\$-0.26
	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.)	19
Float (mil.)	10
Average Daily Volume	70,516

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	-5.1
Return on Equity (TTM)	-19.6

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- **Pfenex has roughly \$50 million in capital, which we believe will sustain the company for at least 18-20 months, based on our current burn rate estimates.** With an estimated enterprise value of about \$123 million and numerous upcoming catalysts that stand to increase value, we believe that current price levels represent an attractive entry point for investors. We therefore maintain our Outperform rating on Pfenex.

Portfolio Manager Summary

After the markets closed on Thursday, November 13, Pfenex reported its third-quarter financial results and provided an update on clinical programs. While the financial results were uneventful, the company updated the clinical development timeline, highlighted by a Phase III initiation and several new compounds entering into clinical testing within the next 12-18 months. Exhibit 1 provides a detailed variance analysis of the company's operating results compared with our financial estimates.

Exhibit 1
Pfenex Inc.
Third Quarter 2014 Variance Analysis
(dollars in millions except EPS)

	PFNX Q3 2014A	WB Q3 2014E
Total Revenues	\$3	\$2
COGS	\$2	\$2
SG&A	\$2	\$3
R&D	\$1	\$2
Net Loss	(\$2)	(\$5)
EPS	(\$0.16)	(\$0.25)

Sources: Pfenex reports and William Blair & Company, L.L.C. estimates.

Exhibit 2
Pfenex Inc.
Guidance and Estimates
(dollars in millions except EPS)

	WB Previous 2014E	WB Revised 2014E	WB Previous 2015E	WB Revised 2015E	WB Previous 2016E	WB Revised 2016E	WB Previous 2017E	WB Revised 2017E
Total Revenues	\$9	\$10	\$8	\$8	\$8	\$8	\$8	\$8
COGS	\$8	\$8	\$8	\$8	\$9	\$9	\$10	\$10
SG&A	\$9	\$8	\$8	\$8	\$9	\$9	\$10	\$10
R&D	\$6	\$6	\$14	\$14	\$18	\$18	\$18	\$18
Net Loss	(\$13)	(\$12)	(\$21)	(\$21)	(\$28)	(\$28)	(\$30)	(\$30)
EPS	(\$3.41)	(\$3.35)	(\$1.01)	(\$1.01)	(\$1.01)	(\$1.01)	(\$1.05)	(\$1.05)

Sources: Pfenex reports and William Blair & Company, L.L.C. estimates.

Exhibit 3
Pfenex Inc.
Timeline

Date	Product	Event
2014	Recombinant Anthrax Vaccine	Phase Ia trial initiation in anthrax (Q4).
	Recombinant Malaria Vaccine	Phase I trial initiation in malaria (Q4).
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 \$8.36 with a market cap of \$170 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 remain optimistic about the compound's path forward.

Our model is included on the following page.

Exhibit 4
Pfenex Inc.
Income Statement
(dollars in thousands except EPS and shares in thousands)

	2013A	Q1A	Q2A	Q3A	Q4E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue	11,914	2,558	3,266	2,801	1,850	10,475	8,200	8,200	8,200	8,200	8,200	9,150	9,550
PF582	0	0	0	0	0	0	0	0	0	6,327	46,812	140,838	373,953
Total revenues	\$11,914	\$2,558	\$3,266	\$2,801	\$1,850	\$10,475	\$8,200	\$8,200	\$8,200	\$14,527	\$55,012	\$149,988	\$383,503
Cost of revenue	6,423	1,908	2,544	1,579	1,550	7,581	8,000	9,000	10,000	10,000	25,285	77,537	220,000
Gross profit	5,491	650	722	1,222	300	2,894	200	(800)	(1,800)	4,527	29,727	72,451	163,503
SG&A	6,698	1,495	2,024	2,447	2,400	8,366	8,000	9,000	10,000	14,500	20,300	41,000	48,000
R&D	5,490	678	860	1,251	2,750	5,539	13,500	17,800	18,135	18,550	19,650	20,575	21,100
Total operating expenses	12,188	2,173	2,884	3,698	5,150	13,905	21,500	26,800	28,135	33,050	39,950	61,575	69,100
Loss from operations	(\$6,697)	(\$1,523)	(\$2,162)	(\$2,476)	(\$4,850)	(\$11,011)	(\$21,300)	(\$27,600)	(\$29,935)	(\$28,523)	(\$10,223)	\$10,876	\$94,403
Other expense, net	(36.0)	(18.0)	(21.0)	(19.0)	(8.5)	(66.5)	(32.0)	(30.0)	(28.0)	(26.0)	(24.0)	(22.0)	(20.0)
Net loss before income taxes	(6,733)	(\$1,541)	(\$2,183)	(\$2,495)	(\$4,859)	(11,078)	(21,332)	(27,630)	(29,963)	(28,549)	(10,247)	10,854	94,383
Income tax benefit	2,671	(1)	0	0	0	(1)	0	0	0	0	0	(2,538)	(14,157)
Net loss	(\$4,062)	(\$1,542)	(\$2,183)	(\$2,495)	(\$4,859)	(\$11,079)	(\$21,332)	(\$27,630)	(\$29,963)	(\$28,549)	(\$10,247)	\$8,315	\$80,226
Net loss attributable to common stockholders	(5,757)	(1,977)	(2,630)	(2,495)	(4,859)	(11,961)	(21,332)	(27,630)	(29,963)	(28,549)	(10,247)	8,315	80,226
Net loss per common share basic and diluted	(\$3.76)	(\$1.28)	(\$1.67)	(\$0.16)	(\$0.23)	(\$3.35)	(\$1.01)	(\$1.01)	(\$1.05)	(\$0.96)	(\$0.33)	\$0.25	\$2.40
Weighted-average common shares basic and diluted	1,531	1,548	1,571	15,319	20,702	9,785	21,217	27,432	28,529	29,670	30,856	32,090	33,373

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PFNX

Sources: Roche and Pfenex reports.

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William Blair is a market maker in the security of Pfenex Inc. and may have a long or short position.

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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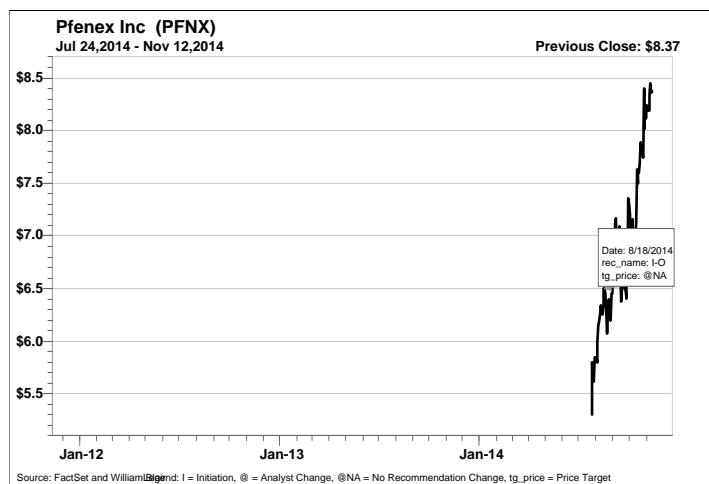
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DOW JONES: 17,612.20

S&P 500: 2,038.25

NASDAQ: 4,675.14



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