Pfenex Reports Second Quarter 2017 Results and Provides Business Update

SAN DIEGO, Aug. 9, 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 second quarter ended June 30, 2017 and provided a business update.

Business Review and Update

Pfenex announced the appointment of Evert (Eef) Schimmelpennink as Chief Executive Officer, President, and Secretary effective August 3, 2017. Mr. Schimmelpennink was also appointed to serve as a Class III member of the board of directors effective August 3, 2017. Schimmelpennink brings to Pfenex a broad base of biotechnology and pharmaceutical experience with strategic and functional expertise across corporate development, commercial operations, manufacturing and R&D. Prior to joining Pfenex, Schimmelpennink served as the Chief Executive Officer of Alvotech, a biosimilar development company, Vice President Global Injectables at Pfizer, and Vice President – Global Generics of Hospira.

PF708 is Pfenex's 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. Enrollment in the pivotal immunogenicity/pharmacokinetics clinical study in osteoporosis patients was initiated in the fourth quarter of 2016. The enrollment of the study is approaching completion and interim pharmacokinetic data from this study is expected in the second half of 2017.The immunogenicity data is expected in the first half of 2018. Pfenex believes this study, along with the positive bioequivalence study, should satisfy the filing requirements for PF708 through the 505(b)(2) regulatory pathway and expects to submit the new drug application (NDA) in the third quarter of 2018 to the FDA.

In August 2016, Pfenex regained full rights from Pfizer to PF582, Pfenex's biosimilar product 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 had a safety profile that was consistent with that of Lucentis. Pfenex has continued to make progress on the strategic review for the PF582 program and will provide an update when appropriate.

Px563L and RPA563, novel anthrax vaccine candidates, are 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. The development of our anthrax candidates 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. Pfenex expects to initiate the phase 2 study by year-end 2018. Ahead of the phase 2 study initiation, the Company expects to continue to demonstrate stability of the vaccine candidates and complete manufacturing of the clinical supply. To date, Pfenex has generated stability data on the 2016 manufactured lot for up to 6 months, demonstrating the maintenance of high purity at 5°C, the expected storage temperature, as well as accelerated stability at 25°C. Pfenex has also generated long-term stability data from our toxicology lot, showing the maintenance of high purity at 5°C at 40 months (Figure 1). Pfenex expects to have FDA discussions in the fourth quarter of 2017 to review Phase 1 results and proposed future nonclinical and clinical investigations.

Pfenex believes the successful completion of the phase 2 study and activities under this contract could lead to a procurement contract for supply to the Strategic National Stockpile.

Financial Highlights for the Second Quarter 2017

Total Revenue decreased to $3.0 million in the three-month period ended June 30, 2017 compared to $3.1 million in same period in 2016. The decrease in revenue compared to the same period in the prior year was due to decreases in government contract revenue for our Px563L product candidate, as two option periods were exercised by the government in January 2017, resulting in lower-cost planning and start-up activities. This was partially offset by several license agreements which became effective in mid- to late-2016, resulting in an increase in license revenue. Given the nature of the novel vaccine development process, revenue will fluctuate depending on stage of development.

Cost of revenue decreased to $0.9 million in the three-month period ended June 30, 2017 compared to $1.4 million in same period in 2016. The decrease in cost of revenue compared to the same period in the prior year was due primarily to a decrease in costs for our Px563L product candidate under our government contracts related to planning and start-up activities for newly exercised option periods. Given the nature of the novel vaccine development process, these costs will fluctuate depending on stage of development.

Research and development expenses increased to $10.2 million in the three-month period ended June 30, 2017 compared to $7.6 million in same period in 2016. The increase in research and development expenses was primarily due to the increase in development activity of our product candidates, including PF708 and PF582, and the hiring of additional personnel dedicated to our research and development efforts.

Selling, general and administrative expenses were $4.3 million for each of the three-month periods ended June 30, 2017 and 2016.

Cash and cash equivalents as of June 30, 2017 was $59.9 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 for the Strategic National Stockpile; 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 and advancement of clinical trials and the types of future clinical trials for its product candidates, including PF708 and Px563L; 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 expectation for its strategic review of PF582; Pfenex's expectation that it will continue to demonstrate stability of Px563L and complete manufacturing of the clinical supply; and Pfenex's expectations with respect to the timing of future regulatory filings for its 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 period ended December 31, 2016 and in its other filings 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 June 30, 2017 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
(unaudited)

(in thousands, except per share data)	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016	Six Months Ended June 30, 2017	Six Months Ended June 30, 2016
Revenue	$ 3,029	$ 3,135	$ 5,847	$ 5,899
Cost of revenue	905	1,440	1,715	2,716
Gross profit	2,124	1,695	4,132	3,183
Operating expense				
Selling, general and administrative	4,288	4,321	9,974	8,530
Research and development	10,198	7,586	16,596	13,073
Total operating expense	14,486	11,907	26,570	21,603
Loss from operations	(12,362)	(10,212)	(22,438)	(18,420)
Other income, net	38	46	82	46
Net loss before income taxes	(12,324)	(10,166)	(22,356)	(18,374)
Income tax expense	—	—	—	(1)
Net loss	$ (12,324)	$ (10,166)	$ (22,356)	$ (18,375)
Net loss per common share basic and diluted	$ (0.52)	$ (0.43)	$ (0.95)	$ (0.79)
Weighted-average common shares used to compute basic and diluted net loss per share	23,486	23,379	23,462	23,366

PFENEX INC.
Consolidated Balance Sheets

	June 30, 2017 (unaudited)	December 31, 2016
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 59,876	$ 81,501
Restricted cash	200	—
Accounts and unbilled receivables, net	1,498	2,822
Income tax receivable	717	717
Other current assets	1,261	1,878
Total current assets	63,552	86,918
Property and equipment, net	6,319	5,246
Other long term assets	80	80
Intangible assets, net	5,036	5,301
Goodwill	5,577	5,577
Total assets	$ 80,564	$ 103,122

Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,783	$ 1,284
Accrued liabilities	10,274	9,412
Current portion of deferred revenue	5,248	6,516
Total current liabilities	17,305	17,212
Deferred revenue, less current portion	3,601	5,739
Other long-term liabilities	22	26
Total liabilities	20,928	22,977
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; 23,528,675 and 23,429,501 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	24	24
Additional paid-in capital	217,991	216,144
Accumulated deficit	(158,379)	(136,023)
Total stockholders' equity	59,636	80,145
Total liabilities and stockholders' equity	$ 80,564	$ 103,122

SOURCE Pfenex Inc.

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Additional assets available online: Photos (1)