Pfenex Reports Third Quarter 2016 Results and Provides Business Update

SAN DIEGO, Nov. 9, 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 third quarter ended September 30, 2016 and provided a business update.

"In the third quarter, Pfenex has continued to make steady progress, advancing our broad pipeline of biosimilar therapeutics and government funded anthrax vaccine candidates," stated Bertrand C. Liang, Chief Executive Officer of Pfenex. "This quarter we announced several important updates, including the formation of our Scientific Advisory Board and the hiring of Steven Sandoval as our Chief Manufacturing Officer. The addition of these key resources will support the advancement of our portfolio towards commercialization. We are looking forward to sharing additional product updates and data over future quarters."

Business Review and Update

In October, Pfenex announced the formation of a Scientific Advisory Board (SAB) to provide expert guidance and insight as the Company advances towards product commercialization. Members of the SAB will assist the Company as it navigates process development and moves closer to product commercialization. The elite group of industry experts providing scientific guidance currently includes Greg Blank, PhD, a recognized global leader in bioprocess development with over 23 years at Genentech, Matthew S. Croughan, PhD, an independent consultant serving on the SAB or External Advisory Panel for several firms, including Pfizer, and Dennis Fenton, PhD, an industry pioneer, with over three decades of experience in biotechnology. Dr. Fenton retired after a lengthy and distinguished career with Amgen, where he held a variety of notable roles, including Executive Vice President, Operations.

Additionally, in October, Pfenex announced the hiring of Steven Sandoval as Chief Manufacturing Officer. Steven has over 25 years of commercial biopharmaceutical engineering and operations experience, specializing in commercial operations, facility design and licensure of large scale biopharmaceutical commercial manufacturing facilities. He has extensive knowledge of cGMP biopharmaceutical engineering as well as significant first-hand experience preparing for and interfacing with the FDA and other global regulatory agencies during pre-licensure and biennial inspections of commercial cGMP biopharmaceutical manufacturing facilities. Prior to joining Pfenex, Steven was a member of Amgen's site executive management leadership team responsible for the aggressive growth at the Puerto Rico manufacturing site.

Following the announcement in August of the positive Phase 1 trial data for Pfenex's recombinant anthrax vaccine, discussions with BARDA have been progressing. The Company is looking forward to continuing to advance the development of that program in collaboration with BARDA with the goal of obtaining a government procurement contract, given 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.

In August, Pfenex regained full rights to PF582, the Company's biosimilar candidate to Lucentis, and announced positive results from the phase 1/2 trial. The Company is continuing to explore the strategic options for PF582 and is engaged in discussions. The timing of the PF582 clinical comparative study is expected to allow for global market access as key patents expire.

Pfenex anticipates initiating the PF708 pivotal clinical program by year end. PF708 is Pfenex's peptide product candidate that the Company is developing as a therapeutic equivalent to Forteo (teriparatide) through the 505(b)(2) regulatory development pathway. The PF708 clinical program is expected to include an immunogenicity/pharmacokinetic study in subjects with osteoporosis.

Pfenex entered into a collaboration with Jazz Pharmaceuticals on multiple hematology/oncology product candidates in July. The collaboration also includes an option for Jazz Pharmaceuticals to negotiate a license for a recombinant pegaspargase product candidate with Pfenex. Pfenex received upfront and option payments totaling $15 million and may be eligible to receive additional payments of up to $166 million based on the achievement of certain development-, regulatory-, and sales-related milestones, including up to $41 million for certain non-sales-related milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration. Both parties will be contributing to development efforts.

Regulatory feedback for PF529, Pfenex's biosimilar candidate to Neulasta (pegfilgrastim), is expected by the end of 2016 and following that feedback, the development path and potential timeline will be outlined.

Financial Highlights for the Third Quarter

Total Revenue increased by $46.7 million to $48.8 million in the three month period ended September 30,

2016 compared to $2.1 million in same period in 2015. As a result of the termination of the development and license agreement with Pfizer, the estimated performance period for the agreement was adjusted to reflect the August 2016 termination date. This accelerated recognition of $45.8 million of revenue in August that had been previously deferred. Other increases were attributable to license revenue from the Jazz license and option agreement, as well as increased revenue due to the stage of development of our Px563L product candidate under our government contracts. Given the nature of the novel vaccine development process, revenue will fluctuate depending on stage of development.

Cost of revenue increased by approximately $0.6 million to $1.3 million in the three month period ended September 30, 2016, compared to $0.7 million in the same period in 2015. The increase in cost of revenue was due primarily to an increase in costs for our Px563L product candidate under our government contracts. The increase was offset by a decrease in product sales, reflecting our customers' product development and clinical progression. 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 $3.0 million to $8.7 million in the three month period ended September 30, 2016 compared to $5.7 million in same period in 2015. The increase in research and development expenses was due to the increase in development activity of our product candidates, including PF708, and the hiring of additional personnel dedicated to our research and development efforts. We expect research and development expenses to increase for the foreseeable future as we advance our lead product candidates and pipeline product candidates.

Selling, general and administrative expenses increased by $1.1 million to $4.4 million in the three month period ended September 30, 2016 compared to $3.3 million in the same period in 2015. The increase in selling, general and administrative expenses was primarily due to an increase in headcount, as well as increases in salaries and other personnel costs. We expect selling, general and administrative costs to continue to increase for activities associated with operating as a publicly-traded company, as well to support our various product and business development efforts, which can vary from period to period.

Cash and cash equivalents as of September 30, 2016 was $93.6 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 rapidly produce and supply large amounts of high value stable recombinant anthrax vaccine and its goal of obtaining a U.S. government procurement contract; Pfenex's expectations regarding its potential to receive future milestone and royalty payments under its collaboration agreements, including its contracts with Jazz; Pfenex's plan to initiate the PF708 clinical program by year end; 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, including PF708, and its other 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 plan to explore strategic opportunities for PF582; Pfenex's anticipation of receiving regulatory feedback for PF529 by the end of 2016; Pfenex's future projections related to fluctuations and changes in revenue; and anticipated 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 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 Annual Report on Form 10-K for the year ended December 31, 2015 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 Quarterly Report on Form 10-Q for the period ended September 30, 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 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.

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PFENEX INC.
Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	**2016**	**2015**	**2016**	**2015**
Revenue	$ 48,824	$ 2,057	$ 54,723	$ 6,322
Cost of revenue	1,285	682	4,001	2,911
Gross profit	47,539	1,375	50,722	3,411
Operating expense				
Selling, general and administrative	4,405	3,276	12,935	10,855
Research and development	8,690	5,679	21,763	12,098
Total operating expense	13,095	8,955	34,698	22,953
Income (loss) from operations	34,444	(7,580)	16,024	(19,542)
Other income (expense), net	52	(9)	98	38
Net income (loss) before income taxes	34,496	(7,589)	16,122	(19,504)
Income tax expense	-	(1)	(1)	(41)
Net income (loss)	$ 34,496	$ (7,590)	$ 16,121	$ (19,545)
Net income (loss) per share:				
Basic	$ 1.47	$ (0.33)	$ 0.69	$ (0.89)
Diluted				

Diluted	$ 1.46	$ (0.33)	$ 0.68	$ (0.89)
Shares used in calculating net income (loss) per share:				
Basic	23,400	23,215	23,378	22,066
Diluted	23,689	23,215	23,674	22,066

PFENEX INC.
Consolidated Balance Sheets

	September 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 93,638	$ 106,162
Restricted cash	—	3,959
Accounts and unbilled receivables, net	1,317	2,683
Income tax receivable	227	508
Other current assets	2,256	1,718
Total current assets	97,438	115,030
Deferred income taxes	1,955	1,955
Property and equipment, net	5,102	3,179
Other long term assets	80	121
Intangible assets, net	5,434	5,832
Goodwill	5,577	5,577
Total assets	$ 115,586	$ 131,694
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,886	$ 886
Accrued liabilities	8,137	5,997
Current portion of deferred revenue	7,280	3,870
Line of credit obligation	—	3,813
Income tax payable	1,644	1,676
Total current liabilities	18,947	16,242
Deferred revenue, less current portion	6,672	44,225
Other long-term liabilities	40	46
Total liabilities	25,659	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, $0.001 par value, 200,000,000 shares authorized; 23,417,774 and 23,316,413 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	24	24
Additional paid-in capital	215,286	212,661
Accumulated deficit	(125,383)	(141,504)
Total stockholders' equity	89,927	71,181
Total liabilities and stockholders' equity	$ 115,586	$ 131,694

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