



## **Pfenex Reports Third Quarter Results and Provides Business Update**

*On track to submit the NDA for PF708 to the FDA in fourth quarter of 2018*

**SAN DIEGO, November 7, 2018** —Pfenex Inc. (NYSE American: PFINX) is a clinical-stage development and licensing biotechnology company focused on leveraging its *Pfēnex* Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented *Pfēnex* 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 third quarter ended September 30, 2018 and provided a business update.

“The Pfenex team continues to be very active across all of our key assets – our Forteo® therapeutic equivalent PF708, PF743 and PF745 which we develop in partnership with Jazz, our anthrax vaccine programs that are funded by BARDA, and our CRM197 business for which we have royalty bearing partnerships with, amongst others, Merck and Serum Institute of India,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex. “PF708 continues to be the major focus of the Pfenex team, as we are in the final stages of completing our 505(b)(2) New Drug Application and are in early stages to prepare for its commercialization in the U.S. with our partner Alvogen. Based on our July pre-NDA meeting discussions with the FDA, we believe we have completed all clinical and non-clinical studies necessary to submit an NDA for PF708 under the 505(b)(2) regulatory pathway in the U.S., referencing Forteo as the Reference Listed Drug. We believe we are on track to submit the NDA for PF708 to the FDA in the fourth quarter of 2018, which, if approved, could allow for a potential commercial launch as early as the fourth quarter of 2019 in the U.S., subject to FDA acceptance, approval and other factors.”

“We are advancing our clinical pipeline, close to filing our first NDA submission, increasing our focus on the approval and commercialization of our existing pipeline, and exploring new pipeline and technology opportunities. As a result, we continue to make progress towards several upcoming milestones that put us on a path towards transforming Pfenex from a development company to a commercial stage biotech company,” concluded Schimmelpennink.

### **Business Review and Update**

#### **PF708 therapeutic equivalent to Forteo (teriparatide)**

Pfenex is in the process of finalizing the PF708 new drug application (NDA) for submission to the U.S. Food and Drug Administration (FDA). This follows a constructive pre-NDA meeting the Company had with the FDA in July 2018 which suggested that no additional clinical, non-clinical or toxicological studies were needed. The NDA will include the positive Phase III clinical data announced earlier this year, which showed comparable overall profiles between PF708 and Forteo after 24 weeks of daily injection in osteoporosis patients. In addition, the NDA will include data from the PF708-101 study, a single-dose, 2-way crossover study comparing the pharmacokinetics of PF708 and Forteo in healthy subjects. Regarding the manufacturing of PF708, the FDA agreed with Pfenex’s plan to complete process validation after the NDA submission and prior to marketing. However, the FDA requested that the

Company include in the NDA release batch data from a batch manufactured in the commercial facility. Pfenex has completed both the manufacturing and analyzing of this batch data, which will be included in the NDA.

The Company believes the studies expected to be required for FDA approval for PF708 have been completed and will meet the requirements for demonstrating clinical safety, effectiveness and bioequivalence under the 505(b)(2) regulatory pathway in the U.S., referencing Forteo as the Reference Listed Drug. The Company believes that it will submit the NDA to the FDA in the fourth quarter of 2018, with a potential commercial launch in the United States as early as the fourth quarter of 2019, subject to FDA acceptance, approval, and other factors.

### **Jazz Collaboration Agreement**

Through its collaboration with Jazz Pharmaceuticals, Pfenex is developing both PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology. Pfenex continues to make good progress on both products and believes its success on these programs further demonstrates the unique capabilities of Pfenex's platform technology.

Through September 30, 2018, Pfenex has received approximately \$36 million through this agreement. Under the agreement, Pfenex is eligible to receive an aggregate total of \$224.5 million in development and sales milestone fees, of which \$188.5 million is still eligible to be received. Of this \$188.5M, \$30M are development milestones, \$34M are regulatory milestones and \$125M are sales milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration.

### **Px563L and RPA563**

The development of Pfenex'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 \$145.2 million. In the second half of 2018, BARDA approved additional funding for analytical work and a non-clinical animal study. The next milestone under the contract could lead to a potential Phase 2 study in 2019, subject to continued funding by BARDA. The Company believes the successful completion of the Phase 2 study and activities under our development contract with BARDA could lead to a procurement contract for supply of Px563L or RPA563 to the Strategic National Stockpile.

### **CRM197**

CRM197 is a non-toxic mutant of diphtheria toxin. It is a well characterized protein and functions as a carrier for polysaccharides and haptens making them immunogenic. CRM197 is currently being used or planned to be used by vaccine development focused pharmaceutical partners, including Merck and the Serum Institute of India, among others, in multiple late-stage clinical trials for such diseases as pneumococcal and meningitis bacterial infections.

In June, Merck announced it initiated its first Phase 3 clinical study of (V114), an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease, using CRM197. Two additional Phase 3 studies for V114 were started in July 2018. Pfenex is eligible to receive annual fees, milestone payments and a tiered royalty based on net sales for all products developed by Merck that use the Pfenex Expression Technology platform.

Pfenex also has a partnership with Serum Institute of India (SII), the world's largest vaccine manufacturer, producing more than 1.3 billion doses in 2017 and distributed to over 170 countries. As part of the partnership with Pfenex, SII built a dedicated facility to produce Pfenex's CRM197 and use it in two conjugate vaccines that are in Phase 3 development. Pfenex is eligible to receive milestone and royalty payments.

Pfenex's other partnerships for CRM197 are in various stages and we continue to sell non-GMP and cGMP grade CRM197 to vaccine development-focused pharma partners.

### **Financial Highlights for the Third Quarter 2018**

**Total Revenue** decreased by \$1.5 million, or 29%, to \$3.6 million in the three months ended September 30, 2018 compared to \$5.0 million in the same period in 2017. The decrease in revenue for the quarter was due to achievement of a milestone related to the Jazz agreement in the third quarter of 2017. There were no similar milestones achieved in the three months ended September 30, 2018. In addition, there was less activity related to the Company's Px563L product candidate under a government contract with BARDA in the third quarter of 2018 compared to the prior year.

**Cost of revenue** decreased by \$0.3 million, or 16%, in the three months ended September 30, 2018 compared to the same period in 2017. This resulted primarily from a decrease in activity related to the Company's government contract with BARDA.

**Research and development expenses** increased by \$0.9 million, or 12%, to \$9.0 million in the three months ended September 30, 2018 compared to \$8.1 million in the same period in 2017. The increase was primarily due to increased activity for the Company's product candidate PF708 to satisfy the clinical and manufacturing filing requirements for an NDA, which the Company expects to submit to the FDA in the fourth quarter of 2018.

**Selling, general and administration expenses** decreased by \$0.2 million, or 4%, to \$3.8 million in the three months ended September 30, 2018 compared to \$4.0 million in the same period in 2017.

**Cash and cash equivalents** as of September 30, 2018, the Company had \$67.8 million in cash and cash equivalents and \$0.2 million in restricted cash as bank collateral for its commercial card program. The Company believes that its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet its anticipated cash needs for at least the next 12 months, including all necessary activities leading up to and including potential commercial launch of PF708 in the United States as early as the fourth quarter of 2019, subject to FDA acceptance, approval of the NDA and other factors.

### **Conference Call Information**

The Pfenex management will host a conference call and webcast today at 4:30 PM Eastern Time. Participants may access the call by dialing 866-376-8058 (Domestic) or 412-542-4131 (International). The call will also be webcast and can be accessed from the Investors section of the Company's website at [www.pfenex.com](http://www.pfenex.com) or <https://www.webcaster4.com/Webcast/Page/1061/28017>

A replay of the call will also be available through November 14<sup>th</sup>. Participants may access the replay of the call by dialing 877-344-7529 (Domestic) or 412-317-0088 (International) and providing the conference ID number: 10125733.

## 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 future 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 submit an NDA for PF708 to the FDA in the fourth quarter of 2018, and the possibility of the potential commercial US launch of PF708 as early as the fourth quarter of 2019; Pfenex's expectations with respect to the sufficiency of its cash resources, including all necessary activities leading up to and including potential commercial launch of PF708 in the United States in the fourth quarter of 2019, subject to FDA acceptance, approval of the NDA and other factors; 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 Px563L and RPA563; Pfenex's expectations regarding the sufficiency of its clinical trials to satisfy regulatory requirements, including that all clinical and non-clinical studies expected to be required for FDA approval for PF708 have been completed and will meet the requirements for demonstrating clinical safety, effectiveness and bioequivalence under the 505(b)(2) regulatory pathway in the U.S., referencing Forteo as the Reference Listed Drug; Pfenex's expectations with regard to future milestones, royalty payments, and reimbursements from Pfenex's collaborations with Jazz Pharmaceuticals, and its other collaboration partners; Pfenex's expectations regarding potential future milestones, clinical trials, and procurement contracts with respect to Px563L and RPA563; Pfenex's expectation with respect to its agreement with Merck and SII, including its potential to receive annual fees, milestone payments and future royalties; Pfenex's expectation that it will potentially initiate a phase 2 study for Px563L and RPA563 in 2019; and Pfenex's belief in its ability to explore new pipeline products and technology opportunities.. 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; litigation and other proceedings regarding intellectual property rights, including potential future litigation by Eli Lilly and Company with respect to PF708; 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 Quarterly Report on Form 10-Q for the period ended September 30, 2018 to be filed with the Securities and Exchange Commission 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 *Pfēnex* Expression Technology<sup>®</sup> to develop and improve protein therapies for unmet patient needs. Using the patented *Pfēnex* Expression Technology platform, we have created an advanced pipeline of therapeutic equivalents, vaccines, biologics and biosimilars. The Company also uses its Pfenex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines. Our lead product candidates are PF708, a therapeutic equivalent candidate to Forteo<sup>®</sup> (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<sup>®</sup> and Neulasta<sup>®</sup>.

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**PFENEX INC.**  
**Consolidated Statements of Operations**  
**(unaudited)**

<i>(in thousands, except per share data)</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Revenue</b>	\$ 3,570	\$ 5,024	\$ 11,506	\$ 10,871
Cost of revenue	1,479	1,766	3,923	3,481
Gross profit	<u>2,091</u>	<u>3,258</u>	<u>7,583</u>	<u>7,390</u>
<b>Operating expense</b>				
Research and development	9,045	8,112	28,590	24,708
Selling, general and administrative	3,823	3,999	11,920	13,973
Total operating expense	<u>12,868</u>	<u>12,111</u>	<u>40,510</u>	<u>38,681</u>
Loss from operations	(10,777)	(8,853)	(32,927)	(31,291)
Other income, net	<u>115</u>	<u>35</u>	<u>157</u>	<u>117</u>
Net loss	<u>\$ (10,662)</u>	<u>\$ (8,818)</u>	<u>\$ (32,770)</u>	<u>\$ (31,174)</u>
Net loss per common share, basic and diluted	<u>\$ (0.34)</u>	<u>\$ (0.37)</u>	<u>\$ (1.20)</u>	<u>\$ (1.33)</u>
Weighted-average common shares used in calculating basic and diluted net loss per share	<u>31,437</u>	<u>23,539</u>	<u>27,288</u>	<u>23,488</u>

**PFENEX INC.**  
**Consolidated Balance Sheets**

	September 30, 2018 (unaudited)	December 31, 2017
(in thousands)		
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 67,825	\$ 57,664
Restricted cash	200	200
Accounts and unbilled receivables, net	1,745	1,306
Income tax receivable	206	638
Other current assets	1,972	1,705
Total current assets	71,948	61,513
Property and equipment, net	7,455	7,397
Other long-term assets	133	133
Intangible assets, net	4,381	4,771
Goodwill	5,577	5,577
Total assets	\$ 89,494	\$ 79,391
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 1,360	\$ 1,905
Accrued liabilities	10,585	8,913
Current portion of deferred revenue	7,141	7,421
Current portion of capital lease obligations	317	228
Total current liabilities	19,403	18,467
Deferred revenue, less current portion	2,500	2,742
Capital lease obligations, less current portion	272	419
Total liabilities	22,175	21,628
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, par value \$0.001, 200,000,000 shares authorized; 31,460,719 and 23,548,280 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	32	24
Additional paid-in capital	261,764	219,446
Accumulated deficit	(194,477)	(161,707)
Total stockholders' equity	67,319	57,763
Total liabilities and stockholders' equity	\$ 89,494	\$ 79,391