Pfenex Reports First Quarter 2016 Results and Provides Business Update

SAN DIEGO, May 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 first quarter ended March 31, 2016 and provided a business update.

"Pfenex continued to make solid progress in the first quarter," stated Bertrand C. Liang, chief executive officer of Pfenex. "Today we announced the positive top-line data from our PF708 initial bioequivalence study which can be referred to in our separate press release issued this afternoon. In the second half of 2016, we expect to initiate the pivotal clinical program for PF530, our biosimilar candidate to Betaseron. Additionally, we expect to present data from our phase 1a study of Px563L, our anthrax vaccine candidate. We are looking forward to the key data readouts and study initiations over the remainder of 2016 which we believe will further highlight our differentiated business strategy and capabilities."

Business Highlights

- The bioequivalence study in healthy subjects for PF708, our peptide product candidate that we are developing as a therapeutic equivalent to Forteo, met the primary outcome measures. We anticipate initiating the clinical program to satisfy the filing requirements for PF708 through the 505(b)(2) regulatory development pathway by year-end which will include an immunogenicity/pharmacokinetic study in subjects with osteoporosis.
- Pfenex completed a Phase 1 trial of PF530, a biosimilar candidate to Betaseron, in 2015 which 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.
- The pivotal clinical comparator trial for PF582, our biosimilar candidate to Lucentis which we partnered with Pfizer in February 2015, is expected to initiate in 2016. Pfizer is responsible for initiating and conducting the trial. The PF582 collaboration with Pfizer 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. We will share costs equally of the clinical comparative trial with Pfizer, 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 2015, Pfenex announced signing 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.

Financial Highlights for the First Quarter

Total Revenue increased by $0.8 million, or 40%, to $2.8 million in the three month period ended March 31, 2016 compared to $2.0 million in same period in 2015. The increase in revenue for the three month period was due to the stage of development of our Px563L product candidate under our government contracts and an increase in license revenue, offset by a decrease in product sales. The Phase 1 trial for Px563L, entirely funded through the U.S. government, was initiated at the end of 2015. Given the nature of the novel vaccine development process, revenue will fluctuate depending on stage of development.

Cost of revenue of $1.3 million decreased by approximately $32 thousand, or 2%, compared to the same period in 2015. The decrease in cost of revenue for the three month period was due primarily to a decrease in product sales, which is impacted by our customers' product development and clinical progression. The decrease was offset by an increase in costs for 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 $2.7 million, or 95%, in the three month period ended March 31, 2016 to $5.5 million in the three month period ended March 31, 2016 compared to $2.8 million in same period in 2015. The increase in research and development expenses during the three month period was due to the increase in development activity on our product candidates PF708 and PF530 and the hiring of additional personnel dedicated to our research and development efforts. A bioequivalence study began at the end of 2015 for PF708, increasing costs over the same period last year. For PF530 and PF708, we expect research and development costs will increase going forward as we independently advance PF530 and PF708 as wholly-owned product candidates. We expect research and development expenses to increase for the foreseeable future as we advance our lead candidates and pipeline product candidates.

Selling, general and administrative expenses increased by $0.3 million, or 8%, to $4.2 million in the three month period ended March 31, 2016 compared to $3.9 million in the same period in 2015. The increase in selling, general and administrative expenses during the three month period was primarily due to an increase in personnel costs and an increase in activities associated with operating as a publicly-traded company. We expect general and administrative costs to continue to increase for activities associated with operating as a publicly-traded company including the hiring of additional personnel. In addition, we intend to continue to incur increased internal and external costs to support our various product development efforts, which can vary from period to period.

Cash and cash equivalents as of March 31, 2016 was $96.5 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 develop, manufacture and commercialize its product candidates, including Pfenex's belief in its potential to rapidly produce and supply large amounts of high value stable recombinant anthrax vaccine to the U.S. government; Pfenex's expectations regarding its potential to receive future milestone and royalty payments under its collaboration agreements, including its contracts with Pfizer and BARDA; Pfenex's expectations regarding the timing of the release of additional clinical trial data for Px563L and its other product candidates, and the anticipated results for its product candidates in clinical trials; Pfenex's expectations regarding the timing of additional clinical trials and the types of future clinical trials for its product candidates, including PF530, PF582, PF708, Px563L, 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 expectations regarding the sufficiency of its clinical trials to satisfy regulatory requirements; and Pfenex's future projections related to fluctuations and increases in revenue and expenses, including increases in research and development costs as Pfenex advances its product candidates and costs associated with advancing PF530 and PF708 as wholly-owned product candidates. 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 March 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 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, therapeutic equivalents to reference listed drug products, and next generation biologics.

PFENEX INC.
Condensed Consolidated Statements of Operations
(unaudited)

(in thousands, except per share data)	Three Months Ended March 31, 2016	2015
Revenue	$ 2,764	$ 1,975
Cost of revenue	1,276	1,308

Gross profit	1,488	667
Operating expense		
Selling, general and administrative	4,209	3,891
Research and development	5,487	2,809
Total operating expense	9,696	6,700
Loss from operations	(8,208)	(6,033)
Other income, net	—	80
Net loss before income taxes	(8,208)	(5,953)
Income tax expense	(1)	(19)
Net loss	$ (8,209)	$ (5,972)
Net loss per common share basic and diluted	$ (0.35)	$ (0.29)
Weighted-average common shares used to compute basic and diluted net loss per share	23,353	20,474

PFENEX INC.
Condensed Consolidated Balance Sheets

	March 31, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 96,527	$ 106,162
Restricted cash	—	3,959
Accounts and unbilled receivables, net	2,969	2,683
Income tax receivable	508	508
Other current assets	2,088	1,718
Total current assets	102,092	115,030
Deferred income taxes	1,955	1,955
Property and equipment, net	4,149	3,179
Other long term assets	121	121
Intangible assets, net	5,699	5,832
Goodwill	5,577	5,577
Total assets	$ 119,593	$ 131,694
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,087	$ 886
Accrued liabilities	5,675	5,997
Current portion of deferred revenue	3,907	3,870
Line of credit obligation	—	3,813
Income tax payable	1,645	1,676
Total current liabilities	12,314	16,242

Deferred revenue, less current portion	43,278	44,225
Other long-term liabilities	61	46
Total liabilities	55,653	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; 23,375,992 and 23,316,413 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	24	24
Additional paid-in capital	213,629	212,661
Accumulated deficit	(149,713)	(141,504)
Total stockholders' equity	63,940	71,181
Total liabilities and stockholders' equity	$ 119,593	$ 131,694

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SOURCE Pfenex Inc.

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Additional assets available online: Photos (1)