Pfenex Reports Fourth Quarter and Full Year 2017 Results and Provides Business Update

SAN DIEGO, March 15, 2018 /PRNewswire/ -- Pfenex Inc. (NYSE American: PFNX) is a clinical-stage development and licensing biotechnology company focused on leveraging its Pfenex Expression Technology® to improve protein therapies for unmet patient needs. Using the patented Pfenex Expression Technology® platform, the Company has created an advanced pipeline of therapeutic equivalents, vaccines, biologics and biosimilars. Today Pfenex Inc. reported financial results for the fourth quarter and full year ended December 31, 2017 and provided a business update.

"Throughout 2017 we made considerable progress in advancing our lead product candidates as well as achieving substantial development milestones on our partnered programs," said Eef Schimmelpennink, chief executive officer of Pfenex. "I joined Pfenex in August as the company's chief executive officer because I saw a company with a unique and validated protein expression platform, a broad differentiated portfolio and a very talented team, but, was in need of change. From day-one the team and I focused on defining our priorities and setting a new course. We ended the year with a clear and concise strategic focus that leverages the strength of the Pfenex Expression Technology® platform through the development of our own key assets in our pipeline, while selectively collaborating with strong partners. Pfenex is at a transformational point in our development, and I look forward to leading the team and continuing to build Pfenex into an industry success."

Business Updates and 2017 Highlights

PF708 therapeutic equivalent to Forteo® (teriparatide). The Company completed the last patient visit in mid-February 2018 from its on-going PF708-301 trial which compares the effects of PF708 and Forteo in osteoporosis patients. The Company expects top-line immunogenicity data results in the second quarter of 2018. Pfenex believes that results from its PF708-301 trial, along with the bioequivalence findings from its PF708-101 trial in healthy subjects announced previously, should satisfy the clinical filing requirements for PF708. Pfenex expects to submit the new drug application (NDA) to the FDA in the third quarter of 2018, with a potential commercial launch possible in the US as early as the third quarter of 2019 upon expiration of the relevant patents and subject to receipt of US FDA marketing authorization.

Jazz Collaboration Agreement. In December 2017, Pfenex announced that under the amended collaboration agreement with Jazz Pharmaceuticals, Pfenex will be eligible to receive an additional $43.5 million in amendment fee and development milestone payments bringing the total value of payments and potential payments associated with the collaboration to $224.5 million. Upon signing the amended and restated agreement, Pfenex received a total of $18.5 million, consisting of an upfront payment of $5.0 million and a payment of $13.5 million for development achievement. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from those under the 2016 agreement. Finally, in the third quarter of 2017, we completed a process development milestone associated with this collaboration.

Px563L and RPA563. The development of the Company's novel anthrax vaccine candidates is funded through an advanced development contract with the Department of Health and Human Services through the Biomedical Advanced Research and Development Authority (BARDA) valued at up to approximately $143.5 million. In January of 2017, BARDA exercised additional phases of the development contract, allowing for the continuing development of both Px563L and RPA563. In the second quarter of 2017, Pfenex completed its long-term follow-up of the Phase 1 study subjects, and the results showed no change to the interim safety or immunogenicity results. In October 2017, Pfenex completed a meeting with the FDA in which the Agency provided guidance for the proposed clinical development and licensure plans for post-exposure prophylaxis indication. Over the course of 2017, the Company continued to collect favorable stability data for both products. Potential next milestones in 2018 are triggering of analytical and non-clinical animal study options leading to potential Phase 2 study in 2019, subject in each case to continued funding by BARDA.

Financial Highlights for the Fourth Quarter and Full Year 2017

Total Revenue increased to $17.9 million in the three-month period ended December 31, 2017 compared to $5.5 million in same period in 2016. The increase in the three month period was due primarily to development achievements related to the Jazz collaboration. Total revenue decreased to $28.8 million in the year ended December 31, 2017 compared to $60.2 million in 2016. The year over year decrease in revenue was primarily due to the termination of the development and license agreement with Pfizer in the third quarter of 2016, which accelerated the recognition of revenue that had been previously deferred. In addition, in 2016 Pfenex recognized revenue of $4.9 million attributable to amortization of a development and license fee. The decrease in revenue was partially offset by $21.5 million of revenue recognized in 2017 from Jazz for development

achievement and achievement of certain development milestones, development services and amortization of license fees.

Cost of revenue increased to $1.7 million in the three-month period ended December 31, 2017 compared to $1.3 million in same period in 2016. The change was due primarily to a net increase in costs for the Company's proprietary novel vaccine program Px563L, which is funded by BARDA. Cost of revenue decreased to $5.2 million in the year ended December 31, 2017 compared to $5.3 million in 2016. The change was primarily due to a net decrease of costs for the Company's proprietary novel vaccine program Px563L, which is funded by BARDA.

Research and development expenses decreased to $7.2 million in the three-month period ended December 31, 2017 compared to $10.7 million in same period in 2016. The decrease was primarily due to the Company's decision to pause the Company's development activities on certain product candidates. Research and development expenses decreased to $31.9 million in the year ended December 31, 2017 compared to $32.4 million in 2016. The decrease was primarily due to the Company's decision to pause the Company's development activities on certain product candidates. The decrease was partially offset by increased costs related to clinical trials for PF708, which began in the first quarter of 2017, and research and development expenses of hematology/oncology products related to the Company's collaboration with Jazz, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, as well as other biosimilar product candidates.

Selling, general and administration expenses decreased to $3.7 million in the three-month period ended December 31, 2017 compared to $4.4 million in same period in 2016. This decrease in costs was primarily due to the departure of the Company's former CFO during the fourth quarter of 2017. In addition, in the fourth quarter of 2016, Pfenex incurred costs associated with the Audit Committee's investigation. Selling, general and administration expenses increased to $17.7 million in the year ended December 31, 2017 compared to $17.3 million in 2016. The year over year increase was primarily due to costs incurred in connection with the separation of former officers.

Cash and cash equivalents as of December 31, 2017 was $57.7 million. Pfenex believes it has sufficient cash to meet the Company's anticipated cash needs for at least the next 12 months. The Company also believes it has sufficient cash resources to fund all necessary activities leading up to and including the submission of a new drug application (NDA) for PF708 to the FDA.

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 and the company in general, including future plans to advance, develop, manufacture and commercialize its product candidates; Pfenex's expectation to receive data from the PF708 clinical program in second quarter of 2018 and its expectation to submit an NDA in the third quarter of 2018, and the possibility of the potential commercial US launch of PF708 in the third quarter of 2019; Pfenex's expectations with respect to the sufficiency of its cash resources; 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 studies and the types of future clinical trials and studies for its product candidates, including PF708 and Px563L/RPA563; Pfenex's expectations regarding the sufficiency of its clinical trials to satisfy regulatory requirements; Pfenex's expectation for potential partnership opportunities for its product candidates; expectations with regard to future milestone and royalty payments from Pfenex's collaboration with Jazz Pharmaceuticals; Pfenex's expectations regarding potential payments from BARDA; Pfenex's expectation that it will potentially initiate a phase 2 study for Px563L/RPA563 in 2019; 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. 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, 2017 and in its other filings 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.

We are a clinical-stage development and licensing biotechnology company focused on leveraging our Pfenex Expression Technology® to improve protein therapies for unmet patient needs. Using the patented Pfenex Expression Technology platform, we have created an advanced pipeline of therapeutic equivalents, vaccines, biologics and biosimilars. Our lead product candidates are PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis, and our novel anthrax vaccine candidates, Px563L and RPA563, funded through an advanced development contract with the U.S. government. In addition, we are developing hematology/oncology products, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, in collaboration with Jazz Pharmaceuticals. Furthermore, our pipeline includes biosimilar candidates to Lucentis® and Neulasta®.

PFENEX INC.
Consolidated Statements of Operations

(in thousands, except per share data)	Three Months Ended December 31, 2017	Three Months Ended December 31, 2016	Twelve Months Ended December 31, 2017	Twelve Months Ended December 31, 2016
Revenue	$ 17,909	$ 5,471	$ 28,780	$ 60,194
Cost of revenue	1,675	1,312	5,156	5,313
Gross profit	16,234	4,159	23,624	54,881
Operating expense				
Selling, general and administrative	3,701	4,405	17,674	17,340
Research and development	7,217	10,655	31,925	32,418
Total operating expense	10,918	15,060	49,599	49,758
(Loss) income from operations	5,316	(10,901)	(25,975)	5,123
Other income, net	2	51	119	149
Net (loss) income before income taxes	5,318	(10,850)	(25,856)	5,272
Income tax benefit	172	210	172	209
Net (loss) income	$ 5,490	$ (10,640)	$ (25,684)	$ 5,481
Net (loss) income per common share				
Basic	$ 0.23	$ (0.45)	$ (1.09)	$ 0.23
Diluted	$ 0.23	$ (0.45)	$ (1.09)	$ 0.23

Weighted-average common shares used to compute net (loss) income per share				
Basic	23,548	23,424	23,503	23,389
Diluted	23,697	23,424	23,503	23,688

PFENEX INC.
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 57,664	$ 81,501
Restricted cash	200	—
Accounts and unbilled receivables, net	1,306	2,822
Income tax receivable	638	717
Other current assets	1,705	1,878
Total current assets	61,513	86,918
Property and equipment, net	7,397	5,246
Other long term assets	133	80
Intangible assets, net	4,771	5,301
Goodwill	5,577	5,577
Total assets	$ 79,391	$ 103,122
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,905	$ 1,284
Accrued liabilities	8,913	9,358
Current portion of deferred revenue	7,421	6,516
Current portion of capital lease obligations	228	54
Total current liabilities	18,467	17,212
Deferred revenue, less current portion	2,742	5,739
Capital lease obligations, less current portion	419	26
Total liabilities	21,628	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; 23,548,280 and 23,429,501 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	24	24
Additional paid-in capital	219,446	216,144
Accumulated deficit	(161,707)	(136,023)
Total stockholders' equity	57,763	80,145
Total liabilities and stockholders' equity	$ 79,391	$ 103,122

SOURCE Pfenex Inc.

For further information: Susan A. Knudson, Chief Financial Officer, (858) 352-4324, sknudson@pfenex.com