Pfenex Reports Fourth Quarter and Full Year 2016 Results and Provides Business Update

SAN DIEGO, March 15, 2017 /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, 2016 and provided a business update.

Business Review and Update

PF708 is the Pfenex product candidate that is being developed as a therapeutic equivalent to Forteo (teriparatide), marketed by Eli Lilly for the treatment of osteoporosis patients at high risk of fracture. The PF708 bioequivalence study, conducted in 70 healthy subjects, was completed in the second quarter of 2016 and met its primary objectives. We initiated an immunogenicity/pharmacokinetics clinical study in osteoporosis patients in the fourth quarter of 2016. The interim pharmacokinetic data from this study is expected in the second half of 2017 and the immunogenicity data is expected in the first half of 2018. Pfenex believes this study, along with the positive bioequivalence study, is anticipated to satisfy the filing requirements for PF708 through the 505(b)(2) regulatory pathway.

In August 2016, Pfenex regained full rights from Pfizer to PF582, our biosimilar candidate to Lucentis (ranibizumab) for the treatment of retinal diseases, and announced positive results from the phase 1/2 trial, which showed that PF582 was pharmacologically active and with a safety profile that was consistent with that of Lucentis. We are continuing to explore strategic options for PF582.

Px563L, a novel anthrax vaccine candidate, is being developed by Pfenex in response to the United States government's unmet demand for increased quantity, stability and dose sparing regimens of anthrax vaccine. We initiated a randomized, placebo-controlled Phase 1a trial in healthy subjects in the second half of 2015 to investigate the safety and immunogenicity of Px563L, and we announced the interim analysis results in the second half of 2016. Findings indicated that the vaccine was well-tolerated, with the potential to afford immunogenicity protection against anthrax infection with fewer injections. The development of Px563L is funded by the U.S. Department of Health and Human Services, through the Biomedical Advanced Research and Development Authority, or BARDA, in accordance with a cost plus fixed fee advanced development contract valued at up to approximately $143.5 million. In addition to the base period, BARDA has now exercised additional phases of the development contract effective January 2017, allowing for the continuing development of Px563L. The phase 2 study could initiate in 2018, provided the program continues to successfully advance with the support of BARDA. Pfenex believes the successful completion of the activities under this contract could lead to a procurement contract for supply of Px563L to the Strategic National Stockpile.

Regulatory feedback for PF529, our biosimilar candidate to Neulasta (pegfilgrastim), was received in 2016 and supported the feasibility of development under the 351(k) biosimilar pathway. Pfenex continues to evaluate the potential resource requirements and timeline for development.

In January 2017, Pfenex announced that Dr. Bertrand C. Liang resigned his position as Chief Executive Officer, President, Secretary and as a member of the Board of Directors of the Company following the completion of an independent investigation overseen by the Audit Committee that revealed Dr. Liang had not acted in accordance with the Company's Board Approval Process Policy and Code of Ethics and Conduct. The misconduct did not impact the operating results for Pfenex. Patrick K. Lucy, the Company's Chief Business Officer, was appointed to serve as Interim Chief Executive Officer, President, and Secretary. The Board of Directors has formed a search committee consisting of select independent directors to initiate an executive search for a replacement CEO.

Financial Highlights for the Fourth Quarter and Full Year 2016

Total Revenue increased by $50.6 million, or 528%, from $9.6 million in 2015 to $60.2 million in 2016. The increase in revenue was primarily due to the termination of our development and license agreement with Pfizer. As a result of the termination in August 2016, the estimated performance period was accelerated resulting in the recognition of $45.8 million of revenue that had been previously deferred. As a result of the termination, we will not recognize any additional future revenue under the Pfizer development and license agreement. Revenue increased by $2.2 million, or 68%, to $5.5 million in the three month period ended December 31, 2016 compared to $3.3 million in the same period in 2015. The increase in the three month period was due primarily to one-time milestone payments which contributed approximately $2 million to license fee revenue for the quarter ended December 31, 2016.

Cost of revenue increased by $0.7 million, or 15%, to $5.3 million in 2016 compared to $4.6 million in 2015. The change was due primarily to a net increase of $0.7 million in costs for our proprietary novel vaccine

program Px563L, which is funded by a government agency. Cost of revenue decreased by approximately $0.4 million, or 24%, to $1.3 million in the three month period ending December 31, 2016 compared to $1.7 million in the same period in 2015 due primarily to timing of costs related to the development of our Px563L product candidate. Given the nature of the novel vaccine development process, cost of revenue will fluctuate depending on stage of development.

Research and development expenses increased by approximately $14.2 million, or 78%, to $32.4 million in 2016 compared to $18.2 million in 2015. The increase in research and development expenses in 2016 compared to 2015 was due to manufacturing and development activities of PF708, which is being developed as a therapeutically equivalent candidate Forteo, and our other biosimilar product candidates. R&D expenses increased by approximately $4.6 million, or 75%, to $10.7 million in the three months ended December 31, 2016 compared to the same period in 2015. The increase in the three month period was due primarily to manufacturing and development costs associated with our product candidates.

Selling, general and administrative expenses increased by $2.7 million, or 19% to $17.3 million in 2016 compared to $14.6 million in 2015 and increased by $0.7 million, or 18%, to $4.4 million in the three month period ended December 31, 2016 from $3.7 million in the same period in 2015. The increases in selling, general and administrative expenses were primarily due to higher personnel-related expenses.

Cash and cash equivalents as of December 31, 2016 was $81.5 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 advance, develop, manufacture and commercialize its product candidates; Pfenex's belief in its potential to obtain a U.S. government procurement contract for Px563L; Pfenex's expectation to receive data from the PF708 clinical program in the second half of 2017 and in the first half of 2018; Pfenex's expectations regarding the timing of the release of additional clinical trial data for its product candidates; Pfenex's expectations regarding the timing of additional clinical trials and the types of future clinical trials for its product candidates; Pfenex's expectations regarding the expected regulatory pathways for its product candidates, including the development of PF708 pursuant to the 505(b)(2) regulatory pathway; Pfenex's expectations regarding the sufficiency of its clinical trials to satisfy regulatory requirements; Pfenex's plan to explore strategic opportunities for PF582; and Pfenex's future projections related to fluctuations and changes in revenue and 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 or may require Pfenex to conduct additional clinical trials or modify ongoing clinical trials or regulatory pathways; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 and in its other filings 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, 2016 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.

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 candidates are PF708, a therapeutic equivalent candidate to Forteo (teriparatide) for the treatment of osteoporosis, and 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.
Consolidated Statements of Operations

	Three Months Ended December 31,		Twelve Months Ended December 31,	
(in thousands, except per share data)	**2016**	**2015**	**2016**	**2015**
Revenue	$ 5,471	$ 3,261	$ 60,194	$ 9,583
Cost of revenue	1,312	1,729	5,313	4,640
Gross profit	4,159	1,532	54,881	4,943
Operating expense				
Selling, general and administrative	4,405	3,743	17,340	14,598
Research and development	10,655	6,085	32,418	18,183
Total operating expense	15,060	9,828	49,758	32,781
Income (loss) from operations	(10,901)	(8,296)	5,123	(27,838)
Other income (expense), net	51	36	149	74
Net income (loss) before income taxes	(10,850)	(8,260)	5,272	(27,764)
Income tax benefit (expense)	210	(411)	209	(452)
Net income (loss)	$ (10,640)	$ (8,671)	$ 5,481	$ (28,216)
Net income (loss) per share:				
Basic	$ (0.45)	$ (0.37)	$ 0.23	$ (1.26)
Diluted	$ (0.45)	$ (0.37)	$ 0.23	$ (1.26)
Shares used in calculating net income (loss) per share:				
Basic	23,424	23,295	23,389	22,376
Diluted	23,424	23,295	23,688	22,376

PFENEX INC.
Consolidated Balance Sheets

	December 31,	
	2016	**2015**
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 81,501	$ 106,162
Restricted cash		

Accounts and unbilled receivables, net	2,822	3,059
Income tax receivable	717	508
Other current assets	1,878	1,718
Total current assets	86,918	115,030
Deferred income taxes	—	1,955
Property and equipment, net	5,246	3,179
Other long term assets	80	121
Intangible assets, net	5,301	5,832
Goodwill	5,577	5,577
Total assets	$ 103,122	$ 131,694
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,284	$ 886
Accrued liabilities	9,412	5,997
Current portion of deferred revenue	6,516	3,870
Line of credit obligation	—	3,813
Income tax payable	—	1,676
Total current liabilities	17,212	16,242
Deferred revenue, less current portion	5,739	44,225
Other long-term liabilities	26	46
Total liabilities	22,977	60,513
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, 2016 and 2015, respectively, 23,429,501 and 23,316,413 shares issued and outstanding at December 31, 2016 and 2015, respectively	24	24
Additional paid-in capital	216,144	212,661
Accumulated deficit	(136,023)	(141,504)
Total stockholders' equity	80,145	71,181
Total liabilities and stockholders' equity	$ 103,122	$ 131,694

SOURCE Pfenex Inc.

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Additional assets available online: Photos (1)