Pfenex Reports First Quarter 2019 Results and Provides Business Update

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

SAN DIEGO, May 9, 2019 —Pfenex Inc. (NYSE American: PFNX) is a clinical-stage development and licensing biotechnology company focused on leveraging its *Pf*ēnex Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented *Pf*ēnex Expression Technology platform, Pfenex has created an advanced pipeline of potential therapeutic equivalents, novel biologics, vaccine and vaccine components, and biosimilars. Today Pfenex Inc. reported financial results for the first quarter ended March 31, 2019 and provided a business update.

"We are excited to report that during the first quarter of 2019 our lead program, PF708, continued to advance along our projected timeline. Importantly, it has the potential to change Pfenex from a clinical stage biotech company to a company with its first commercial product. Our PDUFA date of October 7, 2019, combined with Lilly's decision not to pursue a lawsuit on our paragraph IV certification, as well as our progress on commercial initiatives all support a potential launch as early as the fourth quarter of 2019, subject to FDA approval and other factors. We believe the market potential for PF708 could be significant as a potential cost-efficient alternative to Forteo, which had $1.6 billion in global sales in 2018," said Eef Schimmelpennink, Chief Executive Officer of Pfenex.

"Beyond PF708, we are also progressing with our Jazz partnership and our CRM197 partnerships with Merck and Serum Institute of India, each of which are closing in on milestone clinical studies or regulatory decisions. Just like PF708, these programs were developed using our *Pf*ēnex Expression Technology platform. As PF708 moves toward potential commercial launch, research and development capacity has started to become available, which we are leveraging toward new pipeline and partnership opportunities. To lead this expansion of our research and development efforts, we recently appointed Dr. Martin Brenner as Chief Scientific Officer. He brings decades of experience identifying new therapies at some of the world's leading pharmaceutical companies. This is an exciting time for Pfenex, as we harness near- and long-term opportunities to drive value for our stockholders," concluded Schimmelpennink.

Business Review and Update

PF708 therapeutic equivalent to Forteo (teriparatide)

PF708 is being developed as a therapeutic equivalent candidate to Forteo, which is approved and marketed by Eli Lilly & Co. (Lilly) for the treatment of osteoporosis in certain patients with a high risk of fracture and achieved $1.6 billion in global product sales in 2018.

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. Pfenex 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. Pfenex's development and licensing partner for PF708, Alvogen, has assumed responsibility to manufacture and commercialize PF708 in the United States,

assuming FDA approval, at Alvogen's own cost and expense. 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 PDUFA date.

In February 2019, Pfenex and Alvogen announced expanding their collaboration to develop and commercialize PF708 to the EU, Middle East and North Africa (MENA) and the ROW territories (excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). This collaboration leverages Alvogen's established international experience and expertise in regulatory and supply chain activities, as well as its established network of specialty marketing and sales pharmaceutical companies in these regions. 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. 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 Alvogen's gross profit derived from product sales, depending on geography and cost of goods sold.

In April 2019, Pfenex announced the expiration of the 45-day period for Lilly to file a lawsuit under the Hatch-Waxman Act and stay the approval of PF708 for 30 months. Because Lilly did not file a lawsuit within this time period, there will be no 30-month litigation stay delaying approval of PF708, and if approved by the FDA, Pfenex will be able to engage in the commercial manufacture, use, or sale of PF708.

Jazz Collaboration Agreement

Through its collaboration with Jazz Pharmaceuticals, Pfenex has completed the process development of PF743, a recombinant crisantaspase, while the development is ongoing for PF745, a recombinant crisantaspase with half-life extension technology. Pfenex expects to be eligible to achieve certain development milestones under the collaboration agreement in the near term. Overall, Pfenex has made good progress on both products and believes its success on these programs further demonstrates the unique capabilities of Pfenex's platform technology.

Through March 31, 2019, Pfenex has received approximately $36 million under the Jazz agreement. Under the agreement, Pfenex is eligible to receive an aggregate total of $224.5 million in development, regulatory 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, $34.0 million are regulatory milestones and $125.0 million are sales milestones. Pfenex may also be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration.

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 Pfenex's vaccine development focused pharmaceutical partners, Merck and the Serum Institute of India Private Ltd (SIIPL) for such diseases as pneumococcal and meningitis bacterial infections. Merck is currently using CRM197 in multiple Phase 3 studies of PVC-15 (V114), its investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. SIIPL is using CRM197 in its pneumococcal vaccine, Pneumosil, which recently completed a successful Phase 3 program and as of January 2019 is in the World Health Organization (WHO) pre-qualification marketing process.

Pfenex is eligible to receive tiered royalties based upon net sales by both Merck and SIIPL. Pfenex also has other non-disclosed partnerships in various stages of development and continues to sell non-GMP and cGMP grade CRM197 to vaccine development-focused pharma partners.

Financial Highlights for the First Quarter 2019

Total Revenue increased by $6.6 million, or 177%, to $10.4 million in the three-month period ended March 31, 2019, compared to $3.7 million in the same period in 2018. The increase in revenue was primarily due to a milestone payment from Alvogen and recognition of deferred revenue from NT Pharma upon FDA acceptance of the NDA for PF708, and increases in sales of Pfenex's CRM197 product, partially offset by a decrease in activity related to its Px563L product candidate under government contract.

Cost of revenue increased by approximately $0.1 million, or 3%, to $1.6 million in the three-month period ended March 31, 2019, compared to $1.5 million in the same period in 2018. The increase was primarily due to greater sales of Pfenex's CRM197 product, offset by lower costs for its Px563L product candidate under its government contract.

Research and development expenses decreased by approximately $0.9 million, or 10%, to $7.9 million in the three-month period ended March 31, 2019, compared to $8.8 million in same period in 2018. This was primarily due to timing of expenses related to Pfenex's lead product candidate PF708. Significant activity occurred leading up to submission of the NDA to the FDA, which occurred in December 2018.

Selling, general and administration expenses increased by $0.1 million, or 3%, to $4.6 million in the three-month period ended March 31, 2019, compared to $4.5 million in the same period in 2018.

Cash and cash equivalents As of March 31, 2019, Pfenex had $45.8 million in cash and cash equivalents. Pfenex 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

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 or https://www.webcaster4.com/Webcast/Page/1061/30275

A replay of the call will also be available through May 16th. 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: 10130782.

About Pfenex Inc.

Pfenex is a clinical-stage development and licensing biotechnology company focused on leveraging its *Pf*ēnex Expression Technology® to develop and improve protein therapies for unmet patient needs. Using the patented *Pf*ēnex Expression Technology platform, the Company has created an advanced pipeline of potential therapeutic equivalents, novel biologics, vaccine and vaccine components, and biosimilars. The Company's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis. In addition, in collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz) the Company is developing hematologic oncology products including PF743 a recombinant crisantaspase and PF745 a recombinant crisantaspase with half-life

extension. Both PF743 and PF745 are being developed for the treatment of Acute Lymphoblastic Leukemia (ALL). We also use our Pfēnex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates under development by third parties.

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 size of potential markets; 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; Pfenex's expectations that it will achieve development milestones near-term under its Jazz Agreement; the potential benefits of use of Pfenex's product candidates; Pfenex's belief that its research and development expense will fluctuate; Pfenex believes that it has the potential to change Pfenex from a clinical stage biotech company to a company with its first commercial product; 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; and Pfenex's expectation with respect to its agreement with Merck and SIIPL, including its potential to receive payments. 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; 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 quarter ended March 31, 2019 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

(in thousands, except per share data)	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Revenue	$ 10,362	$ 3,746
Cost of revenue	1,572	1,520
Gross profit	8,790	2,226
Operating expense		
Research and development	7,923	8,806
Selling, general and administrative	4,597	4,450
Total operating expense	12,520	13,256
Loss from operations	(3,730)	(11,030)
Other income, net	69	3
Net loss	$ (3,661)	$ (11,027)
Net loss per common share:		
Basic and diluted	$ (0.12)	$ (0.47)
Weighted-average common shares used in calculating net loss per share:		
Basic and diluted	31,487	23,569

PFENEX INC.
Consolidated Balance Sheets

	March 31, 2019 (unaudited)	December 31, 2018
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 45,754	$ 56,220
Restricted cash	200	200
Accounts and unbilled receivables, net	6,460	5,171
Income tax receivable	159	207
Other current assets	2,116	1,851
Total current assets	54,689	63,649
Property and equipment, net	7,596	7,671
Other long-term assets	170	133
Intangible assets, net	4,115	4,248
Goodwill	5,577	5,577
Total assets	$ 72,147	$ 81,278
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,155	$ 2,005
Accrued liabilities	8,574	9,812
Current portion of deferred revenue	993	5,317
Current portion of capital lease obligations	321	316
Total current liabilities	11,043	17,450
Deferred revenue, less current portion	2,500	2,500
Capital lease obligations, less current portion	135	191
Total liabilities	13,678	20,141
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; 31,499,980 and 31,467,580 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	32	32
Additional paid-in capital	263,398	262,405
Accumulated deficit	(204,961)	(201,300)
Total stockholders' equity	58,469	61,137
Total liabilities and stockholders' equity	$ 72,147	$ 81,278