Pfenex Reports Third Quarter 2019 Results and Provides Business Update

Received U.S. FDA approval for PF708 to treat osteoporosis and submitted comparative use human factors (HF) study report to FDA; Commercial launch by Alvogen expected upon FDA decision on the therapeutic equivalence rating relative to Forteo®

Announced partnership with Arcellx to develop SparX proteins used in cell therapies

Jazz advances PF743 (JZP-458) to pivotal Phase 2/3 Study expected to be initiated later this year; Jazz also announced FDA fast track designation for JZP-458, for the treatment of ALL/LBL

Earned $13.5 million in development and regulatory milestone payments

SAN DIEGO, November 7, 2019 — Pfenex Inc. (NYSE American: PFNX) is a 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 developed the FDA-approved PF708 product indicated for the treatment of osteoporosis in certain patients at high risk of fracture and created an advanced pipeline of therapeutic equivalents, biologics and vaccines. Today Pfenex Inc. reported financial results for the third quarter ended September 30, 2019 and provided a business update.

"The Pfenex team is very excited and proud of our FDA approval for PF708, the first approved drug developed in our proprietary platform. It signifies an important milestone for the company, and we believe sets us up for continued success. In addition, we continue to execute on our plan and achieved several key milestones in the third quarter, including successful completion of the PF708 comparative use HF study, supporting Alvogen in advancing PF708 regulatory and commercial activities outside of the U.S., and process development activities for PF745, a recombinant crisantaspase with half-life extension technology under our Jazz collaboration. As a result, we earned $13.5 million in milestone payments during the third quarter of 2019. Most importantly, all of these milestones continue to validate the company's unique expression technology, as well as our ability to execute successfully," said Eef Schimmelpennink, Chief Executive Officer of Pfenex.

Business Review and Update

FDA-approved PF708 product and proposed therapeutic equivalent to Forteo

On October 7, 2019, Pfenex announced that the U.S. Food and Drug Administration (FDA) approved the new drug application (NDA) for PF708 submitted under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. Like Forteo, the FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk of fracture. Pfenex believes PF708 has the potential to significantly enhance patient access to an important therapy as a cost-effective alternative to Forteo, which had $1.6 billion in global sales in 2018. In October, Pfenex earned a $2.5 million milestone payment from Alvogen for U.S. approval of PF708 and is eligible to earn another $20 million milestone payment if the FDA grants an "A" therapeutic equivalence rating to PF708.

Pfenex is seeking FDA designation of the recently-approved PF708 product as therapeutically equivalent ("A" rated) to Forteo, which would permit PF708 to be automatically substituted for Forteo in many states. To further support an "A" rating, Pfenex recently submitted a comparative use human factors study report, as requested by FDA. Pfenex believes that this completes the information package required by the FDA to evaluate the therapeutic equivalence of PF708. Pfenex currently expects its U.S. commercial partner, Alvogen, to launch PF708 upon an FDA decision on the therapeutic equivalence rating.

Alvogen, which also has exclusive development and commercialization rights for PF708 in the European Union (EU), Middle East and North Africa (MENA) and the Rest-of-World territories (except those licensed to NT Pharma), has in the third quarter entered into additional exclusive commercialization agreements for PF708 with PharmBio Korea in South Korea, JAMP Pharma in Canada and Kamada Ltd. in Israel. Furthermore, Alvogen's partner in the MENA region, SAJA, submitted a Marketing Authorization Application (MAA) to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Additionally, the accepted MAA for PF708 under review by the European Medicines Agency (EMA) continues to make progress, and Pfenex believes PF708 could receive regulatory approval in the EU as early as the second half of 2020, subject to granting of a marketing authorization by the European

Commission under the EU centralized procedure and other factors. If approved, PF708 would receive marketing authorization in all 28 member states of the EU, as well as in Iceland, Liechtenstein and Norway and be commercialized by Alvogen's partner Theramex. The MAA for PF708 was submitted by Alvogen to the EMA as a biosimilar to Forsteo®, which achieved $289 million sales in the E.U. and $1.6 billion in global product sales in 2018.

Jazz Collaboration Agreement

Pfenex announced in the third quarter that it earned an $11 million development milestone payment under its development and license agreement with Jazz Pharmaceuticals (Jazz) and received the milestone payment in October 2019. The milestone is associated with process development activities for PF745 (JZP-341), a long-acting *Erwinia* asparaginase. Jazz announced in its third quarter earnings that they expect to initiate a Phase 2/3 pivotal study for PF743 (JZP-458), a recombinant *Erwinia* asparaginase, later this year and anticipates completing enrollment by fourth quarter 2020. The study is expected to enroll approximately 100 patients with a planned interim analysis at approximately 50 patients. Jazz also announced receiving fast track designation for PF743.

Under the terms of the development and license agreement, Pfenex is eligible to receive an aggregate total of up to $224.5 million in development and sales milestone fees, of which $177.5 million is still eligible to be received by Pfenex. Of this $177.5 million, $18.5 million are development milestones, $34 million are regulatory milestones, and $125 million are sales milestones. Pfenex is also 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.

Merck is using Pfenex's CRM197 in its vaccines including PCV-15 (V114), an investigational 15-valent polyvalent conjugate vaccine for the prevention of pneumococcal disease, currently in 15 Phase 3 studies. Merck stated in their second quarter 2019 earnings results that Phase 3 data from their PCV-15 comprehensive development program may become available by the end of 2019.

SIIPL is using Pfenex's CRM197 in multiple programs. SIIPL announced that it expects that its most advanced product, Pneumosil®, could complete the World Health Organization (WHO) prequalification process and subsequently be launched in the first quarter of 2020. A second product being developed by SIIPL is a thermostable Pentavalent Meningococcal Conjugate Vaccine for which SIIPL initiated a Phase 3 study in the third quarter of 2019. Both of these products are targeting markets in developing countries. Pfenex is eligible to receive a tiered royalty payment based upon net sales for both products, subject to regulatory approval.

Arcellx - sparX Protein Development Agreement

In August, Pfenex announced its 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.

Board of Directors and Scientific Advisory Board

In August, Pfenex welcomed Dr. Lorianne Masuoka to the Pfenex Board of Directors. Her appointment further aligns the Board with the Company's strategy to build a new R&D capability and Pfenex believes Dr. Masuoka's extensive experience successfully expanding the development pipelines of several biotech companies makes her a valuable counselor to the Pfenex executive team. Dr. Masuoka has 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. She is a board-certified neurologist who has successfully created and overseen high performing teams to lead the clinical development of new medicines, with a focus in neurology, CNS, and pain. Dr. Masuoka served as chief medical officer of InVivo Therapeutics, Cubist Pharmaceuticals (now Merck), and Nektar Therapeutics where, as a member of executive management, she oversaw and managed teams in the areas of clinical research, drug safety, biostatistics and data management, regulatory affairs, reimbursement and clinical operations.

In September, Pfenex announced the appointment of Steve Kay, Ph.D., to its Scientific Advisory Board. Dr. Kay is a highly regarded biologist who brings a wealth of research experience to the Scientific Advisory Board and complements the existing board in support of the Pfenex scientific strategy. Dr. Kay is one of the world's top experts on the genetics and genomics of circadian rhythms.

Having published more than 200 papers, he was named by Thomson Reuters as one of "The World's Most Influential Scientific Minds" from 2014 to 2019. Dr. Kay currently serves as the Director of the University of Southern California (USC) MESH (Medicine, Engineering, Sciences, and Humanities) Academy, the Director of the USC Michelson Center for Convergent Bioscience, and is a Provost Professor of Neurology, Biomedical Engineering and Biological Sciences at the Keck School of Medicine of USC.

Financial Highlights for the Third Quarter 2019

Total Revenue increased by $11.6 million, or 327%, to $15.2 million in the three-month period ended September 30, 2019, compared to $3.6 million in the same period in 2018. The increase in revenue was primarily due to an $11 million development milestone reached during the quarter related to the Jazz collaboration agreement.

Cost of Revenue decreased by approximately $0.4 million, or (23%), to $1.1 million in the three- month period ended September 30, 2019, compared to $1.5 million in the same period in 2018. The decrease was primarily due to the decreased activity related to our BARDA program.

Research and development expenses decreased by approximately $2.1 million, or (23%), to $6.9 million in the three-month period ended September 30, 2019, compared to $9.0 million in same period in 2018. The decrease was primarily due to the reduction of labor and subcontractor costs as the majority of the work performed to support the PF708 NDA filing was completed in late 2018.

Selling, general and administrative expenses increased by approximately $0.3 million, or 8%, to $4.1 million in the three-month period ended September 30, 2019, compared to $3.8 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 September 30, 2019, were $32.7 million. This balance excludes $13.5 million of development and regulatory milestones that were earned in September and October 2019. 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.

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/1061/32120

A replay of the call will also be available through November 14th. 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: 10136405.

About PF708

PF708 was approved in the U.S. under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. The FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk of fracture. Pursuant to the Development and License Agreement with Alvogen, Alvogen is responsible for commercializing and manufacturing PF708 in the U.S. and for fulfilling all regulatory requirements associated with maintaining the PF708 NDA. Alvogen also has exclusive rights to commercialize and manufacture PF708 in the EU, certain countries in the Middle East and North Africa (MENA), and the Rest of World (ROW) territories (the latter defined as all countries outside of the EU, U.S. and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). A marketing authorization application for PF708 has been filed and accepted with the EMA using the biosimilar pathway with Forsteo® as the reference medicinal product and has been filed with the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Pursuant to the Development and License Agreement with NT Pharma Group Company Ltd. (NT Pharma) we granted an exclusive license to NT Pharma to commercialize PF708 in Mainland China, Hong Kong, Singapore, Malaysia and Thailand and a non-exclusive license to conduct development activities in such territories with respect to PF708. Forteo® and Forsteo® are approved and marketed by Eli Lilly companies for the treatment of osteoporosis in certain patients with a high risk of fracture. Forteo® and Forsteo® achieved $1.6 billion in global product sales in 2018.

About Pfenex Inc.

Pfenex is a 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, and vaccines. Pfenex's lead product candidate is PF708, a therapeutic equivalent candidate to Forteo® (teriparatide injection). PF708 has been approved in the U.S. for the treatment of osteoporosis in certain patients at high risk of fracture, and marketing authorization applications are pending in other jurisdictions. In addition, Pfenex is developing hematology/oncology products in collaboration with Jazz Pharmaceuticals, including PF743, a

recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology. Pfenex also uses its *Pf*ēnex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccines.

Pfenex investors and others should note that Pfenex announces material information to the public about Pfenex through a variety of means, including its website (http://www.pfenex.com/), its 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 its disclosure obligations under Regulation FD. Pfenex encourages its investors and others to monitor and review the information Pfenex makes 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.

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 timing of the potential commercial launch of PF708 in the U.S.; Pfenex’s expectations with respect to the sufficiency of its cash resources; regulatory developments, including the potential timing of marketing authorization in the E.U. for PF708; potential market opportunities for PF708 and Pfenex’s other product candidates, including the benefits of use of such products; 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 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 with respect to its agreements with Merck, SIIPL and Arcellx, including its potential to receive milestone and royalty payments; and Pfenex’s belief that the comparative use human factors study report completes the information package required by the FDA to evaluate therapeutic equivalence. 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, the FDA may disagree that the human factors study report completes the information package and is sufficient to evaluate therapeutic equivalence; the FDA may not agree with Pfenex's interpretation of the results of the human factors study and may not grant an “A” therapeutic equivalence designation for PF708; 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, manufacturing, 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 September 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.

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PFENEX INC.
Consolidated Statements of Operations
(unaudited)

(in thousands, except per share data)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Revenue				
License revenue	$ 11,562	$ 1,874	$ 20,430	$ 6,869
Service revenue	733	1,339	3,155	3,821
Product revenue	2,953	357	4,836	816
Total revenue	15,248	3,570	28,421	11,506
Cost of revenue	1,143	1,479	3,837	3,923
Gross profit	14,105	2,091	24,584	7,583
Operating expense				
Research and development	6,931	9,045	19,691	28,590
Selling, general and administrative	4,147	3,823	13,296	11,920
Total operating expense	11,078	12,868	32,987	40,510
Net income (loss) from operations	3,027	(10,777)	(8,403)	(32,927)
Other income, net	55	115	195	157
Net income (loss)	$ 3,082	$ (10,662)	$ (8,208)	$ (32,770)
Net income (loss) per common share:				
Basic	$ 0.10	$ (0.34)	$ (0.26)	$ (1.20)
Diluted	$ 0.09	$ (0.34)	$ (0.26)	$ (1.20)
Weighted-average common shares used in calculating net income (loss) per share:				
Basic	31,595	31,437	31,534	27,288
Diluted	32,498	31,437	31,534	27,288

PFENEX INC.
Consolidated Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 32,518	$ 56,220
Restricted cash	200	200
Accounts and unbilled receivables, net	16,215	5,171
Income tax receivable	53	207
Other current assets	2,357	1,851
Total current assets	51,343	63,649
Property and equipment, net	8,374	7,671
Other long-term assets	170	133
Intangible assets, net	3,859	4,248
Goodwill	5,577	5,577
Total assets	$ 69,323	$ 81,278
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,233	$ 2,005
Accrued liabilities	8,352	9,812
Current portion of deferred revenue	105	5,317
Current portion of capital lease obligations	269	316
Total current liabilities	10,959	17,450
Deferred revenue, less current portion	2,500	2,500
Capital lease obligations, less current portion	29	191
Total liabilities	13,488	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; 31,622,914 and 31,467,580 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	32	32
Additional paid-in capital	265,311	262,405
Accumulated deficit	(209,508)	(201,300)
Total stockholders' equity	55,835	61,137
Total liabilities and stockholders' equity	$ 69,323	$ 81,278