Pfenex Reports Second Quarter 2019 Results and Provides Business Update

NDA for PF708 reached the FDA mid-cycle review milestone in May

Positive Phase 1 results for PF743 (JZP-458) and Jazz advances the product to Pivotal Phase 2/3 Study

Agreement with Arcellx Leverages Pfēnex Expression Technology® platform

SAN DIEGO, August 8, 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, the Company has created an advanced pipeline of therapeutic equivalents, biologics, vaccines and biosimilars. Today Pfenex Inc. reported financial results for the second quarter ended June 30, 2019 and provided a business update.

"During the past several months, there was significant progress made toward our key programs and partnerships, including PF708, our Jazz partnership, and our CRM197 partnerships with Merck and Serum Institute of India, which we believe are each on a path towards achieving pivotal clinical or regulatory milestones," said Eef Schimmelpennink, Chief Executive Officer of Pfenex. "Our lead program, PF708, continues to advance and the FDA has set a PDUFA date of October 7, 2019. We are pleased to announce that the FDA completed its mid-cycle review of our NDA for PF708 in May and did not identify any issues that require an advisory committee meeting. In anticipation of the FDA's decision on our NDA for PF708, we continue to make progress on the launch readiness planning with our commercial partner Alvogen, which includes producing commercial materials and finalizing overall commercial strategy plans."

"We are very pleased with the progress by Jazz on PF743 (JZP-458). Jazz announced in their second quarter 2019 earnings that they completed a successful Phase 1 study and expect to initiate a single arm pivotal Phase 2/3 study later this year," mentioned Schimmelpennink, "similarly, we are progressing well with our development of PF745 and look forward to future updates on this program."

"We are moving ahead with our long-term strategy that further leverages our Pfēnex Expression Technology platform and expands and evolves our pipeline with new products and partnership opportunities. Our recently announced collaboration with Arcellx to advance proprietary sparX proteins that activate, silence and reprogram Antigen-Receptor Complex T cell-based therapies fits that strategy well. It provides us with another opportunity create value and enables us to further evolve the company towards novel technologies."

"This is an exciting time for Pfenex, as we harness near- and long-term opportunities to drive value for our shareholders. A combination of the progress made with our existing programs and new focus on R&D activities has attracted several new notable members of the scientific community to join our company's executive team, board of directors and scientific advisory board. Our goal is to continue to build on this momentum and generate greater awareness around our platform technology and its broad potential for new programs and development partnerships," 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. 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 PF708 new drug application (NDA) has reached the Food and Drug Administration (FDA) mid-cycle review milestone. The FDA has set a PDUFA date of October 7, 2019 for this NDA Pfenex believes PF708 is on track for a potential commercial launch in the United States as early as the fourth quarter of 2019, subject to FDA approval, final commercial strategic decisions made by Pfenex's partner Alvogen, and other factors.

Pfenex is also seeking an "A" therapeutic equivalence designation for PF708 to Forteo, which may permit PF708 to be automatically substituted for Forteo. Pfenex submitted the protocol for the comparative human factors study for FDA feedback, but the Agency recently informed Pfenex of its view that it might be premature to comment on the protocol until the details of the PF708 labeling are agreed to, which may be near the PF708 PDUFA date of October 7, 2019. Pfenex has engaged in a discussion with the FDA around this position. Depending on the outcome, it may delay the start of the study, submitting the study results to the FDA, and potentially obtaining a therapeutic equivalence rating.

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 May, the European Medicines Agency (EMA) accepted the Marketing Authorization Application for PF708, which was submitted by Pfenex's partner Alvogen as a biosimilar to Forsteo® in the treatment of osteoporosis. Alvogen expects to receive initial comments on the application in the third quarter of 2019. If EMA approval is received, PF708 will be authorized for marketing in all 28 member states of the EU. Under the licensing agreement with Pfenex and Alvogen, Alvogen's European distribution partner, Theramex, a leading global specialty pharmaceutical company dedicated to women's health, will initiate sales of PF708, if the EMA approval is received.

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 believes its success on these programs further demonstrate the unique capabilities of Pfenex's platform technology.

Jazz announced that they successfully completed a Phase 1 study for PF743 (JZP-458) and expect to initiate a single arm pivotal Phase 2/3 study later this year. In parallel we continue to advance the development of PF745 and are pleased with the progress we are making.

Pfenex believes these programs could be eligible to achieve certain payments in 2019 of the $29.5 million in development milestone payments available under its agreement with Jazz Pharmaceuticals. 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 $188.5 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, including in multiple Phase 3 clinical studies by Merck and the Serum Institute of India Private Ltd (SIIPL) for such diseases as pneumococcal and meningitis bacterial infections.

Arcellx - sparX Protein Development Agreement

Pfenex has entered into a development, evaluation and license agreement with Arcellx which provides access to the *Pf*ēnex Expression Technology platform to advance Arcellx' s proprietary sparX proteins that activate, silence and reprogram Antigen- Receptor Complex T cell-based therapies. Under the terms of the agreement, Pfenex is eligible to receive development funding in addition to development, regulatory and commercial milestones ranging from $2.6 million to $18 million for each product incorporating a sparX protein expressed using the *Pf*ēnex Expression Technology, as well as royalties on worldwide sales of any such products.

Pfenex expects revenue in the near term to be primarily related to monetizing its protein production platform through CRM197 product sales, commercial license agreements and service agreements, which may provide for various types of payments, including upfront payments, royalties on sales, milestone payments, intellectual property access fees and licensing fees.

Board of Directors

Pfenex recently announced the appointment of Lorianne Masuoka, MD to its Board of Directors. In addition to being a board-certified neurologist, she brings to the Board more than 20 years of experience building and expanding high value pipelines in the biopharmaceutical industry that have resulted in drug approvals and strategic alliances. Dr. Masuoka has successfully created and overseen high performing teams to lead the clinical development of new medicines, many with a focus in neurology, CAN and pain. As the company is evolving Sigurdur Olafsson has transitioned off the Board of Directors. Pfenex's Board wants to thank Siggi for his valuable contributions to Pfenex over the last few years and welcomes Lorianne as a valuable counselor to the Pfenex executive team as they further leverage the Pfēnex Expression Technology platform to build out the Company's development pipeline.

Scientific Advisory Board

In April Pfenex announced that Dr. Robert Peach joined Pfenex's Scientific Advisory Board. Dr. Peach has over 25 years of drug discovery and development experience in the pharmaceutical and biotechnology industry. In 2009, he co-founded Receptos, becoming Chief Scientific Officer and raised approximately $59 million in venture capital and approximately $800 million in an IPO and three subsequent follow-on offerings. In August 2015, Receptos was acquired by Celgene for $7.8 billion. Dr. Peach has also held senior executive and scientific positions in other companies, including Apoptos, Biogen Idec, IDEC and Bristol-Myers Squibb. His extensive drug discovery and development experience in autoimmune and inflammatory diseases and cancer has resulted in multiple drugs entering clinical trials and three registered drugs.

Financial Highlights for the Second Quarter 2019

Total Revenue decreased by $1.4 million, or 33%, to $2.8 million in the three-month period ended June 30, 2019, compared to $4.2 million in the same period in 2018. The decrease in revenue was primarily due to completion of revenue amortization for Pfenex's Jazz collaboration agreement, as well as a decrease in revenue related to its BARDA program. This was partially offset by increased service revenue and sales of Pfenex's CRM197 product.

Cost of Revenue increased by approximately $0.2 million, or 21%, to $1.1 million in the three-month period ended June 30, 2019, compared to $0.9 million in the same period in 2018. The increase was primarily due to greater sales of Pfenex's CRM197 product, partially offset by decreased activity related to its BARDA program.

Research and development expenses decreased by approximately $5.9 million, or 55%, to $4.8 million in the three-month period ended June 30, 2019, compared to $10.7 million in same period in 2018. The decrease is primarily due to expenses incurred in the second quarter of 2018 for Pfenex's Phase 3 clinical trial and regulatory activities related to its lead drug candidate PF708. Additionally, in the second quarter of 2019, R&D expenses were offset by $1.2 million for certain costs Alvogen agreed to reimburse the Company for in connection with quality, manufacturing and supply chain activities for the Company's PF708 collaboration.

Selling, general and administrative expenses increased by approximately $1.0 million, or 25%, to $4.6 million in the three-month period ended June 30, 2019, compared to $3.6 million in the same period in 2018. The increases were primarily due to an increase in expenses related to IP legal, consulting, and the expansion of business development efforts.

Cash and cash equivalents as of June 30, 2019, were $41.6 million. Pfenex believes that its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet Pfenex's anticipated cash needs for at least the next 12 months, including all necessary activities leading up to and including potential approval of PF708 in the United States in the fourth quarter of 2019, subject to FDA approval, final commercial strategic decisions made by Pfenex's partner Alvogen 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 or https://www.webcaster4.com/Webcast/Page/1061/31219

A replay of the call will also be available through August 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: 10133889.

About Pfenex Inc.

Pfenex 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, Pfenex has created an advanced pipeline of

therapeutic equivalents, vaccines, biologics and biosimilars. Pfenex also uses its Pfēnex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines. Pfenex's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide) for the treatment of osteoporosis. In addition, Pfenex is 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; regulatory developments; potential market sizes for Pfenex's 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 and product candidates under the Jazz collaboration; Pfenex's expectations that several significant clinical and regulatory Company milestones across Pfenex's pipeline may occur; Pfenex's belief that it has the potential to transform into a commercial stage biotech company 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 expectation with respect to its agreement with Merck, SIIPL and Arcellx, including its potential to receive milestone and royalty payments; and Pfenex's belief in its ability to advance key programs in Pfenex's pipeline, create short- and long-term opportunities and drive stockholder value. 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 quarter ended June 30, 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
(unaudited)

(in thousands, except per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 2,811	$ 4,190	$ 13,173	$ 7,936
Cost of revenue	1,122	924	2,694	2,444
Gross profit	1,689	3,266	10,479	5,492
Operating expense				
Research and development	4,837	10,739	12,760	19,545
Selling, general and administrative	4,552	3,647	9,149	8,097
Total operating expense	9,389	14,386	21,909	27,642
Loss from operations	(7,700)	(11,120)	(11,430)	(22,150)
Other income, net	71	39	140	42
Net loss	$ (7,629)	$ (11,081)	$ (11,290)	$ (22,108)
Net loss per common share:				
Basic and diluted	$ (0.24)	$ (0.41)	$ (0.36)	$ (0.88)
Weighted-average common shares used in calculating net loss per share:				
Basic and diluted	31,527	26,771	31,503	25,178

PFENEX INC.
Consolidated Balance Sheets

	June 30, 2019 (unaudited)	December 31, 2018
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 41,621	$ 56,220
Restricted cash	200	200
Accounts and unbilled receivables, net	3,316	5,171
Income tax receivable	53	207
Other current assets	1,666	1,851
Total current assets	46,856	63,649
Property and equipment, net	7,534	7,671
Other long-term assets	170	133
Intangible assets, net	3,985	4,248
Goodwill	5,577	5,577
Total assets	$ 64,122	$ 81,278
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 520	$ 2,005
Accrued liabilities	8,635	9,812
Current portion of deferred revenue	278	5,317
Current portion of capital lease obligations	305	316
Total current liabilities	9,738	17,450
Deferred revenue, less current portion	2,500	2,500
Capital lease obligations, less current portion	72	191
Total liabilities	12,310	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; 31,557,592 and 31,467,580 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	32	32
Additional paid-in capital	264,370	262,405
Accumulated deficit	(212,590)	(201,300)
Total stockholders' equity	51,812	61,137
Total liabilities and stockholders' equity	$ 64,122	$ 81,278