Pfenex Reports Fourth Quarter and Full Year 2015 Results and Provides Business Update

SAN DIEGO, March 10, 2016 /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 fourth quarter and full year ended December 31, 2015 and provided a business update.

"2015 was a very productive and eventful year for Pfenex," stated Bertrand C. Liang, chief executive officer of Pfenex. "We signed the collaboration agreement for PF582, our biosimilar candidate to Lucentis, with Hospira, now a subsidiary of Pfizer (together, Pfizer) in February 2015, we led our successful secondary offering in April 2015 and we signed a significant contract with the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS) for the advanced development of our anthrax vaccine in August 2015. 2015 was also a year marked by the continued successful progress of our portfolio of biosimilar and vaccine candidates and by the strengthening of Pfenex through key additions to our company and to our board of directors. 2016 should be an exciting year for Pfenex as we look to continue our successful pipeline advancement and provide updates on our key milestones throughout the year."

Business Updates and 2015 Highlights

- Pfenex initiated a Phase 1 trial of PF530, a biosimilar candidate to Betaseron, in the first quarter of 2015 and enrolled 12 healthy subjects. Based on the analysis of the trial PK and PD parameters, no statistical differences between PF530 compared to the reference compound were observed. The pivotal PK/PD study and immunogenicity trial are expected to initiate in 2H2016.
- PF708, our peptide candidate that we are developing as a therapeutic equivalent to Forteo, initiated a bioequivalence study in 2015 and we expect to provide a data read-out from that study in 2H2016.
- The pivotal clinical comparator trial for PF582, our biosimilar candidate to Lucentis, is expected to initiate in 2016. We entered into a collaboration with Pfizer in February 2015. The collaboration included an upfront payment of $51 million and milestone payments valued at up to $291 million as well as tiered double digit royalties on net sales of PF582. Pfizer is responsible for the clinical comparative trial and we will share costs of the trial 50/50 up to a cap for Pfenex of $20 million, with $10 million of that amount offset as a credit against the royalties payable to us.
- Pfenex initiated the Phase 1 trial for its recombinant anthrax vaccine in 2015 and expects an interim data read-out in 2H2016. In August, Pfenex announced it had signed a five year, cost plus fixed fee contract valued at up to $143.5 million with the Biomedical Advanced Research and Development Authority (BARDA) of the Department of Health and Human Services (HHS), for the advanced development of our mutant recombinant protective antigen anthrax vaccine which offers the potential for a dramatic improvement in the rapid production of large amounts of high value stable recombinant anthrax vaccine for the U.S. Government.
- During 2015 we further strengthened our board of directors. In September 2015, we announced that Dennis M. Fenton, Ph.D., was appointed to the company's board of directors, deepening the manufacturing and product development expertise of the biosimilar company. Dr. Fenton has over three decades of experience in the biotechnology industry. Additionally, in April 2015 we announced that John Taylor was elected to the company's board of directors. Mr. Taylor brings more than 20 years of regulatory experience working with the U.S. Food and Drug Administration (FDA).
- In April 2015, Pfenex announced the closing of our follow on offering. The net proceeds to Pfenex from this offering were approximately $38.0 million, after deducting underwriting discounts and commissions but before deducting estimated offering expenses.

Financial Highlights for the Fourth Quarter

Total Revenue increased by $1.2 million, or 62%, to $3.3 million for the quarter ended December 31, 2015 compared to $2.0 million in same period in 2014. The increase in revenue was due to the stage of development of our Px563L product candidate under our government contracts and by an increase in license revenue from our collaboration with Pfizer, partially offset by a decline in protein production services. We expect revenue related to our protein production services to decline in the near-term as we shift our resources to developing our product pipeline.

Cost of revenue increased by approximately $0.5 million, or 44%, to $1.7 million in the three month period ended December 31, 2015 compared to $1.2 million in same period in 2014. The increase in cost of revenue was due primarily to the stage of development of our Px563L product candidate under our government contracts. Given the nature of the novel vaccine development process, these costs will fluctuate depending on stage of development.

Research and development expenses increased by approximately $4.7 million, or 355%, to $6.1 million in the three month period ended December 31, 2015 compared to $1.3 million in same period in 2014. The increase in research and development expenses was due primarily to the increase in development activity on our product candidates PF708, PF530 and PF529 and the hiring of additional personnel dedicated to our research and development efforts. We expect research and development costs will increase going forward as we independently advance PF530 as a wholly-owned product candidate, as well as continuing to advance our wholly-owned pipeline including PF708, our therapeutic equivalent candidate to Forteo, and PF529, our biosimilar candidate to Neulasta. Additionally, we expect research and development expenses to increase as we advance our other lead candidates and pipeline product candidates. For example, under our agreement with Pfizer, we will share the confirmatory clinical study costs for PF582 with our share capped at $20 million, $10 million of which will be setoff as a credit against royalties payable to us unless the collaboration agreement is terminated prior to such setoff.

Selling, general and administrative expenses increased by $0.7 million, or 23%, to $3.7 million in the three month period ended December 31, 2015 compared to $3.0 million in the same period in 2014. The increase in selling, general and administrative expenses was due to an increase in activities associated with operating as a publicly-traded company. We expect general and administrative costs to increase for activities associated with company operations. These increases will likely include the hiring of additional personnel. In addition, we intend to continue to incur increased internal and external business development costs to support our various product development efforts, which can vary from period to period.

Cash and cash equivalents as of December 31, 2015 was $106.2 million.

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. Forward-looking statements generally relate to future events or Pfenex's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern Pfenex's expectations, strategy, plans or intentions. Forward-looking statements in this press release include, but are not limited to, statements regarding the future potential of Pfenex's product candidates, including future plans to develop, manufacture and commercialize its product candidates and the potential to receive future milestone and royalty payments under its collaboration agreements; Pfenex's expectations regarding the timing of the release of additional data and results for its product candidates, and the timing of the initiation of additional studies for its

product candidates; and Pfenex's future projections related to increases in expenses and reductions in protein production revenue. 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 or may require Pfenex to conduct additional clinical trials or modify ongoing clinical trials; challenges related to commencement, patient enrollment, completion, and analysis of 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; unexpected expenditures; and difficulties in obtaining and maintaining intellectual property protection for its product candidates. Information on these and additional risks, uncertainties, and other information affecting Pfenex's business and operating results is contained in Pfenex's Annual Report on Form 10-K for the year ended December 31, 2014 and in Pfenex's subsequent reports on Form 10-Q and Form 8-K, filed with the Securities and Exchange Commission. Additional information will also be set forth in Pfenex's Annual Report on Form 10-K for the period ended December 31, 2015 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.

Pfenex investors and others should note that we announce material information to the public about the Company through a variety of means, including our website (http://www.pfenex.com/), our investor relations website (http://pfenex.investorroom.com/), press releases, SEC filings, public conference calls, corporate Twitter account (https://twitter.com/pfenex), Facebook page (https://www.facebook.com/Pfenex-Inc-105908276167776/timeline/), and LinkedIn page (https://www.linkedin.com/company/pfenex-inc) in order to achieve broad, non-exclusionary distribution of information to the public and to comply with our disclosure obligations under Regulation FD. We encourage our investors and others to monitor and review the information we make public in these locations as such information could be deemed to be material information. Please note that this list may be updated from time to time. For a link to our most recent corporate presentation, visit our investor relations website (http://pfenex.investorroom.com/).

About Pfenex Inc.

Pfenex Inc. is a clinical-stage biotechnology company engaged in the development of biosimilar therapeutics and 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*enex Expression Technology® platform to build a pipeline of product candidates and preclinical products under development including other biosimilars, as well as vaccines,therapeutic equivalents to reference listed drug products, and next generation biologics.

PFENEX INC.
Condensed Consolidated Statements of Operations

	Three Months Ended December 31, (unaudited)	Twelve months ended December 31, (audited)

(in thousands, except per share data)	2015	2014	2015	2014
Revenue	$ 3,261	$ 2,019	$ 9,583	$ 10,644
Cost of revenue	1,729	1,202	4,640	7,233
Gross profit	1,532	817	4,943	3,411
Operating expense				
Selling, general and administrative	3,743	3,037	14,598	9,003
Research and development	6,085	1,336	18,183	4,125
Total operating expense	9,828	4,373	32,781	13,128
Loss from operations	(8,296)	(3,556)	(27,838)	(9,717)
Other income (expense), net	36	(19)	74	(77)
Net loss before income taxes	(8,260)	(3,575)	(27,764)	(9,794)
Income tax benefit (expense)	(411)	1	(452)	—
Net loss	$ (8,671)	$ (3,574)	$ (28,216)	$ (9,794)
Net loss per common share basic and diluted	$ (0.37)	$ (0.18)	$ (1.26)	$ (1.04)
Weighted-average common shares used to compute basic and diluted net loss per share	23,295	20,388	22,376	9,441

PFENEX INC.
Consolidated Balance Sheets

	December 31,	
	2015	2014
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 106,162	$ 45,722
Restricted cash	3,959	—
Accounts and unbilled receivables, net	2,683	1,584
Inventories	24	23
Income tax receivable	508	402
Deferred income taxes	—	3,281
Other current assets	1,694	1,753
Total current assets	115,030	52,765
Restricted cash	—	3,955
Deferred income taxes	1,955	—
Property and equipment, net	3,179	2,310

Other long term assets	121	53
Intangible assets, net	5,832	6,363
Goodwill	5,577	5,577
Total assets	$ 131,694	$ 71,023
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 886	$ 1,129
Accrued liabilities	5,997	2,633
Current portion of deferred revenue	3,870	201
Line of credit obligation	3,813	3,813
Income tax payable	1,676	—
Total current liabilities	16,242	7,776
Deferred revenue, less current portion	44,225	—
Deferred tax liability	—	3,281
Other long-term liabilities	46	92
Total liabilities	60,513	11,149
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding		
Common stock, par value $0.001, 200,000,000 shares authorized at December 31, 2015 and 2014, respectively, 23,316,413 and 20,405,066 shares issued and outstanding at December 31, 2015 and 2014, respectively	24	21
Additional paid-in capital	212,661	173,141
Accumulated deficit	(141,504)	(113,288)
Total stockholders' equity	71,181	59,874
Total liabilities and stockholders' equity	$ 131,694	$ 71,023

SOURCE Pfenex Inc.

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