Pfenex Reports Third Quarter 2015 Results and Provides Business Update

SAN DIEGO, Nov. 13, 2015 /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, 2015 and provided a business update.

"Pfenex has made significant progress in advancing its portfolio of biosimilar product candidates in the third quarter," stated Bertrand C. Liang, chief executive officer of Pfenex. "Today we are pleased to provide an update on the Phase 1 trial for PF530, our Betaseron biosimilar candidate. The study enrolled 12 subjects who received an initial dose of either PF530 or reference product to assess pharmacokinetic (PK) and pharmacodynamic (PD) parameters. After a subsequent wash out period, subjects were crossed over to receive the other product. There were no statistically significant differences in PK and PD between the groups administered PF530 versus the reference product. While the study enrolled just 12 subjects and was therefore not powered for further statistical testing, this pilot PK/PD study has provided the necessary PK/PD variability information for PF530 further development. Following our discussions with FDA, we intend to pursue an abbreviated development path for PF530 consisting of a pivotal PK/PD study in healthy subjects and an immunogenicity trial in multiple sclerosis patients, pending the agency's review of additional bioanalytical data. Over the remainder of this year and into early next year, we will supplement our bioanalytical package and have additional discussions with FDA to refine the study design. We expect to initiate the clinical program in the second half of 2016."

Business Updates

- Pfenex initiated a Phase 1 trial of PF530, a biosimilar candidate to Betaseron, in the first quarter of 2015 and enrolled 12 healthy subjects. Based on the analysis of the trial PK and PD parameters, no statistical differences between PF530 compared to Betaferon were observed. The clinical program is expected to initiate in the second half of 2016.
- PF708, our peptide generic to Forteo, is expected to enter a bioequivalence study by the end of 2015.
- Pfenex is continuing to assist in the manufacturing technology transfer of PF582, our biosimilar candidate to Lucentis, to the manufacturing site of Hospira, Inc., a subsidiary of Pfizer, and we expect that the pivotal clinical comparator trial for PF582 trial will initiate in 2016.
- Pfenex expects to initiate the Phase 1 trial for its recombinant anthrax vaccine by the end of 2015.
- In August, Pfenex announced it had signed 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 Px563L, a 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.
- In September, Pfenex announced that Dennis M. Fenton, Ph.D. was appointed to the company's board of directors, deepening Pfenex's manufacturing and product development expertise. Dr. Fenton, an industry pioneer, has over three decades of experience in the biotechnology industry.

Financial Highlights for the Third Quarter

Total Revenue decreased by $2.3 million, or 27%, to $6.3 million in the nine month period ended September 30, 2015 compared to $8.6 million in same period in 2014. Revenue decreased by $0.7 million, or 27%, to $2.1 million in the three month period ended September 30, 2015 compared to $2.8 million in same period in 2014. The decreases in revenue for the periods presented were due to the stage of development of our Px563L product candidate under our government contracts and the decrease in activity related to our protein production service work, partially offset by an increase in license revenue. We expect revenue related to our protein production services to decline in the near-term as we shift our resources to developing our product pipeline. Given the nature of the novel vaccine development process, revenue will fluctuate depending on stage of development.

Cost of revenue decreased by approximately $3.1 million, or 52%, to $2.9 million in the nine month period ended September 30, 2015 compared to $6.0 million in same period in 2014. Cost of revenue decreased by approximately $0.9 million, or 57%, to $0.7 million in the three month period ended September 30, 2015 compared to $1.6 million in same period in 2014. The decreases in cost of revenue for the periods presented were due primarily to the stage of development of 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 $9.3 million, or 334%, to $12.1 million in the nine month period ended September 30, 2015 compared to $2.8 million in the same period in 2014.

Research and development expenses increased by approximately $4.4 million, or 354%, to $5.7 million in the three month period ended September 30, 2015 compared to $1.3 million in same period in 2014. The increase in research and development expenses during the periods presented 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. PF530 was removed from the Joint Development License Agreement ("JDLA") with Strides Arcolab in February 2015 and we initiated a Phase 1 trial for PF530 in March 2015. We expect research and development costs will increase going forward as we independently advance PF530 as a wholly-owned product candidate. Additionally, we expect research and development expenses to increase as we advance our other lead candidates and pipeline product candidates. For example, under our agreement with Pfizer, we will share the confirmatory clinical study costs for PF582 with our share capped at $20 million, $10 million of which will be setoff as a credit against royalties payable to us unless the collaboration agreement is terminated prior to such setoff. We will also share the costs of seeking regulatory approval of PF582 and a certain portion of other costs that are related to PF582, and that may begin after any filings for regulatory approval of PF582 would be made.

Selling, general and administrative expenses increased by $4.9 million, or 82%, to $10.9 million in the nine month period ended September 30, 2015 compared to $6.0 million in the same period in 2014. Selling, general and administrative expenses increased by $0.8 million, or 34%, to $3.3 million in the three month period ended September 30, 2015 compared to $2.5 million in the same period in 2014. The increases in selling, general and administrative expenses during the periods presented were due to an increase in activities associated with operating as a publicly-traded company. We expect general and administrative costs to increase for activities associated with operating as a publicly-traded company, including maintaining compliance with exchange listing and Securities and Exchange Commission requirements. These increases will likely include legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations. These increases will also likely include the hiring of additional personnel. In addition, we intend to continue to incur increased internal and external business development costs to support our various product development efforts, which can vary from period to period.

Cash and cash equivalents as of September 30, 2015 was $115.9 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 develop, manufacture and commercialize its product candidates and the potential to receive future payments under its development agreements; Pfenex's expectations regarding the timing of the release of additional data and results for its product candidates and the timing of the initiation of additional studies for its product candidates; and Pfenex's future projections related to increases in expenses and reductions in protein production revenue. 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; challenges related to commencement, patient enrollment, completion, and analysis of clinical trials; difficulties in achieving and demonstrating similarity or sameness 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, 2014 and in Pfenex's subsequent reports on Form 10-Q and Form 8-K, filed with the Securities and Exchange Commission, including Pfenex's Quarterly Report on Form 10-Q for the period ended September 30, 2015 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. We encourage our investors and others to 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, generics and next generation biologics.

PF530-101: Study Design
(see infographic)

PF530-101: Summary of Key Findings
(see infographic)

PFENEX INC.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	**2015**	**2014**	**2015**	**2014**
Revenue	$ 2,057	$ 2,801	$ 6,322	$ 8,625
Cost of revenue	682	1,579	2,911	6,031
Gross profit	1,375	1,222	3,411	2,594
Operating expense				
Selling, general and administrative	3,276	2,447	10,855	5,966
Research and development	5,679	1,251	12,098	2,789
Total operating expense	8,955	3,698	22,953	8,755
Loss from operations	(7,580)	(2,476)	(19,542)	(6,161)
Other income (expense), net	(9)	(19)	38	(58)
Net loss before income taxes	(7,589)	(2,495)	(19,504)	(6,219)
Income tax expense	(1)	—	(41)	(1)
Net loss	$ (7,590)	$ (2,495)	$ (19,545)	$ (6,220)
Net loss per common share basic and diluted	$ (0.33)	$ (0.16)	$ (0.89)	$ (1.06)
Weighted-average common shares used to compute basic and diluted net loss per share	23,215	15,319	22,066	5,849

PFENEX INC.
Condensed Consolidated Balance Sheets

	September 30,

	2015 (unaudited)	December 31, 2014
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 115,924	$ 45,722
Accounts and unbilled receivables, net	1,097	1,584
Inventories	25	23
Income tax receivable	281	402
Deferred income taxes	3,281	3,281
Other current assets	1,976	1,753
Total current assets	122,584	52,765
Restricted cash	3,958	3,955
Income tax receivable	918	—
Property and equipment, net	3,076	2,310
Other long term assets	53	53
Intangible assets, net	5,965	6,363
Goodwill	5,577	5,577
Total assets	$ 142,131	$ 71,023
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,402	$ 1,129
Accrued liabilities	5,331	2,633
Current portion of deferred revenue	3,882	201
Line of credit obligation	—	3,813
Total current liabilities	10,615	7,776
Deferred revenue, less current portion	45,173	—
Deferred tax liability	3,281	3,281
Line of credit obligation	3,813	—
Other long-term liabilities	57	92
Total liabilities	62,939	11,149
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; 23,254,132 and 20,405,066 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	24	21
Additional paid-in capital	212,001	173,141
Accumulated deficit	(132,833)	(113,288)
Total stockholders' equity	79,192	59,874
Total liabilities and stockholders' equity	$ 142,131	$ 71,023

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Additional assets available online: Photos (3)