Pfenex Reports Third Quarter 2014 Results and Provides Business Update

SAN DIEGO, Nov. 13, 2014 /PRNewswire/ -- Pfenex Inc. (NYSE MKT: PFNX), a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics including high value and difficult to manufacture proteins, today reported financial results for the third quarter ended September 30, 2014 and provided a business update.

"We are pleased to have completed the enrollment for our Phase 1b/2a trial for our lead product candidate, PF582, a biosimilar to Lucentis. We expect to have interim data from the primary endpoint of safety and tolerability for the Phase 1b/2a trial in the first quarter of 2015 and initiate the Phase 3 trial in mid-2015," stated Bertrand C. Liang, President and Chief Executive Officer of Pfenex.

Business Updates

- The Phase 1b/2a trial for PF582, our biosimilar candidate to Lucentis, completed patient enrollment and Pfenex expects interim safety and tolerability data in the first quarter of 2015. The Phase 3 trial is expected to initiate in mid-2015 with data expected in 2017.
- Pfenex expects to initiate a Phase 1 trial of PF530, a biosimilar candidate to Betaseron, in early 2015.
- Pfenex expects to file IND's for both its recombinant anthrax vaccine and recombinant malaria vaccine programs by the end of 2014.
- On November 3, 2014, Pfenex appointed Dr. Hubert Chen as its Chief Medical Officer. Dr. Chen is a veteran in clinical development, having been involved in product development for well over a decade, most recently leading all clinical development activities at Aileron Therapeutics, as well as having extensive clinical development experience at Regulus, Amylin and Amgen.
- Pfenex expanded its leadership team through the addition of a new board member, Robin Campbell, Ph.D. Dr. Campbell has over 25 years of experience in pharmaceutical and biotechnology sales, marketing, product development and general management in United States and international markets.
- Pfenex announced the initiation of a multi-product vaccine research program with PATH, a global health nonprofit organization, as part of an initiative to enhance production of vaccines.

Financial Highlights for the Third Quarter

- Total revenue for the third quarter of 2014 was $2.8 million compared to $2.0 million in the third quarter of 2013. The increase in revenue was due to an increase in activity related to our Px563L and Px533 product candidate development under our government contracts, offset in part by a decrease in reagent product sales.
- Cost of revenue was $1.6 million in the third quarter of 2014 compared to $1.2 million in the third quarter of 2013. The increase in cost of revenue was due primarily to the increased development costs for our proprietary novel vaccine programs which are funded by various government agencies.
- Research and development expenses were $1.3 million for the third quarter of 2014 compared to $2.0 million in the third quarter of 2013. The decrease in research and development expenses was due in part to an increase in development activity by collaboration partner, Strides Arcolab, and resulting decrease in activity by Pfenex, of PF530, as well as manufacturing activity and purchase of comparator material for our product candidate, PF582, Phase 1b/2a trial in the comparative period. We expect research and development expense to increase as we advance our lead candidates and pipeline products.
- Selling, general and administrative expenses were $2.4 million in the third quarter of 2014 compared to $1.6 million in the third quarter of 2013. The increase in selling, general and administrative expenses was due to an increase in activities associated with becoming and operating as a publicly-traded

company. We expect selling, general and administrative expenses to increase for activities associated with operating as a public company.

- Cash, cash equivalents and short-term investments, excluding restricted cash, was $51.5 million as of September 30, 2014, compared to $5.2 million as of December 31, 2013. As of September 30, 2014 we had $3.8 million drawn under our $3.9 million revolving credit facility and $3.9 million of restricted cash as collateral for the credit facility.

Cautionary Note Regarding Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, among others, statements regarding Pfenex's expectations regarding the timing of the release of additional data for its product candidates, the timing of the initiation of additional studies for its product candidates, the timing of filing IND's for its product candidates; and future increases in expenses. Pfenex's expectations and beliefs regarding these matters may not materialize, and actual results in future periods are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Actual results may differ materially from those indicated by these forward-looking statements as a result of the uncertainties inherent in the clinical drug development process, including, without limitation, Pfenex's ability to successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not support further development of product candidates, challenges related to patient enrollment in clinical trials, difficulties in achieving and demonstrating biosimilarity in formulations, Pfenex's ability to manage operating expenses, Pfenex's ability to obtain additional funding to support its business activities and establish and maintain strategic business alliances and new business initiatives, Pfenex's dependence on third parties for development, manufacture, marketing, sales and distribution of products, and unexpected expenditures, as well as those risks more fully discussed in the section entitled "Risk Factors" in Pfenex's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 and its subsequent periodic reports, including its Form 10-Q for the quarter ended September 30, 2014 to be filed with the Securities and Exchange Commission. The forward-looking statements in this press release are based on information available to Pfenex as of the date hereof, and Pfenex disclaims any obligation to update any forward-looking statements, except as required by law.

About Pfenex Inc.

Pfenex Inc. is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics focused on high-value and difficult to manufacture proteins. The company's lead product candidate is PF582, a biosimilar candidate to Lucentis (ranibizumab), for the potential treatment of patients with retinal diseases. Pfenex has leveraged its *Pf*ēnex Expression Technology™ platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines, generics and next generation biologics.

Pfenex has used, and intends to continue to use, its Investor Relations website (http://pfenex.investorroom.com), as means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. For more information, including a copy of our Corporate Presentation dated November 2014, visit (http://pfenex.investorroom.com).

PFENEX INC.
Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue	$ 2,801	$ 1,989	$ 8,625	$ 7,683
Cost of revenue	1,579	1,153	6,031	4,488
Gross profit	1,222	836	2,594	3,195
Operating expenses:				
Selling, general and administrative	2,447	1,599	5,966	5,058
Research and development	1,251	2,036	2,789	4,088
Total operating expenses	3,698	3,635	8,755	9,146
Loss from operations	(2,476)	(2,799)	(6,161)	(5,951)
Other expense, net	(19)	(7)	(58)	(17)
Net loss before income taxes	(2,495)	(2,806)	(6,219)	(5,968)
Income tax benefit (expense)	—	1,116	(1)	2,376
Net loss	$ (2,495)	$ (1,690)	$ (6,220)	$ (3,592)
Effective preferred stock dividends	$ —	$ (430)	$ —	$ (1,257)
Net loss attributable to common stockholders	$ (2,495)	$ (2,120)	$ (6,220)	$ (4,849)
Net loss per common share basic and diluted	$ (0.16)	$ (2.08)	$ (1.06)	$ (4.83)
Weighted-average common shares used to compute basic and diluted net loss per share	15,319	1,019	5,849	1,004

PFENEX INC.
Balance Sheets
(In thousands, except share and par value amounts)

	September 30, 2014	December 31, 2013
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents		

	$ 51,501	$ 1,250
Short-term investments		
Accounts and unbilled receivables, net	1,785	3,461
Inventories finished goods	24	26
Income tax receivable	401	398
Deferred income taxes	3,481	3,481
Other current assets	426	284
Total current assets	57,618	12,854
Restricted cash	3,904	4,029
Property and equipment, net	1,999	2,329
Notes receivable from related parties	—	95
Other long term assets	53	36
Intangible assets, net	6,495	6,893
Goodwill	5,577	5,577
Total assets	$ 75,646	$ 31,813
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,480	$ 1,804
Accrued liabilities	2,860	2,953
Deferred revenue	768	1,253
Line of credit obligation	3,813	—
Total current liabilities	8,921	6,010
Deferred tax liability	3,481	3,481
Line of credit obligation	—	3,590
Other long-term liabilities	2	3
Total liabilities	12,404	13,084
Commitments and contingencies (Note 8)		
Redeemable convertible Series A-2 preferred stock, par value $0.001, 4,978,662 shares authorized, 3,556,186 shares issued and outstanding at December 31, 2013	—	49,200
Redeemable convertible Series A-1 preferred stock, par value $0.001, 4,978,662 shares authorized, 4,978,661 shares issued and outstanding at December 31, 2013	—	63,980
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2014	----	---
Common stock, $0.001 par value, 200,000,000 and 12,514,224 shares authorized at September 30, 2014 and December 31, 2013, respectively, 20,376,974 and 1,541,781 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	21	2
Additional paid-in capital	172,937	—
Accumulated deficit	(109,716)	(94,453)

Total stockholders' equity (deficit)	63,242	(94,451)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 75,646	$ 31,813

Logo - http://photos.prnewswire.com/prnh/20140715/127348

SOURCE Pfenex Inc.

For further information: Company, Paul Wagner, Ph.D., Chief Financial Officer, (858) 352-4333, pwagner@pfenex.com, or Investor Relations, Westwicke Partners, LLC, Robert H. Uhl, Managing Director, (858) 356-5932, robert.uhl@westwicke.com

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Additional assets available online: Photos (1)