



## **Pfenex Reports Fourth Quarter and Full Year 2018 Results and Provides Business Update**

*We believe PF708 is on track to enter the U.S. market as early as Q4 2019, subject to FDA approval and other factors*

*Several significant milestones across the Company's pipeline are expected in 2019*

**SAN DIEGO, March 11, 2019** —Pfenex Inc. (NYSE American: PFNX) is a clinical-stage development and licensing biotechnology company focused on leveraging its *Pfēnex* Expression Technology<sup>®</sup> 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 fourth quarter and year ended December 31, 2018 and provided a business update.

“We are excited about the opportunities before us in 2019 as we look to advance our key programs and expand our pipeline. This year we have multiple key milestones across our portfolio that hold the potential to transform Pfenex into a commercial stage biotech company and create significant value for our stockholders,” said Eef Schimmelpennink, Chief Executive Officer of Pfenex. “With the FDA acceptance of our 505(b)(2) New Drug Application for substantive review of PF708 and setting a PDUFA date of October 7, 2019, we are working with our development and licensing partner, Alvogen, to prepare for the commercialization of PF708 in the U.S. We believe that PF708 is on track for a potential launch in the U.S. market as early as the fourth quarter of 2019, subject to FDA approval and other factors. Building on this momentum, we have expanded our collaboration with Alvogen for PF708 to include Europe, MENA and ROW, which positions us to leverage Alvogen’s global supply chain and market access experience to maximize potential commercial success in these markets as well.”

“We have four key programs and partnerships in or nearing clinical studies or in regulatory review including PF708, our Jazz partnership, our anthrax vaccine candidates, and our CRM197 partnerships with Merck and Serum Institute of India. To ensure success we remain fully focused on the approval and commercialization of these core value drivers. In addition, we are exploring new pipeline and partnership opportunities that leverage our *Pfēnex* Expression Technology. This is an exciting time for the Company and our stockholders, and we look forward to a fruitful 2019,” concluded Schimmelpennink.

### **Business Review and Update**

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

The new drug application (NDA) for PF708 was accepted by the U.S. Food and Drug Administration (FDA) for substantive review with a PDUFA date of October 7, 2019. The Company believes that this

puts PF708 on track for a potential commercial launch in the United States as early as the fourth quarter of 2019, subject to FDA approval and other factors.

The Company's development and licensing partner for PF708, Alvogen, has supported Pfenex throughout the NDA process. Assuming the receipt of FDA approval, Alvogen will assume responsibilities to continue to develop, manufacture and commercialize PF708 in the United States at its cost and expense. Currently, Pfenex and Alvogen are working together on implementing initial stages of the commercialization strategy for PF708 in preparation for a U.S. launch following the FDA's decision.

Pfenex believes that the data collected for PF708 and a positive regulatory decision by the FDA could be leveraged in other countries and support the global commercialization of PF708. As such, the Company will utilize Alvogen's established international presence to centralize the development, IP, regulatory, supply chain and other commercialization activities for PF708, by expanding the collaboration agreement with Alvogen to include the EU, certain countries in Middle East and North Africa (MENA), and to the ROW territories (*i.e.* all countries outside of the EU, US and MENA, other than Mainland China, Hong Kong, Singapore, Malaysia and Thailand). Subject to applicable regulatory approvals, PF708 will be commercialized in Europe and Switzerland by Theramex, a leading global specialty pharmaceutical company dedicated to Women's Health, in MENA by SAJA, a Tamer Group company, and in ROW by Alvogen's current and/or future commercialization partners. Under the terms of the agreements, Alvogen will be responsible for the local activities through Theramex, SAJA and its other commercialization partners and for overseeing any clinical development, regulatory, litigation, commercial manufacturing and commercialization. Pfenex will be eligible to receive additional upfront and milestone payments of \$2.5 million for EU and MENA and additional potential milestone payments for ROW. For EU, MENA and ROW, Pfenex may also be eligible to receive a gross profit split of up to 60% on product sales, depending on geography and cost of goods sold. China NT Pharma Group Company Limited has an exclusive license to commercialize PF708 in mainland China, Hong Kong, Singapore, Malaysia and Thailand, as well as a non-exclusive license to conduct development activities in such territories with respect to PF708.

### **Jazz Collaboration Agreement**

Through its collaboration with Jazz Pharmaceuticals, Pfenex has completed the process development of PF743, a recombinant crisantaspase, and the development is ongoing for PF745, a recombinant crisantaspase with half-life extension technology. Pfenex has continued to successfully advance both products and believes its success on these programs further demonstrates the unique capabilities of Pfenex's platform technology.

Through December 31, 2018, Pfenex has received approximately \$36 million under the Jazz agreement. Under the Jazz 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 \$188.5 million, \$29.5 million are development milestones, \$34 million are regulatory milestones and \$125 million 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 December 2018, the Company held a Type C meeting with the FDA to discuss Px563L's potency release method. An In Process Review (IPR) meeting was held in January 2019 with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Milestone Decision Authority (MDA). The Company believes these two meetings are helping create a pathway which could potentially trigger the next option periods for GMP manufacturing and preparation for a Phase 1b/2 study in late 2019, subject in each case to continued funding by BARDA.

## **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 by our vaccine development focused pharmaceutical partners, including Merck and the Serum Institute of India Private Ltd (SIPL), in multiple late-stage clinical trials for such diseases as pneumococcal and meningitis bacterial infections.

During mid-2018, Merck announced that it had initiated multiple Phase 3 clinical studies of PCV-15 (V114), an investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease, using CRM197. In January of 2019, Merck received Breakthrough Therapy Designation from the FDA for the prevention of invasive pneumococcal disease (IPD) caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age. 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 CRM197 produced via the Pfenex Expression Technology platform.

Pfenex also has a partnership with SIPL the world's largest vaccine manufacturer, producing more than 1.3 billion doses in 2017 and distributed to over 170 countries. SIPL recently announced that the SIPL vaccine, Pneumosil®, recently completed a Phase 3 program in which all primary and secondary objectives were met and received an export license for Pneumosil. The commercial market will include India and the developing world, covering over 71% IPD causing serotypes, and targeting the Indian UIP and Asian, African and other low- and middle-income countries under the Gavi Advanced Market Commitment (AMC). Pfenex is eligible to receive a tiered royalty based upon net sales by SIPL.

## **Financial Highlights for the Fourth Quarter and Full Year 2018**

**Total Revenue** decreased by \$14.5 million, or 81%, to \$3.4 million in the three months ended December 31, 2018 compared to \$17.9 million in the same period in 2017. Total revenue in the year ended December 31, 2018 decreased by \$13.9 million, or 48%, to \$14.9 million compared to \$28.8 million in 2017. The decreases in revenue were primarily due to significant development achievements and milestones related to the Jazz collaboration that occurred in the fourth quarter of 2017.

**Cost of revenue** decreased by \$0.6 million, or 34%, to \$1.1 million in the three months ended December 31, 2018 compared to \$1.7 million in the same period in 2017. Cost of revenue decreased by \$0.2 million, or 3%, to \$5.0 million in 2018 compared to cost of revenue of \$5.2 million in 2017. The changes were primarily due to decreased activity related to the Company's government contracts.

**Research and development expenses** decreased by \$1.9 million, or 27%, to \$5.3 million in the three months ended December 31, 2018 compared to \$7.2 million in the same period in 2017. The decrease resulted from recognition of support payments from Alvogen related to PF708, which offset expenses. Research and development increased by \$2.0 million, or 6%, to \$33.9 million in 2018 compared to research and development of \$31.9 million in 2017. The increase was primarily due to increased activity for PF708 to satisfy the clinical and manufacturing filing requirements for the NDA, which the Company submitted to the FDA in December of 2018.

**Selling, general and administration expenses** increased by \$0.2 million, or 6%, to \$3.9 million in the three months ended December 31, 2018, compared to \$3.7 million in the same period in 2017. Selling, general and administration decreased by \$1.9 million or 10% to \$15.8 million in 2018 compared to \$17.7 million in 2017. The decrease was primarily due to higher expenditures related to legal and the separation of former officers in the first half of 2017.

**Cash and cash equivalents** As of December 31, 2018, the Company had \$56.2 million in cash and cash equivalents. The Company believes that its existing cash and cash equivalents will be sufficient to meet its anticipated cash needs for at least the next 12 months.

### **Conference Call Information**

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/1061/29295>

A replay of the call will also be available through March 18<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: 10128639.

### **About Pfenex Inc.**

We are a clinical-stage development and licensing biotechnology company focused on leveraging our Pfenex Expression Technology<sup>®</sup> to develop and 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. 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

### **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; 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; 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 that several significant milestones across the Company's pipeline will occur in 2019;*

*Pfenex's belief that it has the potential to transform into a commercial stage biotech company and create significant value for its stockholders; Pfenex's belief that the data collected for PF708 and a positive regulatory decision by the FDA could be leveraged in other countries and support the global commercialization of PF708; Pfenex's expectations with regard to future milestones, royalty payments, and reimbursements from Pfenex's collaborations with Jazz Pharmaceuticals, Alvogen, 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 SIIPL, including its potential to receive annual fees, milestone payments and future royalties; Pfenex's expectation that it could potentially help to trigger the option periods for GMP manufacturing and preparation for a Phase 1b/2 study in late 2019 for Px563L and RPA563 under the BARDA contract; and Pfenex's belief in its ability to advance key programs in Pfenex's pipeline and expand Pfenex's pipeline in 2019. 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 Annual Report on Form 10-K for the year ended December 31, 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.

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**PFENEX INC.**  
**Consolidated Statements of Operations**

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
<i>(in thousands, except per share data)</i>	2018	2017	2018	2017
<b>Revenue</b> .....	\$ 3,351	\$ 17,909	\$ 14,857	\$ 28,780
Cost of revenue.....	<u>1,099</u>	<u>1,675</u>	<u>5,022</u>	<u>5,156</u>
Gross profit.....	<u>2,252</u>	<u>16,234</u>	<u>9,835</u>	<u>23,624</u>
<b>Operating expense</b>				
Selling, general and administrative.....	3,912	3,701	15,832	17,674
Research and development.....	<u>5,264</u>	<u>7,217</u>	<u>33,854</u>	<u>31,925</u>
Total operating expense.....	<u>9,176</u>	<u>10,918</u>	<u>49,686</u>	<u>49,599</u>
(Loss) income from operations.....	(6,924)	5,316	(39,851)	(25,975)
Other income, net.....	<u>101</u>	<u>2</u>	<u>258</u>	<u>119</u>
Net (loss) income before income taxes.....	(6,823)	5,318	(39,593)	(25,856)
Income tax benefit.....	<u>-</u>	<u>172</u>	<u>-</u>	<u>172</u>
Net (loss) income.....	<u>\$ (6,823)</u>	<u>\$ 5,490</u>	<u>\$ (39,593)</u>	<u>\$ (25,684)</u>
Net (loss) income per common share				
Basic.....	<u>\$ (0.22)</u>	<u>\$ 0.23</u>	<u>\$ (1.40)</u>	<u>\$ (1.09)</u>
Diluted.....	<u>\$ (0.22)</u>	<u>\$ 0.23</u>	<u>\$ (1.40)</u>	<u>\$ (1.09)</u>
Weighted-average common shares used to compute net (loss) income per share				
Basic.....	<u>31,461</u>	<u>23,548</u>	<u>28,340</u>	<u>23,503</u>
Diluted.....	<u>31,461</u>	<u>23,697</u>	<u>28,340</u>	<u>23,503</u>

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

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
	<i>(in thousands)</i>	
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 56,220	\$ 57,664
Restricted cash	200	200
Accounts and unbilled receivables, net	5,171	1,306
Income tax receivable	207	638
Other current assets	<u>1,851</u>	<u>1,705</u>
Total current assets	63,649	61,513
Property and equipment, net	7,671	7,397
Other long-term assets	133	133
Intangible assets, net	4,248	4,771
Goodwill	<u>5,577</u>	<u>5,577</u>
Total assets	\$ <u>81,278</u>	\$ <u>79,391</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 2,005	\$ 1,905
Accrued liabilities	9,812	8,913
Current portion of deferred revenue	5,317	7,421
Current portion of capital lease obligations	<u>316</u>	<u>228</u>
Total current liabilities	17,450	18,467
Deferred revenue, less current portion	2,500	2,742
Capital lease obligations, less current portion	<u>191</u>	<u>419</u>
Total liabilities	20,141	21,628
Commitments and contingencies		
Stockholders' equity		
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 at December 31, 2018 and 2017, respectively, 31,467,580 and 23,548,280 shares issued and outstanding at December 31, 2018 and 2017, respectively	32	24
Additional paid-in capital	262,405	219,446
Accumulated deficit	<u>(201,300)</u>	<u>(161,707)</u>
Total stockholders' equity	<u>61,137</u>	<u>57,763</u>
Total liabilities and stockholders' equity	\$ <u>81,278</u>	\$ <u>79,391</u>