2019 ANNUAL REPORT

We are a development and licensing biotechnology company focused on leveraging our proprietary protein production platform, Pfenex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. We have extensive experience in protein therapeutic development and our proven platform enables deliberate and rapid candidate selection, fast drug development, and potentially higher success rates for a wide range of complex modalities. We aim to leverage existing drug development successes into a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration approved, next generation and novel biopharmaceutical products.

Evert B. Schimmelpennink
Chief Executive Officer

Dear Stockholders,

Reflecting on the past year, it is clear that 2019 was one of the most exciting years in Pfenex's history, which I believe could help drive long-term value. I continue to be proud of the Pfenex team and our proven ability to execute against our focused strategy. I believe that we are in a strong position to build on recent successes and leverage our proprietary protein production platform, the Pfenex Expression Technology, to expand our development pipeline.

The initial focus of our strategy was to execute on three key pipeline opportunities: development of PF708 for the treatment of osteoporosis, our partnership with Jazz Pharmaceuticals in hematologic oncology, and our CRM197 carrier protein partnerships with Merck & Co., Inc. (Merck) and Serum Institute of India Private Ltd. (SIIPL). The advancement we made on these three programs allowed us to begin our work on the selective expansion of our portfolio by leveraging our platform to develop novel biopharmaceuticals.

Over the past twelve months, we have announced several key pipeline milestones that just a couple of years ago, each one, on its own, would have stood out as a notable success for the Company. During 2019, our lead programs advanced significantly. We earned approximately $31 million in milestone payments, and we achieved our first FDA approval with PF708.

I believe these achievements speak to the focused execution of the Pfenex team and to the ability of our protein platform to successfully produce a broad range of therapeutic candidates, from peptides to large, complex proteins. As a result, I believe our platform offers multiple opportunities to generate near- and long-term shareholder value as we enter our next phase of growth.

PF708 Approval by FDA and Commercialization Strategy

At the forefront of our progress in 2019 was our lead product candidate, PF708. In October of 2019, we celebrated the FDA's approval of our new drug application (NDA) for PF708 under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide) as the reference drug. We consider this to be a transformative milestone for Pfenex. We believe achieving FDA approval for a product developed by the Pfenex team validates our internal product development capabilities. Like Forteo, which generated over $1.4 billion in global product sales in 2019, the FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture.

We have been continuing our efforts to obtain an "A" therapeutic equivalence designation for PF708 relative to its reference drug, Forteo. If achieved, an A rating may permit the FDA-approved PF708 product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the U.S. An A rating for a product like PF708 is primarily based on the FDA evaluating

three requirements: pharmaceutical equivalence, bioequivalence, and human factor (HF) comparability. Information and data supporting both pharmaceutical equivalence and bioequivalence to Forteo were part of our NDA, and we believe approval of our NDA suggests the first two elements may be satisfied. To further enable the FDA to assess the third element of human factors comparability, in 2019, we executed a fifth human factors study that compared the PF708 injection device head-to-head with Forteo's device, the results of which we shared publicly and submitted to the FDA in October. We believe this submission completes the information package required by the FDA to evaluate the therapeutic equivalence of our PF708 product.

As we await the FDA's decision on the therapeutic equivalence rating, we have been working diligently with our partner, Alvogen, on commercial manufacturing and sales planning activities as part of the launch preparedness plan for PF708 in the U.S. Alvogen, to whom we have transferred the NDA, intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. If we receive an A rating from the FDA, we will be eligible to receive from Alvogen under the terms of our agreement up to an additional $20 million in support and regulatory milestone payments (or up to an additional $15 million if more than six months after FDA approval) and 50% of gross profits from U.S. sales of PF708.

The global strategy for PF708 also includes a development and licensing agreement with Alvogen pursuant to which Alvogen has the 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). We believe our collaboration with Alvogen aligns the interests and strengths of both companies to secure regulatory approvals and commercialize PF708, including Alvogen's established international expertise in regulatory, intellectual property (IP), and supply chain activities, as well as its established network of specialty marketing and pharmaceutical sales organizations in these regions. Alvogen has already established several agreements with their partners across several countries and regions and has begun to engage the regulatory agencies in these other countries. For example, marketing authorization applications for PF708 have been accepted by both the European Medicines Agency and the Kingdom of Saudi Arabia's Saudi FDA.

We also have an exclusive license agreement with 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.

Advancement of Products in Collaboration with Jazz Pharmaceuticals

Our collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz) underscores the uniquely enabling nature of our platform as we facilitate the development of PF743 (JZP-458) to meet patient demand. Through this agreement we are developing two products: PF743 (or JZP-458, as it is named in the Jazz portfolio), a recombinant Erwinia asparaginase, and PF745 (JZP-341), a half-life extended Erwinia asparaginase. In December 2019, Jazz enrolled the first patient in a pivotal Phase 2/3 clinical study for PF743, for which the FDA has granted fast track designation for the treatment of acute lymphoblastic leukemia.

Through December 31, 2019, we have received approximately $62 million under the Jazz agreement. Under our agreement with Jazz, we are eligible to receive an aggregate total of up to $224.5 million in development and sales milestone fees, of which $162.5 million is still eligible to be received. This includes up to $3.5 million in development milestones, $34.0 million in regulatory milestones and $125.0 million in sales milestones. We may also be eligible to receive tiered mid-single-digit royalties based on worldwide sales of any products resulting from the collaboration.

CRM197 – SIIPL Pneumosil® Achieves WHO Prequalification, Merck's V114 in Fifteen Phase 3 Studies

CRM197 is a well-characterized protein that functions as a carrier for polysaccharides and haptens, making them immunogenic. We have license agreements with both Merck and SIIPL, as well as supply agreements with several partners.

Merck's V114 is an investigational 15-valent pneumococcal conjugate vaccine for the prevention of pneumococcal disease. V114 is currently being evaluated in fifteen Phase 3 studies. If licensed, V114 is expected to be positioned as a key product in the pneumococcal vaccine market. Pfenex is eligible to receive tiered royalty payments based on net sales for all products we develop that use our CRM197 production strains licensed to Merck and produced via the Pfenex Expression Technology platform.

During the fourth quarter of 2019, we also saw the World Health Organization (WHO) prequalification of a vaccine from SIIPL. SIIPL has developed a 10-valent pneumococcal conjugate vaccine, Pneumosil®, which utilizes CRM197 from a Pfenex-based production strain, and initiated the process of WHO prequalification for Pneumosil in the first quarter of 2019. The commercial market for Pneumosil is expected to include India, Asia, Africa and other low- and middle-income countries under the Gavi Advanced Market Commitment (AMC).

A second product being developed by SIIPL, which also utilizes CRM197 and is subject to the Pfenex Expression Technology license, is a thermostable pentavalent meningococcal conjugate vaccine that has entered a Phase 3 study. This product is also targeting markets in developing countries.

This is another potential revenue source for us, as Pfenex is eligible to receive annual fees, milestone payments, and a tiered royalty payment based on net sales for all products developed by SIIPL that use the CRM197 carrier protein produced via the Pfenex Expression Technology.

Also, we have additional partnerships in various stages and continue to sell non-GMP and cGMP grade CRM197 to vaccine development-focused pharma partners.

Expanding the Development Pipeline

As these three key programs and collaborations advance, we continue to explore new collaborations through our business and corporate development efforts. Most recently, we announced a development, evaluation, and license agreement with ArcellX, which provides access to the Pfenex Expression Technology platform to advance ArcellX's proprietary sparX proteins that activate, silence and reprogram Antigen-Receptor Complex T cell-based therapies. Our team recently completed the development of both sparX 1 (PF753) and sparX 2 (PF754), and ArcellX has opted in to the commercial license for both production strains.

In a further effort to build out our pipeline, we are looking to develop additional novel biopharmaceutical products. With more than a decade of experience in expressing natural and engineered proteins, and a historical success rate of over 80%, we have a proven track record in the development of novel peptide and protein-based therapeutics. Following extensive research, we have identified a set of high value, validated biological targets that we intend to pursue. The targets of interest are in disease areas of unmet medical need with moderately sized patient populations, which would allow Pfenex to develop the products through Phase 3 clinical studies. We look forward to keeping you abreast of these new programs as they progress.

We believe Pfenex is at a transformational point in its history with its first FDA approved product nearing commercialization, and several programs in late-stage studies and regulatory review. We believe there are many possible opportunities to drive near and long-term growth for our business. I look forward to continuing to lead the team and helping to build long-term value for our stockholders.

Evert B. Schimmelpennink
Chief Executive Officer

April 1, 2020

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-36540

Pfenex Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-1356759**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
10790 Roselle Street San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 352-4400
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**PFNX**	**NYSE American LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act: Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based on the closing sale price of the Registrant's common stock on the last business day of its most recently completed second fiscal quarter, as reported on NYSE American, was approximately $211.6 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of March 2, 2020, there were 34,203,250 shares of the registrant's common stock, $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

Pfenex Inc.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2019

TABLE OF CONTENTS

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created thereunder and which involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our 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 our expectations, strategy, plans or intentions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- *the sufficiency of our cash and cash equivalents and cash generated from operations to meet our working capital and capital expenditure needs for the next 12 months;*
- *the performance of our collaboration partner Alvogen, upon which we are dependent on to commercialize the FDA-approved PF708 product;*
- *our reliance on Jazz, Alvogen, NT Pharma, Merck, SIIPL and any future collaboration partner's performance over which we do not have control;*
- *our and any potential future collaboration partner's ability to enroll patients in our clinical studies at the pace that we project;*
- *our expectation to expand our product pipeline;*
- *our expectations regarding the initiation, timing, progress and the success of the design, primary and secondary end points, and duration of the clinical trials and planned clinical trials and studies for our current product candidates and reporting results from same;*
- *whether we are able to obtain an "A" therapeutic equivalence designation for the FDA-approved PF708 product relative to the reference drug Forteo;*
- *our and our collaboration partners' ability to maintain regulatory approval of the FDA-approved PF708 product or seek and obtain regulatory approval for PF708 and our other product candidates, and if approved, maintain regulatory approval and the timing of such potential regulatory approvals;*
- *our expectations with respect to the commercialization of the FDA-approved PF708 product by Alvogen;*
- *our reliance on third-parties to conduct clinical studies;*
- *our reliance on third-party contract manufacturers and Alvogen to manufacture and supply the FDA-approved PF708 product, PF708 and our other product candidates for us;*
- *the benefits of the use of the FDA-approved PF708 product, PF708, or any of our other product candidates;*
- *the rate and degree of market acceptance of the FDA-approved PF708 product, PF708 or any of our other product candidates, if approved for sale;*
- *regulatory developments in the United States and foreign countries;*
- *our expectations regarding government and third-party payor coverage and reimbursement;*
- *our and our collaboration partners' ability to manufacture the FDA-approved PF708 product, PF708 and our other product candidates in conformity with regulatory requirements and to scale up manufacturing of the FDA-approved PF708 product, PF708 and our other product candidates to commercial scale;*
- *our ability to successfully build a specialty sales force, or collaborate with third-parties including our existing collaboration partners, Alvogen and NT Pharma, to commercialize the FDA-approved PF708 product, PF708 and our other product candidates;*
- *our and our collaboration partners' ability to compete with companies currently producing the reference products, including Forteo;*
- *our ability to compete with companies that may also seek and obtain approval for therapeutically equivalent versions of Forteo;*
- *our ability to retain and recruit key personnel, including development of a sales and marketing function;*
- *our ability to obtain and maintain intellectual property protection for the FDA-approved PF708 product, PF708, our Pfēnex Expression Technology® or any other product candidates;*

- *our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;*
- *our expectations regarding the market size, size of patient populations, and growth potential for the FDA-approved PF708 product, PF708 and our product candidates, if approved for commercial use;*
- *our estimates of the expected patent expiration timelines for Forteo and other branded reference drugs and biologics;*
- *our ability to develop new products and product candidates;*
- *our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;*
- *our financial performance; and*
- *developments and projections relating to our competitors and our industry.*

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We cannot assure you that the results, events, and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K are based on information available to us on the date of this Annual Report on Form 10-K. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Pfenex™, Pfenex Biopharmaceuticals™ the Pfenex Biopharmaceuticals logo, and Pfēnex Expression Technology® are trademarks of Pfenex Inc. This Annual Report on Form 10-K contains these trademarks and some of our other trademarks, trade names and service marks. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 10-K belongs to its respective holder.

As used in this Annual Report on Form 10-K, the terms "the Company," "we," "us" and "our" refer to Pfenex Inc. and its subsidiaries, unless the context indicates otherwise.

PART I

Item 1. *Business*

Overview

We are a development and licensing biotechnology company focused on leveraging our proprietary protein production platform, *Pf*ēnex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. We have extensive experience in protein therapeutic development and our proven platform enables deliberate and rapid candidate selection, fast drug development, and potentially higher success rates for a wide range of complex modalities. We aim to leverage existing drug development successes into a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration (FDA) approved, next generation and novel biopharmaceutical products.

In October 2019, the FDA approved the new drug application (NDA) for PF708 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 for fracture. Marketing authorization applications are pending in other jurisdictions. This FDA-approved PF708 product will be commercialized and manufactured in the U.S. by our collaboration partner, Alvogen. In November of 2019, in accordance with the Development and License Agreement (US Alvogen Agreement), we transferred the NDA to Alvogen. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product.

Our other products and collaborations include PF743 (JZP-458), which we are developing in collaboration with Jazz Pharmaceuticals for the treatment of acute lymphoblastic leukemia (ALL) and which commenced a pivotal Phase 2/3 clinical study in December 2019. We also have collaborations based on CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates with Merck & Co., Inc. (Merck) and Serum Institute of India Private Limited (SIIPL). Both Merck and SIIPL have licenses to the Pfēnex Expression Technology for the production of CRM197 for use in conjugate vaccine products. Merck's V114, a 15-valent Pneumococcal conjugate vaccine is currently in 15 Phase 3 clinical trials, and SIIPL's Pneumosil®, a 10-valent Pneumococcal vaccine designed for the developing world, recently achieved World Health Organization (WHO) Prequalification allowing the product to be procured by United Nations agencies and Gavi, the Vaccine Alliance. In addition, a Phase 3, randomized, double-blind study to evaluate the immunogenicity, safety and tolerability of Pneumosil in healthy Indian infants has been completed and SIIPL is currently in the process of submitting the data from the Phase 3 trial to the Drug Controller General of India (DCGI) in support of India marketing authorization.

In the third quarter of 2019 we added PF810, a peptide based next generation therapeutic, to our wholly owned pipeline. PF810 is currently in preclinical development. In addition, we have established a strategic collaboration with Arcellx, Inc. (Arcellx) to advance multiple proprietary sparX proteins that activate, silence and reprogram Antigen-Receptor Complex T cell based therapies based on the Arcellx product platform.

Our FDA-Approved Product, Our Product Candidates and Collaborations

The following summarizes certain information about the FDA-approved product that we developed, our pipeline candidates, and collaborations:

Our FDA-Approved Product, Product Candidates and Collaborations	Branded Reference Drug	Program
FDA-Approved PF708 Product	Forteo®	• Approved in the United States; licensed to Alvogen
PF708	Forteo®	• Product candidate in EU, MENA, and Rest of World licensed to Alvogen (excluding areas licensed to NT Pharma) • Product candidate in Mainland China, Hong Kong, Singapore, Malaysia, Thailand licensed to NT Pharma
Multiple Hematologic Oncology Product Candidates	N/A	• PF743 (JZP-458) – Recombinant Erwinia asparaginase • PF745 (JZP-341) – Long-acting recombinant Erwinia asparaginase • PF690* – pegaspargase
Peptide based next generation therapeutic	N/A	• PF810
Arcellx sparX programs	N/A	• PF753 • PF754

* Jazz retains an exclusive option to license this product pursuant to certain option triggers.

In pursuit of novel wholly-owned product candidates, we have also established a collaboration with a third-party technology platform company who is screening our selected, validated biological targets with its novel binding modality library in an effort to identify potential lead product candidates. Those candidates will be transferred to us and could become wholly owned product candidates developed by us.

The FDA-approved PF708 product, our other product candidates, and collaborations are enabled by our patented protein production platform, Pfēnex Expression Technology, which we believe confers several important competitive advantages compared to traditional techniques for protein production. The platform has demonstrated a high success rate for the production of complex proteins with higher titers of high quality protein purity, as well as speed and cost advantages. The development of proteins requires several competencies which represent both challenges and barriers to entry. Due to their inherent complexity, proteins require the use of living organisms to efficiently produce them at a large scale. Traditional techniques for protein production employ a trial and error approach to production organism, or strain, selection and process optimization, which is inherently inefficient and typically produces suboptimal results. This historically inefficient process provides barriers to creating or replicating complex proteins, adds significant time to market and results in the high cost of goods typical of biologic therapeutics. Together, these limitations pose significant hurdles for companies interested in entering the market with novel biologics, biosimilars and therapeutic equivalents. Our platform utilizes a proprietary high throughput robotically-enabled parallel approach, which allows the construction and testing of thousands of unique protein production strains in parallel, thereby allowing us to produce and characterize complex proteins while reducing the time and cost of development and long-term production.

Our Strategy

Our strategy is to leverage our *Pf*ēnex Expression Technology® protein production platform and product development infrastructure to become a leading biotechnology company focused on developing a portfolio of wholly-owned and partnered novel and next generation therapeutics. Given the historical success rates of over 80% in expressing natural and engineered proteins and our demonstrated success in achieving regulatory approval for our lead product we believe our platform, team and infrastructure provides a competitive advantage in the development of novel peptide and protein based therapeutics.

The key elements to execute on our strategy include three focus areas:

Advance Core Products and Partnerships:

- Maximize PF708's commercial potential. We received US FDA marketing authorization in October 2019 and are requesting that the FDA designate the FDA-approved PF708 product as therapeutically equivalent ("A" rated) to Forteo, which would potentially permit the product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the US. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. In February 2019, we and Alvogen entered into additional agreements, extending Alvogen's rights to commercialize and manufacture PF708 to include the European Union (EU), certain countries in the MENA and to the ROW territories (excluding certain Asian countries granted to NT Pharma). Alvogen has also been seeking marketing authorizations in certain other regions around the world.
- Advance the Jazz partnered programs. In July 2016, we entered into an agreement with Jazz Pharmaceuticals, which we amended in December 2017, to collaboratively develop hematologic oncology products, including PF743 (JZP-458), a recombinant Erwinia asparaginase, and PF745 (JZP-341), a long acting recombinant Erwinia asparaginase. PF743 (JZP-458) commenced a pivotal Phase 2/3 clinical study in December 2019, and we achieved a $15 million development milestone for the PF745 (JZP-341) program in December 2019.
- Expand our portfolio of license and supply relationships for our CRM197 vaccine carrier protein. We have both licenses and supply agreements in place with vaccine developers like Merck and Serum Institute of India (SIIPL) for the production and supply of CRM197, which is a non-toxic mutant of diphtheria toxin that serves as a carrier protein for therapeutic and prophylactic vaccines. Merck's V114, a 15-valent Pneumococcal conjugate vaccine is currently in 15 Phase 3 clinical trials, and SIIPL's Pneumosil®, a 10-valent Pneumococcal vaccine, recently achieved World Health Organization (WHO) Prequalification. With the first products moving closer to commercialization, we aim to continue to expand our portfolio of license and supply agreements for CRM 197.

Selectively add wholly owned next generation therapeutics and partnerships where our platform is uniquely enabling:

- Add wholly owned next generation therapeutic programs. We believe our platform enables the development of next generation therapeutics to improve and/or enhance the performance of existing approved products. We have commenced the development of a next generation peptide based therapeutic candidate, PF810, which is currently in preclinical development.
- Establish additional product development partnerships. Given our history of expressing a broad range of protein types we believe that the *Pf*enex Expression Technology presents a competitive advantage to the biopharmaceutical industry. We aim to further maximize value from the platform and internal capabilities through strategic collaborations where there is compatibility with third party platforms and/or products and our platform is uniquely enabling. An existing collaboration with Arcellx currently has two sparX proteins in development.

Expand into the development of novel biologics based on targeting validated biological targets with novel modalities in select disease areas.

- Advance novel modalities via a third-party collaboration. Following a research effort, we have identified a set of high value, validated biological targets that we intend to pursue. The targets of interest are in disease areas of unmet medical need with a moderately sized patient population allowing us to independently develop the products through Phase 3 clinical studies. In the fourth quarter of 2019, we engaged a third-party collaborator to deploy their internal libraries of novel modalities to screen against our targets of interest in order to identify molecules that could potentially become our wholly owned novel products. We are currently in the process of target screening in an effort to isolate the first set of putative lead candidates. Those candidates, PF91X will be transferred to us and could become wholly owned product candidates developed by us.

Our Approach

Our patented protein production platform, *Pf*ēnex Expression Technology®, allows us to address hurdles to development and enable our product candidates and those being developed under collaborations. We believe our technology confers several important competitive advantages compared to traditional techniques for protein production, including the ability to produce complex proteins with higher accuracy and greater degree of protein purity, as well as speed and cost advantages. Our platform utilizes a proprietary high throughput robotically enabled parallel approach, which allows the construction and testing of thousands of unique protein production variables in parallel, thereby allowing us to produce and characterize complex proteins while reducing the time and cost of development and long-term production.

We have replaced the traditional, trial and error approach to protein production with a simultaneous, parallel processing model that allows the construction and testing of thousands of unique protein production variables in parallel. We believe our platform delivers a significant competitive advantage for protein production, including higher accuracy, greater degree of protein purity, speed and lower costs.

*Pf*ēnex Expression Technology®

Protein Production Overview

Protein production is a fundamental activity necessary for biological drug development and manufacturing. The most common method of manufacturing therapeutic proteins involves the use of engineered microorganisms. Proteins produced using these organisms are referred to as recombinant proteins. Recombinant proteins are produced by inserting DNA, or a gene, that codes for the protein, into a cell which then acts as a protein production factory. Typically, this is accomplished by inserting a synthetic gene into an expression vector, which contains genetic control elements that can be used to turn the gene on and off. This vector is then transformed into a set of selected host strains each with a unique phenotype.

Our platform is based on automated high-throughput screening of large libraries of novel, genetically engineered *P. fluorescens* bacterial expression strains. The libraries contain thousands of expression strains which are constructed from a large inventory of expression vectors, or genetic elements, incorporated into engineered *P. fluorescens* host strains. We then employ automated, robotically enabled parallel high-throughput screening, incorporating extensive bioanalytical testing, in order to select strains from the library which express the protein of interest at optimal yields, purity and potency. Extensive fermentation scouting experiments on the selected strains allows for the identification of a final production strain with further improvements in the yield of the active therapeutic protein.

Our patented *Pf*ēnex Expression Technology® illustrated in the diagram below utilizes a parallel, high throughput method for microbial strain development compared to the more traditional linear approach of trial and error.

Our *Pf*ēnex Expression Technology® platform consists of three primary elements that, when combined, deliver a significant competitive advantage for protein production that differentiates us in the biopharmaceutical industry.

The three elements include:

- *Pseudomonas fluorescens*, A Robust Protein Production Organism
- Extensive Library of Expression Vectors and Host Strain Phenotypes
- Robotically Enabled High Throughput Screening Capability

Robust Protein Production Organism

P. fluorescens has been used industrially where it has efficiently produced complex proteins. We exploit certain attributes of the *P. fluorescens* bacterium that enables us to rapidly identify the optimal strain for a specific protein of interest. The favorable attributes of the *P. fluorescens* bacterium include:

- Secretion of soluble protein into the bacterial periplasm, the space between the inner and outer membrane in gram negative bacteria, resulting in increased recovery yields of properly folded protein
- *P. fluorescens* genome allows for modifications, including deleting protease genes, or nucleotides that provide instructions for synthesis of RNA into a specific protease, and inserting chaperone and/or disulfide bond isomerase genes, or nucleotides that provide instructions for synthesis of RNA into a specific chaperone or disulfide isomerase, which overall increase the quality and production of properly folded active full length proteins
- Selection of expression strains without the use of antibiotics
- High cell density fermentation due to its obligate aerobe growth nature, or bacterium that can only grow in the presence of oxygen, which improves the protein production for characterization, enables consistent scale-up and long-term low cost of goods

Creation of Extensive Library of Protein Expression Strains

We have developed an extensive toolbox of engineered production strains and expression vectors that can be readily accessed for finding the best product strain for manufacturing of a specific protein. This toolbox is continuously growing due to our ongoing research and development efforts. We construct thousands of unique expression strains by combining engineered *P. fluorescens* host strains with proprietary expression vectors. The engineered *P. fluorescens* strains have reduced expression of protein degrading enzymes and/or increased levels of folding elements while the expression vectors consist of plasmids with engineered genetic elements including promoters, ribosome binding sites and secretion leaders. Determining which of these variants will improve production of any particular protein cannot be determined from the amino acid sequence of the protein of interest. As a result, we employ the automated high throughput screening of the engineered production strains in order to select the strain that produces the protein of interest at optimal purity, yield and potency.

Robotically Enabled High Throughput Screening

Our high-throughput automation supports simultaneous, parallel evaluation of thousands of unique protein production alternatives, enabling rapid identification of the optimal production strain for the protein of interest. Our protein production technology employs rapid construction of protein production strains and testing thousands of unique production strains evaluated through automated sample analysis to determine the titer, or quantity of the product per unit volume, of high quality protein each expression strain produces, which can then be analyzed through our high throughput analytical capacity. Our proprietary, robotically enabled automated high throughput screening process, along with our optimized production organism and toolbox of engineered strains and vectors, as well as our expertise in analytical characterization, expedites the development of an optimal protein production engine from approximately one year in a typical case for traditional approaches, if at all possible, to approximately twelve weeks with our *Pf*ēnex Expression Technology®.

Our FDA-Approved Product, Our Product Candidates and Collaborations

The development of our own portfolio of product candidates and the candidates we have licensed to collaboration partners has been enabled by our successful history of meeting analytically rigorous product specifications for protein quality, yield and potency using our *Pf*ēnex Expression Technology®. Our pipeline includes product candidates and preclinical products under development in various stages of development. Details of our pipeline and collaborations are included below.

FDA-Approved PF708 Product

In October 2019, the FDA approved the NDA for PF708 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 for fracture. The FDA-approved PF708 product will be commercialized and manufactured in the U.S. by our collaboration partner, Alvogen. In November 2019 we transferred the NDA to Alvogen pursuant to our collaboration agreement. Forteo (marketed by Eli Lilly and Company) achieved $1.4 billion in global product sales in 2019. Almost half of these product sales came from the United States alone. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product.

The FDA approval of the FDA-approved PF708 product was supported by data from Study PF708-301, which compared the effect of PF708 and Forteo in osteoporosis patients. The PF708-301 study enrolled a total of 181 patients, with 90 patients receiving PF708 and 91 patients receiving Forteo. Eighty-two patients completed the study in the FDA-approved PF708 product treatment group, compared with 81 patients in the Forteo treatment group. The primary study endpoint was anti-drug antibody (ADA) incidence after 24 weeks of drug treatment. 2.2% (2/90) of patients who received PF708 and 2.2% (2/91) of patients who received Forteo had detectable antibodies to teriparatide, and one of the two patients who received PF708 developed neutralizing antibodies to teriparatide. The secondary study endpoints included mean percentage changes in lumbar-spine bone mineral density (BMD) and median percentage changes in bone turnover markers (BTM) after 24 weeks of drug treatment, as well as pharmacokinetic (PK) parameters for up to four hours after the first dose. Safety endpoints were incidences of adverse events (AE) and serious adverse events (SAE).

The PF708-301 study showed comparable overall profiles between PF708 and Forteo across multiple endpoints. These results from the PF708-301 study, along with bioequivalence findings from Study PF708-101 in healthy subjects, supported the PF708 NDA submitted in December 2018 pursuant to the 505(b)(2) pathway. On October 4, 2019 the NDA was approved by the FDA.

In addition to obtaining FDA approval of PF708, we have been continuing our efforts to obtain an "A" therapeutic equivalence designation for the product relative to its reference drug, Forteo. A determination of therapeutic equivalence (as shown by an "A" rating) may permit the FDA-approved PF708 product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the U.S. Consistent with our interactions with the FDA and the agency's draft guidance document on comparative use human factors studies for demonstrating the therapeutic equivalence of drug-device combination products, we successfully completed the PF708 comparative use human factors (HF) study and submitted the final study report to the FDA in October 2019. The study data demonstrate that the user interface of the FDA-approved PF708 product was noninferior to that of Forteo for each critical user task evaluated in the study based on a pre-specified statistical analysis of critical patient and caregiver tasks.

The comparative use HF study was a simulated use study intended to evaluate the effect of each product's delivery device and user interface on critical task performance by untrained osteoporosis patients and caregivers. The study used a paired design of the FDA-approved PF708 and the Forteo products.

A total of 102 untrained participants, 52 osteoporosis patients and 50 caregivers, completed the study. For 67% (12 of 18) of critical tasks performed in the patient user group, and 83% (15 of 18) performed in the caregiver group, PF708 had fewer or equal user errors when compared to Forteo. Importantly, in each of the instances where PF708 had marginally higher user error rates 33% (6/18) of critical tasks performed in the patient user group, and 17% (3/18) of critical tasks performed in the caregiver user group, the magnitude of the differences ($\leq$ 2 UEs and $\leq$ 3 UEs, respectively) did not exceed the predetermined maximum allowable difference in either user group. For these reasons, we believe the study data demonstrate that the user interface of the FDA-approved PF708 product is noninferior to that of Forteo based on pre-specified statistical analysis of critical patient and caregiver tasks. With submission of the final study report to FDA, we believe this completes the information package required by the FDA to evaluate the therapeutic equivalence of the PF708 product. For a discussion of certain significant risks relating to the FDA-approved PF708 product, please see the following Risk Factors: "*The FDA-approved PF708 product, PF708 and our other product candidates, if approved, face significant competition from the reference products and from therapeutic equivalent products of the reference products, and from other products. Our or our collaboration partners' failure to effectively compete may prevent us from achieving significant market penetration and expansion.*" and "*If the FDA-approved PF708 product does not receive an "A" therapeutic equivalence designation from the FDA, our business may suffer*."

In June 2018, we and Alvogen, entered into the US Alvogen Agreement pursuant to which Alvogen received the exclusive right to commercialize and manufacture PF708 in the United States. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. In February 2019 we and Alvogen expanded our collaboration, granting Alvogen exclusive rights to commercialize and manufacture PF708 in the EU, certain countries in the Middle East and North Africa (MENA), and the rest of the world (ROW) territories (the latter defined as all countries outside of the EU, US and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). We believe this collaboration leverages Alvogen's established international experience and expertise in regulatory, IP and supply chain activities, as well as its established network of specialty pharmaceutical companies to conduct sales and marketing activities in these regions.

Alvogen submitted a centralized application to the European Medicines Agency (EMA) for PF708 on May 6, 2019, and the filing was accepted by the EMA on May 23, 2019. We believe that PF708 could be approved in the EU as early as the second half of 2020, pending marketing authorization by the European Commission under the EU centralized procedure and other factors. In October 2019, Alvogen's partner SAJA, submitted a Marketing Authorization Application (MAA) for PF708 to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Subject to applicable regulatory approvals, PF708 will be commercialized in Europe and other jurisdictions by Alvogen's current and/or future commercialization partners and including Theramex in Europe, SAJA, a Tamer Group company in MENA, JAMP Pharma in Canada, Kamada Ltd. in Israel, and Pharmbio Korea, Inc. in South Korea. Alvogen is responsible for overseeing any clinical development, regulatory, litigation, commercial manufacturing or commercialization activities of its partners in these jurisdictions. We are eligible to receive additional upfront and milestone payments of $1.5 million for the EU, MENA and ROW agreements, and we may also be eligible to receive up to 60% of Alvogen's gross profit derived from product sales, if approved, depending on geography and cost of goods sold. In connection with the October 2019 FDA approval of PF708, we earned a $2.5 million milestone payment under our collaboration with Alvogen payable upon Alvogen's receipt of notice of NDA approval.

In April 2018, we and China NT Pharma Group Company Ltd. (NT Pharma) entered into a Development and License Agreement (NT Pharma Agreement), pursuant to which 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. In accordance with the agreement, we received a payment of $2.5 million upon signing the NT Pharma Agreement and may be eligible to receive additional payments of up to $22.5 million based on the achievement of certain development, regulatory, and sales-related milestones. We may also be eligible to receive double-digit royalties on net sales of PF708. NT Pharma is responsible for any further development required to achieve regulatory approval as well as commercialization activities in the applicable territories.

In accordance with regulatory requirements we provided notice of Paragraph IV certification (Notice Letter) to Eli Lilly and Company (Lilly) on February 19, 2019 that PF708 does not infringe any valid claim of the '334 patent. Under the Hatch-Waxman Act, Lilly had 45 days from the receipt of the Notice Letter to file a patent infringement lawsuit against us that would cause a 30-month litigation stay of approval for PF708. On April 11, 2019 we 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. Lilly did not file a lawsuit within this time period, and there was no 30-month litigation stay that delayed approval of the FDA-approved PF708 product.

In May 2019, we entered into an agreement with Alvogen for us to provide PF708 drug substance batches and pen components in exchange for $2.3 million. This product sold to Alvogen was initially manufactured by our CMO for manufacturing process validation purposes as part of the PF708 NDA submission to the FDA for approval.

Jazz Collaboration – multiple hematologic oncology product candidates

In July 2016, we entered into a license and option agreement with Jazz, pursuant to which we and Jazz are developing hematologic oncology products, including PF743 (JZP-458), a recombinant Erwinia asparaginase, and PF745 (JZP-341), a long-acting recombinant Erwinia asparaginase, and Jazz will have the exclusive right to manufacture and commercialize such products throughout the world. In addition, pursuant to the agreement, we have granted Jazz certain other rights to negotiate the exclusive right to develop, manufacture and commercialize throughout the world other hematologic oncology products that are currently or in the future may be developed by us. Both PF743 (JZP-458) and PF745 (JZP-341) are being developed for the treatment of Acute Lymphoblastic Leukemia (ALL) and other hematological malignancies. In the third quarter of 2017, we achieved a process development milestone associated with this collaboration. In December 2017, we and Jazz signed an amended and restated agreement under which we will be eligible to receive an additional $43.5 million in amendment fee and development milestone payments as compared to the 2016 agreement, increasing the total value of upfront, option and amendment fee payments and potential payments for the achievement of development, regulatory and sales-related milestones associated with the collaboration to an aggregate of $224.5 million. We will also continue to be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from

those under the 2016 agreement. In December 2017, as part of the amended and restated agreement, we received a total payment of $18.5 million, consisting of an upfront payment of $5.0 million and a payment of $13.5 million for development achievement. In the second quarter of 2018, we achieved two development milestones and received $0.8 million for successful achievement of process development milestones for PF745. In August 2019, Jazz reported that they completed a Phase 1 study for PF743 (JZP-458). After receiving Fast Track designation from the FDA in October 2019, Jazz announced the initiation of a Phase 2/3 pivotal study for PF743 (JZP-458) in December 2019 and recently announced their intent to submit a Biologics License Application (BLA) with the US FDA as early as the fourth quarter of 2020. In September 2019 and December 2019, we achieved a development milestone and received $11 million and $15 million, respectively, in connection with process development activities for PF745 (JZP-341).

CRM197

We have both licenses and supply agreements in place for CRM197, which 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. We have developed unique CRM197 production strains based on our Pfēnex Expression Technology platform. As a result of our development efforts, we previously entered into commercial licenses for production strains capable of producing CRM197 with both Merck and SIIPL. Merck and SIIPL are using the CRM197 produced via the licensed production strain in multiple clinical and pre-clinical stage products. The clinical stage products currently include Merck's 15-valent pneumococcal conjugate vaccine, PCV-15 (V114), currently in several ongoing Phase 3 clinical studies, and SIIPL's 10-valent pneumococcal conjugate vaccine, Pneumosil®, which achieved WHO Prequalification in December 2019, and a pentavalent meningococcal conjugate vaccine currently in a Phase 3 clinical study. The CRM197 production strains utilized by both Merck and SIIPL are unique and exclusively licensed to each party. The commercial license agreements with Merck and SIIPL contemplate potential maintenance and milestone fees as well as royalties on net sales. Additionally, as part of the SIIPL commercial license agreement, SIIPL supplies both reagent grade and cGMP CRM197 to Pfenex, which supplies the product to vaccine development-focused pharmaceutical partners.

Arcellx Development, Evaluation and License Agreement

We previously entered into a development, evaluation and license agreement with Arcellx which provides access to the P*fē*nex 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, we are 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 a production strain based on the P*fē*nex Expression Technology, as well as royalties on worldwide sales of any such products. We have completed the development of both sparX-1 (PF753) and sparX-2 (PF754) and Arcellx has opted into the commercial license for both production strains. As of December 31, 2019, we have earned $2.4 million in development funding from Arcellx.

Other Pipeline Products

In the third quarter of 2019 we added PF810, a peptide based next generation therapeutic, to our wholly owned pipeline. PF810 is currently in preclinical development.

Collaborations, Joint Development and Licenses

PF708 & Jazz Pharmaceuticals

For a discussion of our collaborations relating to PF708 and our collaborations relating to Jazz Pharmaceuticals, please see "*Business—Our FDA-Approved Product, Our Product Candidates and Collaborations—FDA-Approved PF708 Product"* and *"Business—Our FDA-Approved Product, Our Product Candidates and Collaborations—Jazz Collaboration—multiple hematologic oncology product candidates*," respectively.

The Dow Chemical Company

On November 30, 2009, we entered into a series of agreements with Dow Global Technologies LLC and/or The Dow Chemical Company, or collectively, Dow, including a technology assignment agreement, a technology licensing agreement, and a grant-back and technology license agreement. Under the technology assignment agreement, Dow assigned to us certain patents, know-how and trademarks relating to our *Pfē*nex Expression Technology®. Under the technology licensing agreement, Dow granted us exclusive licenses to exploit certain patents relating to RNA viruses and oral immunization methods (each of which were subsequently terminated), and certain amended recombinant cells, and a non-exclusive license to exploit certain patents relating to production and isolation techniques for peptides and proteins made using our *Pfē*nex Expression Technology®. Under the grant-back and technology license agreement, we granted to Dow exclusive and non-exclusive licenses under certain patents and know-how relating to our *Pfē*nex Expression Technology® to use certain biological materials to make, use and commercialize products in certain fields of use that do not include human therapeutics.

The U.S. Department of Health and Human Services

The development of Px563L and RPA563 is funded by the U.S. Department of Health and Human Services (HHS) through BARDA. In March 2019 the Company received a notice from BARDA advising it of BARDA's decision not to exercise development options for cGMP manufacturing, preclinical studies and Phase 1/2b study readiness in connection with the Company's Px563L and RPA563 novel anthrax vaccine program. Following the receipt of the notice from BARDA and pursuant to discussions with BARDA, the Company deprioritized this program in its portfolio.

Customers

As of December 31, 2019, we had generated revenue from government contracts, service agreements, collaboration agreements, and reagent protein product sales. Our total revenue was $50.3 million, $14.9 million and $28.8 million in 2019, 2018 and 2017, respectively. In 2019 and 2017, our achievement of certain development milestones related to our collaboration agreement with Jazz resulted in significant revenue. Our development and license agreement with Alvogen also resulted in significant revenue in 2019. The advanced development contract we have with BARDA provided additional revenue in 2019, 2018 and 2017.

For the year ended December 31, 2019, Jazz and Alvogen each accounted for more than 10% of our revenue. For the years ended December 31, 2018 and 2017, Jazz and BARDA each accounted for more than 10% of our revenue.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in the European Economic Area, at the European Union and national Member State level, extensively regulate, among other things, the research, development, testing, manufacturing, labeling, packaging, promotion, advertising, storage, distribution, marketing, post-approval monitoring and reporting, and export and import of drugs and biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

BLA/NDA Development and Approval Process

The process generally required by the FDA before a biologic or drug product candidate may be marketed in the United States involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, application which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the proposed drug for each indication;
- preparation of and submission to the FDA of a BLA or NDA after successful completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for substantive review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the biologic product in the United States.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical studies to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices (cGCPs), which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each clinical protocol and any subsequent protocol amendments must be submitted to the FDA as part of the IND, and an IRB for each site where the study is conducted must also approve the study. The IRB must monitor the study until completed. There are also requirements governing the registration of ongoing clinical studies and the reporting of clinical study results to public registries. Clinical trials typically are conducted in three or four sequential phases, but the phases may overlap or be combined.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical study sites, to generate enough data to evaluate, in a statistically rigorous manner, dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product labeling and approval.
- Phase 4. In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the product. Such post-approval studies are typically referred to as Phase 4 clinical trials.

A pivotal trial is a clinical study that is designed to generate substantial evidence of a product's safety and efficacy that adequately meets regulatory agency requirements to justify the approval of the product. Generally, pivotal trials are Phase 3 trials, but the FDA may accept results from Phase 2 trials if the trial design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust.

Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Furthermore, the FDA, the IRB, or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or data monitoring committee. Such a group recommends to the sponsor whether or not a trial should move forward at designated check points based on access to certain data from the trial. A sponsor may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The NDA or BLA must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee, and the sponsor of an approved NDA or BLA is also subject to annual program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application has been granted priority review because the proposed drug addresses an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often extended by FDA requests for additional information or clarification. Generally, the FDA reviews an NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's quality and purity.

Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, clinical data, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA is required to refer an application for a product with active ingredients that have not been previously approved to an advisory committee or explain why such referral was not made. The FDA also can seek advice from an advisory committee at its own discretion when an NDA or BLA presents scientific, technical, or policy questions on which the agency believes it would benefit from the perspectives of outside experts. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The development, testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we and our partners may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA or NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product under the conditions of use described in the product's prescribing information. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data, an additional pivotal Phase 3 trial or trials, and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical trials or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The FDA may also approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to assure that the benefits of the drug outweigh its risks. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval.

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, many changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for marketed products. Manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies enforce the laws and regulations prohibiting the promotion of unapproved uses, and a company that is found to have improperly promoted unapproved uses may be subject to significant enforcement action and liability.

The FDA may withdraw or suspend approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in a variety of consequences, including revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- adverse publicity, fines, untitled or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

505(b)(2) New Drug Applications

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved branded product by demonstrating the proposed generic product's sameness to the approved drug. Additionally, a pharmaceutical manufacturer may, under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), file a new drug application (NDA) that relies on studies not conducted by the applicant and for which the applicant has not obtained a right of reference as part of the data demonstrating the product's safety and effectiveness. Often, this is done by relying on FDA's previous approval of a product to which the proposed drug is similar (but for which there are differences that preclude an ANDA). Among other things, this kind of reliance avoids unnecessary duplication of studies performed on a previously approved ("reference" or "listed") drug that can reasonably be extrapolated to the proposed product. We pursued a Section 505(b)(2) regulatory pathway for our FDA-approved PF708 product; the NDA references Forteo (teriparatide), which is marketed by Eli Lilly for the treatment of osteoporosis, as a listed drug.

An NDA sponsor must list with the FDA patents that claim the subject product (the drug substance or product formulation) or an FDA-approved method of using the product. Those patents are published in the Orange Book with the product listing. A 505(b)(2) NDA referencing a listed drug must contain one of the following certifications regarding each of the patents listed in the Orange Book with the referenced product: (1) that no such patent information has been listed in the Orange Book, referred to as a Paragraph I Certification; (2) that such patent has expired, referred to as a Paragraph II

Certification; (3) the date on which such patent expires, referred to as a Paragraph III Certification; or (4) that such patent is invalid or will not be infringed by the manufacture, use or sale of the drug product for which the application is submitted, referred to as a Paragraph IV Certification. With regard to patents that claim a method of use, the applicant may instead submit a "section viii" statement certifying that the proposed labeling does not contain any language regarding the patented method of use; this typically reflects the sponsor having "carved out" any such labeling. A Paragraph III Certification conveys that the applicant will wait to obtain approval until the subject patent expires. A Paragraph IV Certification is a challenge to the ability of the subject patent to prevent approval of the proposed product. An applicant making a Paragraph IV Certification must provide notice of the patent challenge to the owner of the subject patent and to the reference product sponsor. If, with 45 days of the Paragraph IV notice, either of those entities files a lawsuit alleging patent infringement, the FDA is prohibited from approving the 505(b)(2) NDA for 30 months (or a shorter period if the patent expires or there are certain settlements or judicial decisions in the patent litigation).

Additionally, a 505(b)(2) NDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced drug has expired. These exclusivities include new chemical entity, or NCE, exclusivity, which is awarded to a product that contains an active moiety that has not previously been approved by the FDA. An "active moiety" is the molecule or ion responsible for the drug substance's physiological or pharmacologic action. NCE exclusivity provides a five-year period during which the FDA cannot accept for filing any ANDA or 505(b)(2) NDA for a product containing the same active moiety. The five-year period is shortened to four years if the proposed application contains a Paragraph IV Certification. A drug may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted or sponsored by the applicant. This exclusivity precludes the FDA granting final approval to any ANDA or 505(b)(2) NDA that references the product until three years after the product was approved. Unlike NCE exclusivity, however, three-year exclusivity does not prevent the FDA accepting and reviewing the ANDA or 505(b)(2) NDA.

Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of our product candidates, the term of some of our U.S. patents may be eligible for limited extension under the Hatch-Waxman Act. For a product that represents the first permitted commercial marketing of an active ingredient, we may have the opportunity to extend the term of a patent that claims the drug or a method of using or manufacturing the drug. The extension cannot exceed five years or extend the patent term beyond fourteen years after approval, but it is calculated generally as half the time between the effective date of an IND and the submission date of the NDA or Biologics License Application, or BLA, plus the time between the submission date and approval of the application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA or BLA.

Abbreviated Licensure Pathway of Biological Products as Biosimilar or Interchangeable

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA and created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological product. Such a product, known as a "biosimilar," is a biological product that is highly similar to a previously approved biological (the "reference product"), notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences in safety, purity, and potency between the biosimilar and the reference product. The abbreviated approval pathway is intended to allow the biosimilar to be approved in part in reliance on what is known about the reference product. In addition, if certain additional conditions are shown, a biosimilar product can be designated as "interchangeable" with the reference product, meaning that the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. To date, the FDA has not approved any biosimilar product as being interchangeable to the reference product. FDA approval is required before a biosimilar may be marketed in the United States. Because of complexities associated with the large and intricate structures of biological products and the processes by which such products are manufactured, FDA has discretion over the kind and amount of scientific evidence—including laboratory, preclinical and/or clinical data—required to demonstrate biosimilarity to a licensed biological product. The FDA considers the totality of the evidence provided by a sponsor to support a demonstration of biosimilarity and recommends that sponsors use a stepwise approach in the development of their biosimilar products.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the reference product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the reference product. The FDA cannot approve a biosimilar application for twelve years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application for four years from the date of first licensure of the reference product. A reference product may also be entitled to other types of exclusivities, such as orphan drug exclusivity (which provides seven years of exclusivity against approval of the same drug intended to treat the same disease or condition) or pediatric exclusivity (which adds six months to existing exclusivities, among other things). The first biosimilar product determined to be interchangeable with a reference product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use.

In addition, the BPCIA includes a detailed framework for addressing potential patent disputes between the sponsors of a biosimilar product and the reference product.

While it may be possible for a biosimilar applicant and reference product sponsor to settle any patent disputes prior to approval, patent litigation may delay the ability of a biosimilar applicant to commercially launch its product.

We anticipate that the contours of the BPCIA will continue to be defined as the statute is implemented over a period of years. This likely will be accomplished by a variety of means, including decisions related to the statute by relevant federal courts, FDA issuance of guidance documents, and FDA decisions in the course of considering specific applications.

European Economic Area Regulation

In the European Economic Area, or EEA, comprising the European Union plus Iceland, Liechtenstein and Norway, the information that must be submitted to the European Medicines Agency, or EMA, or to the competent authorities in the relevant European Union Member States varies depending on whether the biological medicinal product is a new product, whose quality, safety and efficacy has not previously been demonstrated in humans or a product whose known biological active substance and certain other properties are similar to those of a previously authorized (reference) biological medicinal product. The European Directive 2001/83/EC as amended defines a medicinal product as any substance or combination of substances:

- presented as having properties for treating or preventing disease in human beings; or
- which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Directive 2001/83/EC as amended further defines the category of biological medicinal products as:

- a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterization and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control.

Examples of biological medicinal products include recombinant proteins, monoclonal antibodies, vaccines, and products derived from human blood or plasma.

Approval of New Biological Medicinal Products

In the EEA, all medicinal products (biological or not) can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MA:

The Centralized MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the CHMP of the EMA, is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as medicinal products derived from certain biotechnology processes (including biotechnology-derived proteins such as the ones we make), orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes and auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

More concretely, the requirements for centralized marketing authorization of a new biological medicinal product in the EEA generally include but are not limited to:

- submission of the results of pharmaceutical (physico-chemical, biological or microbiological) tests and preclinical (toxicological and pharmacological) tests through laboratory tests and animal studies in compliance with Good Laboratory Practice, or GLP;
- submission of the results of adequate and well-controlled clinical trials to establish the quality, safety and efficacy of the product for each indication;
- a statement to the effect that clinical trials carried outside the European Union meet the ethical requirements of Directive 2001/20/EC;
- submission of an application for marketing authorization to the EMA or to the competent authorities of the relevant EU Member States;
- establishment of the applicant in the EEA;
- description of the qualitative and quantitative particulars of all constituents of the medicinal product;
- evaluation of the potential environmental risks posed by the medicinal product;
- description of the manufacturing method, description of the control measures employed by the manufacturer, and a document showing that the manufacturer is authorized in his own country to produce medicinal products;
- a summary of product characteristics, therapeutic indications, adverse reactions, dosage, pharmaceutical form, route of administration and expected shelf life;
- additional information for specific classes of medicinal products, such as a Vaccine Antigen Master File documentation for vaccine products;
- a summary of the pharmacovigilance system, the risk management plan describing the risk-management system, and proof that the applicant has the services of a qualified person responsible for pharmacovigilance as well as the necessary means for fulfilling the EU pharmacovigilance obligations including the notification of any adverse reaction suspected of occurring either in the EEA or in a third country; and
- review by EMA's CHMP or the competent authorities in the relevant European Union Member States and approval of the marketing authorization application.

Preclinical tests include laboratory evaluations of the product's structure, purity and biological activity, as well as animal studies to determine toxicity and pharmacology. An Investigational Medicinal Product (IMP) sponsor must submit a Clinical Trial Application (CTA) to the competent authority prior to initiation of human clinical trials. The application process to perform a clinical trial in the EEA is governed on a country-by-country basis. A sponsor must apply in each country in which it intends to conduct any part of a human clinical trial. While the process is similar in most countries, additional materials may be required in certain instances. For example, in many, but not all European countries, a sponsor must submit a copy of the insurance coverage obtained to cover the clinical study. Australia and New Zealand adhere to EMA guidelines with respect to the regulation of IMPs and clinical trials.

Assuming successful completion of the required clinical testing and having met all criteria set forth by Directive 2001/83/EC and Regulation (EC) No 726/2004, the applicant may choose to proceed with submission of marketing authorization application. If the application is accepted for review in the Centralized Procedure, within 210 days (excluding clock stops), the EMA's CHMP will issue an opinion on whether the conditions for granting marketing authorization are satisfied. During the review period, the scientific committees will review the scientific data, may request for independent testing of the medicinal product, its starting materials, or other constituent materials, may request supplemental information from the applicant, may request for proof of cGMP compliance of the manufacturer, and may request for said manufacturing facilities to be inspected.

Accelerated Review

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA's CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Approval of Similar Biological Medicinal Products

Similar biological medicinal product applications of medicinal products authorized via the Centralized Procedure have automatic access to the Centralized Procedure. A similar biological medicinal product, also known as a biosimilar, is a product that is similar to a biological medicine that has already been authorized, the so-called "reference medicinal product". The active substance of a similar biological medicinal product is a known biological active substance and similar to the one of the reference medicinal product. A similar biological medicinal product and its reference medicinal product are expected to have the same safety and efficacy profile and are generally used to treat the same conditions.

The similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy. The minimum expectation of data supplied with the application will include pharmaceutical, chemical, and biological preclinical data, as well as bioequivalence and bioavailability (bodily distribution and concentration) clinical data. The type and amount of additional information, such as toxicological and other preclinical and clinical data, is determined on a case-by-case basis.

European Union legislation provides (with respect to reference products for which a marketing authorization was applied for after October 30, 2005 under the Decentralized, Mutual Recognition and national procedures, or after November 20, 2005, for products authorized under the Centralized Procedure) for an eight-year period of data protection and ten-year period of market exclusivity for medicinal products which received marketing authorization in accordance with, respectively, Directive 2001/83/EC as amended or Regulation (EC) No 726/2004 as amended. The provisions also state that if, during the first eight years of authorization, the holder obtains an authorization for one or more new therapeutic indications which are deemed to have significant clinical benefit as compared to existing therapies, the original market exclusivity can be extended to a maximum of 11 years. The data and market exclusivity periods start from the date of the initial authorization, which for reference medicinal products authorized through the Centralized Procedure is the date of notification of the marketing authorization decision to the marketing authorization holder of the reference product.

Post-Approval Requirements

Once granted, initial marketing authorization of a medicinal product is valid for five years. The authorization may be renewed after five years on the basis of a reevaluation of the risk-benefit balance. At that point, once renewed, the marketing authorization is valid indefinitely or, if justified on grounds of pharmacovigilance, may be restricted to an additional five-year authorization period.

Marketing authorization holders are required to maintain a pharmacovigilance system and to maintain detailed records of all suspected adverse reactions in the EEA or in a third country. Serious suspected adverse reactions are to be communicated to the appropriate EEA regulatory authorities no later than 15 days after receipt of the information. EEA regulations require periodic safety reporting leading up to and following marketing authorization, based on a defined schedule, for as long as the product is marketed, or when immediately requested by regulatory authorities. An increase in incidents of adverse events or any cause for a change in opinion by the EMA pertaining to the risk-benefit balance may lead to suspension, variation, or revocation of marketing authorization and would severely impact our business.

EEA regulations also stipulate that regulators, such as the Competent Authorities of the EEA Member States, independently or coordinated by the EMA, may carry out repeated or unannounced inspections of the medicinal product manufacturer or at the premises of the marketing authorization holder, regarding compliance with cGMP principles and guidelines. Compliance issues identified at our facilities or at third-party manufacturers may disrupt clinical or commercial production or distribution or require substantial resources to correct. This may result in the delay of clinical trials or commercial product launch. Discovery or problems with the product or the failure to comply with applicable requirements may result in restrictions on a product, the manufacturer or the holder of a marketing authorization, including withdrawal or recall of the product from the market or other EMA or EEA Competent Authority initiated action that could delay or prohibit future marketing. Additionally, new government regulations may be established that could delay or prevent regulatory approval of our products under development.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of therapeutic equivalent products for branded prescription drugs. The ACA contains provisions that may reduce the profitability of drug products, including, for example, increased the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care plans, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Furthermore, the current presidential administration and Congress are expected to attempt changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act" or the "ACA"), including as a result of current and future executive orders, legislative actions, and court cases. The impact of those changes on us is currently unknown. But, any changes to the ACA are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulations in the United States may have on our business.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we and our collaboration partner receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on cost containment measures in the United States and other countries has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we and our collaboration partners obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws that may impact, among other things, our or our collaboration partners' proposed sales, marketing and education programs. The laws that may affect our operations include:

- The U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual for, or the purchase or recommendation of any good or service for which payment may be made, in whole or in part, by federal healthcare programs, such as Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, purchasers and formulary managers on the other. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent, to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- Federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using or causing to be made or used a false record or statement material to an obligation pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring FCA qui tam actions on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), imposes criminal and civil liability for, among other things executing a scheme to defraud any healthcare benefit program and knowingly and willfully falsifying, concealing or covering up a material fact in connection with the delivery of or payment for healthcare benefits, items or services. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA;
- The federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value provided to physicians and teaching hospitals as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws.

We and our collaboration partners also may be subject to the Foreign Corrupt Practices Act, or FCPA, which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards implemented to discourage improper payments or offers of payments by our or our collaboration partners' employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us or our collaboration partners, any of which would likely harm our or our collaboration partners' reputation, business, financial condition and result of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Hazardous Materials

Our research and development processes may involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Competition

The development and commercialization of protein therapeutics is highly competitive. While we believe that our *Pf*ēnex Expression Technology®, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, generic pharmaceutical, specialty pharmaceutical and biotechnology companies. In the event that we and our collaboration partners were to market and sell any of our biopharmaceutical products, we would face competition from the companies producing branded reference drugs, as well as biosimilars, therapeutic equivalents, and other products that would compete with our product candidates, if approved. For example, PF708, our FDA approved product, may face competition from the reference product sponsor, Eli Lilly and Company, or other competition from companies like Teva and Gedeon Richter Plc., and from Amgen Inc. and Radius Health, Inc. as developers of novel products. For example, in April 2017, the FDA approved Radius Health's TYMLOS®, and in April 2019 approved Amgen's Evenity (romosozumab), each of which could potentially compete with PF708. Key competitive factors affecting the success of our product candidates, if approved, are likely to be price, the level of biosimilar, therapeutic equivalent and novel product competition and the availability of coverage and reimbursement from government and other third-party payors.

Similarly, our novel vaccine development programs face substantial competition from major pharmaceutical and other biotechnology companies that are actively working on improved and novel vaccines. We believe that our primary competitors include Emergent BioSolutions, Inc. and Altimmune, Inc. These companies are receiving funding from BARDA for the development of next generation anthrax vaccines. All of our novel vaccine efforts will face competition for limited government funding from other non-vaccine defensive measures as well, including medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

Further, many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than we are in obtaining approval for treatments and achieving widespread market acceptance. Our competitors' treatments may be more effective or more effectively marketed and sold than any treatment we may commercialize and may render our treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. For further discussion of risks related to government contracting, see the discussion in Item 1A, "*Risk Factors*" in this Form 10-K.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject registration for clinical studies, as well as in acquiring technologies complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Sales and Marketing

To date, PF708 is our only FDA-approved product under 505(b)(2) regulatory pathway, with Forteo as the reference drug. None of our other product candidates have received marketing authorization from any regulatory agency. For our product candidates, we generally seek to license rights regionally to commercially proficient partners. To the extent that we retain commercial rights to product candidates, we may use an internal sales force to commercialize products for which we may receive marketing approvals in territories in which we believe it is possible to access the market through a focused, specialty sales force.

In June 2018, we and Alvogen entered into a Development and License Agreement (US Alvogen Agreement) pursuant to which Alvogen has the exclusive right to commercialize and manufacture PF708 in the United States. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. In February 2019 we and Alvogen expanded our collaboration, granting Alvogen exclusive rights to commercialize and manufacture PF708 in the EU, certain countries in the MENA, and the ROW territories (the latter defined as all countries outside of the EU, US and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). We believe this collaboration leverages Alvogen's established international experience and expertise in regulatory, IP and supply chain activities, as well as its established network of specialty pharmaceutical companies to conduct sales and marketing activities in these regions.

Alvogen submitted a centralized application to the European Medicines Agency (EMA) for PF708 on May 6, 2019, and the filing was accepted by the EMA on May 23, 2019. We believe that PF708 could be approved in the EU as early as the second half of 2020, pending marketing authorization by the European Commission under the EU centralized procedure and other factors. In October 2019, Alvogen's partner SAJA, submitted a Marketing Authorization Application (MAA) for PF708 to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Subject to applicable regulatory approvals, PF708 will be commercialized in Europe and other jurisdictions by Alvogen's current and/or future commercialization partners including Theramex in Europe, SAJA, a Tamer Group company in MENA, JAMP Pharma in Canada, Kamada Ltd. in Israel, and Pharmbio Korea, Inc. in South Korea. Alvogen is responsible for overseeing any clinical development, regulatory, litigation, commercial manufacturing or commercialization activities of its partners in these jurisdictions. We are eligible to receive additional upfront and milestone payments of $1.5 million for the EU, MENA and ROW agreements, and we may also be eligible to receive up to 60% of Alvogen's gross profit derived from product sales, if approved, depending on geography and cost of goods sold. In connection with the October 2019 FDA approval of PF708, we earned a $2.5 million milestone payment under our collaboration with Alvogen payable upon Alvogen's receipt of notice of NDA approval.

In April 2018, we and China NT Pharma Group Company Ltd. (NT Pharma) entered into a Development and License Agreement (NT Pharma Agreement), pursuant to which 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. In accordance with the agreement, we received a payment of $2.5 million upon signing the NT Pharma Agreement and may be eligible to receive additional payments of up to $22.5 million based on the achievement of certain development, regulatory, and sales-related milestones. We may also be eligible to receive double-digit royalties on net sales of PF708. NT Pharma is responsible for any further development required to achieve regulatory approval as well as commercialization activities in the applicable territories.

Upon marketing approval for products developed under our collaboration with Jazz, Jazz will assume responsibility for the manufacturing and commercialization of certain hematologic oncology products globally.

We have sales and marketing capabilities to support our commercial efforts for our platform partnership and CRM197 sales.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek to obtain and maintain patents for any patentable aspects of our platform technology and our products or product candidates, their methods of use and any other inventions that are important to the development of our business. Our success depends substantially on our ability to obtain and maintain patent and other proprietary protection for our technology and product candidates, to defend and enforce our patents to prevent others from infringing our proprietary rights, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology and product candidates that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position relating to our platform technology and product candidates.

We are the owner or licensee of a portfolio of patents and patent applications and possess substantial know-how and trade secrets which protect various aspects of our business. As of December 31, 2019, we are the sole owner of a patent portfolio that consisted of a total of 24 U.S. issued patents and six U.S. non-provisional patent applications that provide material coverage for our platform technology and our lead product candidates as well as foreign granted and pending patent applications which are counterparts to certain of the foregoing U.S. patents and patent applications. Our U.S. issued patents expire during the time period beginning in 2023 and ending in 2036. Our owned and exclusively licensed patent portfolio includes claims directed to:

- methods for bacterial protein production and methods for rapid screening of an array of expression systems
- *P. fluorescens* promoter sequences and secretion leader sequences
- auxotrophic marker systems for antibiotic free maintenance of expression plasmids in high cell density cultures,
- improved incorporation of non-natural amino acids
- expression of classes of proteins such as cytokines
- antibody derivatives
- microbial toxins in *P. fluorescens*
- methods and expression strains for production and/or purification of soluble full length human cytokines, Interferon beta and G-CSF
- vaccine antigens recombinant anthrax protective antigen, microbial toxins and toxoids, and the malarial vaccine candidate antigen *P. falciparum* circumsporozoite protein (CSP)
- fusion partners for peptide production

Pursuant to the technology licensing agreement, The Dow Chemical Company, or TDCC, and Dow Global Technologies LLC, or DGTI, also granted to us non-exclusive licenses to U.S. patents and applications and their foreign counterparts covering methods and technologies for recovery of proteins and peptides from *P. fluorescens* cells. In conjunction with the licenses granted by TDCC and DGTI to us under the technology licensing agreement, we also entered into a grant-back and technology license agreement, pursuant to which we granted to TDCC exclusive and non-exclusive licenses under certain patent rights and know-how relating to our *Pf*ēnex Expression Technology® to use certain biological materials to make, use and commercialize products in certain fields of use that do not include human therapeutics. See "*Business—Collaborations, Joint Development and Licenses*" for a detailed description of our agreements with TDCC and DGTI.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to obtain and maintain our proprietary position for our technology will depend on our success in obtaining issued claims that cover our technology and product candidates and being able to enforce those claims against our competitors once granted. We do not know whether any of our pending patent applications will result in the issuance of any patents. Moreover, even our issued patents do not guarantee us the right to practice the patented technology in relation to the commercialization of our product candidates. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of the term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, consultants, advisors, contractors and collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see "*Risk Factors—Risks Relating to Our Intellectual Property.*"

Environmental Matters

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including, small quantities of acetonitrile, methanol, ethanol, ethidium bromide and compressed gases, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We seek to comply with applicable laws regarding the handling and disposal of such materials. Given the small volume of such materials used or generated at our facilities, we do not expect our compliance efforts to have a material effect on our capital expenditures, earnings, and competitive position. However, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages, and suspension of our operations.

Suppliers

We currently rely on, and expect to continue to rely on, contract manufacturers to produce sufficient quantities of our product candidates for use in our clinical trials. With the exception of PF708 for which we have granted Alvogen the exclusive rights to commercialize for select territories, we intend to rely on third parties to manufacture any products that we may commercialize in the future. We have established an internal pharmaceutical development group to develop manufacturing methods for our product candidates, to optimize manufacturing processes, and to select and transfer these manufacturing technologies to our suppliers. We contract with multiple manufacturers to ensure adequate product supply and to mitigate risk.

There currently are a limited number of these manufacturers. Furthermore, some of the contract manufacturers that we have identified to date only have limited experience at manufacturing, formulating, analyzing and packaging our product candidates in quantities sufficient for conducting clinical trials or for commercialization. For further discussion of risks related to government contracting, see the discussion in Item 1A, "*Risk Factors*" in this Form 10-K.

Manufacturing

We do not own or operate facilities for cGMP manufacturing of any products. We intend to rely on Alvogen for PF708 manufacturing. We have personnel with experience in the development of United States and European Union cGMP-compliant processes and management of Contract Manufacturing Organizations (CMOs), to oversee the technology transfer to the manufacturers of PF708, and other product candidates that we may develop. Our manufacturing processes employ standard equipment common to CMOs. Our processes also use common and widely available materials, and our well-established manufacturing procedures are robust, scalable, and readily transferable to support our clinical development programs and commercialization of our products. We believe that there are alternate sources of supply that can satisfy our clinical and commercial requirements, although we cannot be certain that identifying and establishing relationships with such sources, if necessary, would not result in significant delay or material additional costs. For a discussion of risks related to our sources and availability of supplies, see *"Risk Factors—Risks Relating to our Reliance on Third Parties—We rely on third-party suppliers, and in some instances a single third-party supplier, for the manufacture and supply of certain materials in our protein production services, and these suppliers could cease to manufacture the materials, go out of business or otherwise not perform as anticipated."*

In each of our agreements with contract manufacturers, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contract manufacturer intellectual property for purposes of exploiting the products that are the subject of the agreement, and in a few instances, we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. In each contract, we have the right to terminate for convenience. The agreements also contain typical provisions for both parties to terminate for material breach, and bankruptcy and insolvency.

Protein Production

Utilizing our *Pf*ēnex Expression Technology®, we provide protein production and process development services to third parties on a fee for service basis in support of the development of novel biopharmaceuticals. Pursuant to a license agreement, the third-party licenses a production strain from us and then pays us an up-front payment, milestone payments based upon clinical progression and regulatory filings, and a royalty based on product net sales. Our protein production efforts enable us to maximize the utilization of our *Pf*ēnex Expression Technology®, expand our institutional knowledge and generate revenue.

Seasonality

Our revenues are not seasonal in nature.

U.S. Government Contracts

Revenue from U.S. Government Contracts varies by year. A portion of our government business is subject to renegotiation of profits or termination of contracts or subcontracts at the election of the U.S. Government. In addition to contract terms, we must comply with procurement laws and regulations relating to the formation, administration, and performance of U.S. Government contracts. Failure to comply with these laws and regulations could lead to the termination of contracts at the election of the government or the suspension or debarment from U.S. Government contracting or subcontracting. U.S. Government revenue as a percentage of our total revenue was approximately 3%, 32% and 20% for fiscal years 2019, 2018 and 2017, respectively. For further discussion of risks related to government contracting, see the discussion in Item 1A, "*Risk Factors*" in this Form 10-K.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2019, we had 81 employees, including a total of 21 employees who hold Ph.D. or other doctoral degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Backlog

We have no material backlog of orders.

Corporate Information

We were founded in November 2009 as a Delaware corporation spun out of The Dow Chemical Company. Our principal executive offices are located at 10790 Roselle St., San Diego, California 92121 and our telephone number is (858) 352-4400. Our website is www.pfenex.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC). Our SEC reports can be accessed through the investor relations page of our website located at http://pfenex.investorroom.com.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on our investor relations page of our website. Corporate governance information, including our board committee charters, code of ethics and conduct, and corporate governance principles, is also available on our investor relations page of our website located at http://pfenex.investorroom.com/corporate-governance. In addition, we use 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. We encourage our investors and others to 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.

The contents of our website and the information we post through social media are not a part of, and are not incorporated by reference into, this Annual Report on Form 10-K or any other report or document we file with the SEC, and any references to our website and social media sites are intended to be inactive textual references only.

Pfenex™, Pfenex Biopharmaceuticals™ the Pfenex Biopharmaceuticals logo, and *Pf*enex Expression Technology® appearing in this Annual Report on Form 10-K are trademarks of Pfenex and are the property of Pfenex Inc. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 10-K are the property of their respective holders.

Information about our Executive Officers

The following table identifies certain information about our executive officers as of March 2, 2020.

Name	Age	Position
Evert B. Schimmelpennink	48	Chief Executive Officer, President, Secretary and Chief Financial Officer
Patrick K. Lucy	52	Chief Business Officer
Dr. Shawn A. Scranton	56	Chief Operating Officer
Dr. Martin B. Brenner	49	Chief Scientific Officer

Evert B. Schimmelpennink has served as our Chief Executive Officer, President and Secretary since August 2017 and as our Chief Financial Officer since November 2019. Prior to his appointment, Mr. Schimmelpennink served as the Chief Executive Officer of Alvotech, a biosimilar development company from 2015 to July 2017. From September 2015 to November 2015, Mr. Schimmelpennink served as Vice President—Global Sterile Injectables of Pfizer Inc., a pharmaceutical company. Prior to that, Mr. Schimmelpennink served as Vice President—Global Generics from 2012 to 2015 and Director of Specialty Injectable Pharma Marketing EMEA & Director of Distributor Operations EMEA from 2011 to 2012 of Hospira, Inc., a pharmaceutical company. From 2002 to 2011, Mr. Schimmelpennink held various roles at Synthon BV, a generics medicine company, including Vice President Marketing and Sales from 2008 to 2011. From 1997 to 2002 he held various roles with Numico NV, a Dutch maker of baby foods and nutritional bars and shakes, including International Product Manager from 2000 to 2002 and Researcher Product Development from 1999 to 2000. Prior to Numico, Mr. Schimmelpennink served as a vaccine technologist at the Dutch National Institute for Public Health and the Environment from 1998 to 1999. Mr. Schimmelpennink received a master's in bioprocess engineering from the Wageningen University in the Netherlands. The board of directors believes Mr. Schimmelpennink is qualified to serve as a director because of his extensive knowledge of our industry and his prior and current experience as a senior officer of healthcare companies.

Patrick K. Lucy has served as our Senior Vice President, Chief Business Officer since 2014. Mr. Lucy also served as our Interim Chief Executive Officer, President and Secretary from January 2017 to August 2017, when Mr. Schimmelpennink was appointed to those roles. Mr. Lucy previously served as our Vice President of Business Development and Marketing between 2009 and 2014. Prior to joining us, Mr. Lucy held the position of Director of Business Development at DowPharma, a business within The Dow Chemical Company, a chemicals manufacturer, from 2002 to 2009. From 1999 to 2002, he held the position of Director of Business Development at Collaborative BioAlliance, Inc., a biotechnology company, which was acquired by The Dow Chemical Company. From 1998 to 1999, Mr. Lucy worked as a Validation Manager and Capital Project Manager and from 1996 to 1998, as a Quality Control Biochemistry Supervisor at Lonza Biologics Inc., a chemicals and biotechnology company. From 1991 to 1996, Mr. Lucy held various positions at Repligen Corporation, a life sciences company. Mr. Lucy currently serves on the Scientific Advisory Board of Explorations in Global Health (ExGloH) a division within the Leidos Health Group. Mr. Lucy holds a bachelor's degree in Biology from Villanova University.

Dr. Shawn A. Scranton has served as our Senior Vice President, Chief Operating Officer since October 2018. He previously served as Chief Scientific Consultant for Sentynl Therapeutics, Inc. a wholly owned subsidiarity of Zydus-Cadila, a pharmaceutical company, from 2017 to 2018. From 2015 to 2017, Dr. Scranton served as Senior Vice President, Chief Scientific Officer at Sentynl Therapeutics, Inc., a pharmaceutical company. Prior to Sentynl, Dr. Scranton served as Consultant, Managing Director at Strategic Therapeutic Solutions, LLC, a pharmaceutical consulting company, and from 2007 to 2012, Dr. Scranton served as VP, Scientific Operations at Victory Pharma, Inc., a specialty pharmaceutical company. Dr. Scranton served as Sr. Director of Translational Medicine at Kalypsys, Inc., a pharmaceutical company, from 2005 to 2007, and as Director of Clinical Research/Program Director at Salmedix Corporation, a drug development company, from 2001 to 2005. From 1998 to 2000, Dr. Scranton served as Senior Clinical Research Scientist, Clinical Development at Dura Pharmaceuticals, Inc., a pharmaceutical company. Dr. Scranton holds a Doctor of Pharmacy from the University of the Pacific School of Pharmacy (1994) and a B.A. in Animal Physiology from the University of California, San Diego (1988).

Dr. Martin B. Brenner has served as our Senior Vice President, Chief Scientific Officer since March 2019. From 2017 to 2018, Dr. Brenner served as Chief Scientific Officer at Recursion Pharmaceuticals, Inc., a biotechnology company. From 2016 to 2017, Dr. Brenner served as Vice President and Head of Research and Early Development at Stoke Therapeutics, Inc., a biotechnology company. From 2013 to 2016, Dr. Brenner served as Executive Director, Diabetes & NASH, and Chair of Diabetes & NASH Early Discovery Unit at Merck Research Laboratories of Merck & Co., Inc., a pharmaceutical company. From 2012 to 2013, Dr. Brenner served as Senior Director, Head of Bioscience, CVMD at AstraZeneca PLC, a pharmaceutical company. From 2009 to 2012, Dr. Brenner served as an Associate Research Fellow for the Diabetes Prevention and Remission Group at Pfizer Inc., a pharmaceutical company. From 2003 to 2009, Dr. Brenner served as Senior Research Scientist for the Diabetes Drug Hunting Team at Eli Lilly and Company, a pharmaceutical company. Dr. Brenner holds a Ph.D. in Pharmacology from the Veterinary School of Hannover in Hannover, Germany and a DVM from Veterinary School of Ludwig-Maximilians-University in Munich, Germany.

Item 1A. ***Risk Factors***

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Relating to our Financial Condition and Need for Additional Capital

We have a limited operating history and expect to generate significant losses for the foreseeable future. If we or our collaboration partners are not successful in completing the development of our product candidates or in commercializing the FDA-approved PF708 product, PF708 or our other product candidates and generating significant revenue, we will not be profitable.

With the exception of three years, we have incurred annual net operating losses since inception, and to date have generated only limited revenue from government contracts, service agreements, collaboration agreements, and reagent protein product sales. We have recognized net income of $1.1 million and net loss of $39.6 million for years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $197.7 million and net working capital of $54.1 million. To date, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. As of December 31, 2019, we had capital resources consisting of cash and cash equivalents of $55.6 million. As we continue to develop and invest more resources into the development and commercialization of our product candidates, our net operating losses will continue over the next several years. For Pfenex to become profitable, Alvogen must successfully commercialize and manufacture the FDA-approved PF708 product and we must successfully develop and obtain regulatory approval for additional product candidates, and effectively manufacture and commercialize the additional product candidates we develop. In June 2018 and February 2019, we entered into agreements with Alvogen in which we granted Alvogen exclusive rights to commercialize PF708 in the United States, MENA, and ROW. In October 2019, we received FDA approval for PF708 and Alvogen is responsible for marketing the FDA-approved PF708 product in the United States. The loss for any reason of Alvogen as a key partner could have a significant and adverse impact on our business. If we are unable to retain Alvogen as a partner on commercially acceptable terms, PF708 may not be commercialized as planned and there could be delays in or suspension of the U.S. commercial launch of the FDA-approved PF708 product. In May 2019, Alvogen, our collaboration partner, submitted a centralized application to the EMA for PF708 and the application was accepted for review. In October 2019, Alvogen's partner SAJA submitted a Marketing Authorization Application (MAA) for PF708 to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA).

With respect to the FDA-approved PF708 product, our future revenue will depend upon the performance of our collaboration partner, Alvogen, whether we obtain, in a timely manner or at all, an "A" therapeutic equivalence designation for the FDA-approved PF708 product that may allow such product to be automatically substituted for Forteo depending on applicable laws and policies within each of the 50 states, the size of any markets in which PF708 or such other product candidate may receive approval, and our and our collaboration partners' ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for the FDA-approved PF708 product, PF708 and our other product candidates in those markets. We, Alvogen, and our other collaboration partners may never succeed in these activities and therefore may never generate revenue that is significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

We will require substantial additional funds to seek and obtain regulatory approval and commercialize our current product candidates and, if additional capital is not available, we may need to limit, scale back or cease our operations.

Since our inception, a significant portion of our resources have been dedicated to the preclinical and clinical development of the FDA-approved PF708 product, PF708, and our other product candidates. We believe that we will continue to expend substantial resources for the foreseeable future for the preclinical and clinical development of our current product pipeline, and the development of any other indications and product candidates we may choose to pursue, either alone or with a strategic collaboration partner. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical studies, and manufacturing and supply as well as marketing and selling any products that receive marketing authorization. Because the outcome of any clinical trial is highly uncertain and we are

substantially dependent on third parties, including Alvogen, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of the FDA-approved PF708 product, PF708, and our other product candidates and preclinical products under development. We may also need to obtain substantial additional sources of funding to develop our other product candidates and our preclinical products under development as currently contemplated. If such additional funding is not available on favorable terms or at all, we may need to delay or reduce the scope of our product candidate development programs, or grant rights in the United States, as well as outside the United States, to our product candidates to one or more partners.

We believe that our available cash and cash equivalents, including the proceeds from any revenue from our government contracts, service agreements, collaboration agreements, and reagent protein product sales will be sufficient to meet our anticipated cash needs for at least the next twelve months. However, changing circumstances and risks and uncertainties associated with our product development efforts may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected. Our future capital requirements may vary depending on the following:

- the timing and extent of spending on our research and development efforts;
- our ability to enter into and maintain collaboration, licensing, commercialization and other arrangements and the terms and timing of such arrangements;
- our ability to retain Alvogen as a collaboration partner for the FDA-approved PF708 product and PF708 on commercially acceptable terms;
- the cost of manufacturing and commercialization activities, if any;
- the receipt of any collaboration or milestone payments;
- the scope, rate of progress, results and FDA acceptance of the results, and cost of our clinical trials, preclinical testing and other related activities for our product candidates;
- the emergence of competing technologies or other adverse market developments;
- the time and costs involved in seeking and obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- whether we and Alvogen obtain, in a timely manner or at all, an "A" therapeutic equivalence designation for the FDA-approved PF708 product that may allow such product to be automatically substituted for Forteo depending on applicable laws and policies within each of the 50 states;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from the FDA-approved PF708 product, PF708, and any other potential products;
- the degree and rate of market acceptance and coverage and reimbursement by payors of the FDA-approved PF708 product, PF708 and any of our other product candidates launched by us or our collaboration partners;
- the potential expansion of our sales and marketing activities; and
- the potential acquisition and in-licensing of other technologies, products or assets.

If we were to experience any delays or encounter issues with any of the above, including with respect to obtaining an "A" therapeutic equivalence designation for the FDA-approved PF708 product, Alvogen's commercial launch of the FDA-approved PF708 product in the U.S., clinical holds, failed studies, inconclusive or hard-to-interpret results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional major studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above and delay or suspend revenues.

We may need to raise additional capital to fund our operations in the near future. If we seek additional funding in the future, additional funds may not be available to us on acceptable terms or at all. We may seek to raise additional funds through equity, equity-linked or debt financings. If we raise additional funds through the incurrence of indebtedness, such indebtedness would have rights that are senior to holders of our equity securities and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail the advancement of one or more of our product candidates. We also could be required to seek funds through arrangements with collaboration partners or others that may require us to relinquish rights to some of our technologies or product candidates which we would otherwise pursue on our own.

Our quarterly operating results may fluctuate significantly.

Our operating results are subject to quarterly fluctuations. Our operating results are and will be affected by numerous factors, including:

- variations in the level of expenses related to our development and any future commercialization programs;
- sales by Alvogen of the FDA-approved PF708 product;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- any disruptions to our and our collaboration partners' manufacturers or suppliers due to the effect of exposure to infectious disease and epidemics, including the coronavirus outbreak;
- regulatory developments affecting any of our products; and
- our execution of any service, collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the market price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the market price of our stock to fluctuate substantially.

Risks Relating to our Business and our Industry

Our business operations are dependent upon our senior management team and the ability of our other employees to execute on our business strategy. If we fail to attract, integrate, and keep senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize any product candidates we develop.

Our success depends in part on our continued ability to attract, integrate, retain, and motivate highly qualified management, clinical and scientific personnel, including our ability to develop an effective working relationship among senior management. Our president and chief executive officer, Eef Schimmelpennink, joined us in August 2017; our senior vice president, chief operating officer, Dr. Shawn Scranton, joined us in October 2018; and our senior vice president, chief scientific officer, Dr. Martin Brenner, joined us in March 2019.

As new employees gain experience in their roles, we could experience inefficiencies or a lack of business continuity due to loss of historical knowledge and a lack of familiarity of new employees with business processes, operating requirements, policies and procedures, and we may experience additional costs as new employees gain necessary experience. It is important to our success that these key employees quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected. In addition, the loss of the services of any member of our senior management or our scientific or technical support staff might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business.

We believe that our future success is highly dependent upon the contributions of our senior management, particularly our Chief Executive Officer, Chief Business Officer, Chief Operating Officer, and Chief Scientific Officer, as well as our senior scientists and other members of our senior management team. Employment agreements with our Chief Executive Officer, Chief Business Officer, Chief Operating Officer, and Chief Scientific Officer, as well as our offer letters with our senior scientists, all provide for "at-will" employment. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of any product candidates we develop.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To help attract, retain, and motivate qualified employees, we use share-based incentive awards such as employee stock options. Other companies may provide more generous compensation and benefits, more diverse opportunities and better chances for career advancement than we do. Some of these advantages may be more appealing to high-quality candidates and employees than those we have to offer. In addition, any decline in our stock price could create additional challenges related to our ability to compete effectively with respect to equity compensation. We may need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

If an improved version of a reference product, such as Forteo, is developed, or if the market for a reference product significantly declines, sales or potential sales of the FDA-approved PF708 product or PF708 may suffer.

Reference product ("originator") sponsor companies may develop improved versions as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a supplemental biologics license application (BLA) or NDA. If an originator sponsor company, such as Eli Lilly, succeeds in obtaining an approval of an improved product, such as for Forteo, it may capture a significant share of the collective market and significantly reduce the market for the reference product, and thereby reduce the size of the market for the FDA-approved PF708 product or PF708, if approved in other territories. The improved product also may be protected by additional patent rights.

Competition in the pharmaceutical market is intense. Reference products face competition on numerous fronts as technological advances are made that may offer patients a more convenient form of administration or increased efficacy, or as new products are introduced. As new products are approved that compete with the reference product for PF708, such as Forteo, sales may be significantly and adversely impacted and may render the originator obsolete. If the market for Forteo is impacted, we and Alvogen in turn may lose significant market share or market potential for the FDA-approved PF708 product and PF708. As a result, the value of the FDA-approved PF708 product, PF708 and our product pipeline could be negatively impacted and our business, prospects and financial condition could suffer.

The FDA-approved PF708 product, PF708 and our other product candidates, if approved, face significant competition from the reference products and from therapeutic equivalent products of the reference products, and from other products. Our or our collaboration partners' failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We and Alvogen face highly competitive pharmaceutical markets. With the FDA approval for PF708, Alvogen is responsible for commercializing and manufacturing the FDA-approved PF708 product in the U.S. Successful competitors in the pharmaceutical market have the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to consumers and medical professionals. Numerous companies, universities, and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with the FDA-approved PF708 product, PF708 and other product candidates we are developing. For example, in April 2017, the FDA approved Radius Health's TYMLOS® (abaloparatide), and in April 2019, the FDA approved Evenity (romosozumab) a once monthly monoclonal antibody product developed by Amgen and UCB, each of which compete with the FDA-approved PF708 product. Teva Pharmaceuticals USA, Inc. has filed an ANDA referencing Forteo that, if approved, could compete with the FDA-approved PF708 product. Apotex Corp. also has submitted an ANDA for a generic version of Forteo, and other generic drug manufacturers may have filed and/or in the future may file ANDAs referencing Forteo that, if approved, could compete with the FDA-approved PF708 product. Any such competition could also adversely affect the market size and opportunity for the FDA-approved PF708 product and PF708. Many of these potential competitors, such as Amgen Inc., Eli Lilly and Company, Teva Pharmaceutical Industries Limited, and Radius Health are large, experienced companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. Recent and potential future merger and acquisition

activity in the biotechnology and pharmaceutical industries is likely to result in even more resources being concentrated among a smaller number of our competitors. These companies also maintain greater brand recognition and more experience and expertise in undertaking preclinical testing and clinical trials of product candidates and obtaining the FDA and other regulatory approvals of products. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds that could make the FDA-approved PF708 product, PF708 and our other product candidates obsolete.

In addition, the FDA has approved PF708 pursuant to the 505(b)(2) regulatory pathway in the U.S. with Forteo as the reference product. Only if the FDA-approved PF708 product obtains an "A" therapeutic equivalence designation may the FDA-approved PF708 product be permitted to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states. In the case of Teva's and Apotex's competitive products, upon any approval of such competitor's ANDA by the FDA, such competitor's product would be permitted to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states, without the need to obtain an "A" therapeutic equivalence designation.

In addition, the FDA-approved PF708 product, and if approved, PF708 and our other product candidates, face competition from companies that develop and commercialize products that compete directly with our products. See *"Risks Related to Government Regulation-If the FDA approves other therapeutic equivalent or generic products with Forteo as the reference drug and these drug products are successfully commercialized, the FDA-approved PF708 product may face additional competition and our business could suffer."*

If any competitor products are approved that compete with the FDA-approved PF708 product, PF708 or our other product candidates as described herein, our product revenue could suffer and it would have a material adverse effect on our financial condition and results of operations.

Use of the FDA-approved PF708 product, PF708 or our other product candidates could be associated with side effects or adverse events.

Use of the FDA-approved PF708 product, PF708 or our other product candidates could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of the FDA-approved PF708 product, PF708 or our other product candidates may be observed at any time, including in clinical trials or when a product is commercialized, and any such side effects or adverse events may negatively affect our and our collaboration partners' ability to obtain and maintain regulatory approval or market the FDA-approved PF708 product, PF708 or our product candidates. Side effects such as toxicity or other safety issues associated with the use of the FDA-approved PF708 product, PF708 or our product candidates could require us, Alvogen, or our other collaboration partners to perform additional studies or halt development or sale of the FDA-approved PF708 product, PF708 or these other product candidates or expose us, Alvogen, or our other collaboration partners to product liability lawsuits which would harm our business. We, Alvogen, or our other collaboration partners may be required by regulatory agencies to conduct additional animal or human studies regarding the safety and efficacy of the FDA-approved PF708 product, PF708 or our other product candidates which were not planned or anticipated. We, Alvogen, or our other collaboration partners may also be required to change product labeling, including increasing the prominence and content of warnings and contraindications for our products. The FDA could require us or our collaboration partners to develop a Risk Evaluation and Mitigation Strategy (REMS) for such product or, if a REMS is already in place, to incorporate additional requirements under the REMS, and foreign regulatory authorities may require similar risk management strategies. There can be no assurance that we or our collaboration partners will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

In addition, if we, Alvogen, and our other collaboration partners are successful in commercializing the FDA-approved PF708 product, or if approved, PF708 outside the U.S., or any other product candidates, the FDA, European Medicines Agency (EMA), competent authorities of the Member States of the European Economic Area (EEA), and other foreign regulatory agency regulations require that the application holder timely report certain information about adverse medical events. We, Alvogen, or our other collaboration partners may fail to report adverse events we become aware of within the prescribed timeframe. We, Alvogen, or our other collaboration partners may also fail to appreciate that we or our collaboration partners have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or delayed in time from the use of our products. If we or our collaboration partners fail to comply with our reporting obligations, the FDA, the EMA, competent authorities of the Member States of the EEA, or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of our products.

With the FDA approval of the PF708 product, we are substantially dependent on the commercial success of the FDA-approved PF708 product to be marketed by Alvogen in the U.S. In addition, we currently rely on a limited number of third parties for a substantial portion of our revenue. The loss of or a change in Alvogen or any of these third parties, including its creditworthiness, could materially reduce our revenue and adversely impact our financial position.

Alvogen's ability to successfully commercialize the FDA-approved PF708 product, the first FDA-approved product that we developed, is critical to the execution of our business strategy. For a discussion of risks relating to the degree of market acceptance and commercial success of the PF708 product, please see the risk factors entitled: *"The FDA-approved PF708 product, PF708 and our other product candidates, if approved, face significant competition from the reference products and from therapeutic equivalent products of the reference products, and from other products. Our or our collaboration partners' failure to effectively compete may prevent us from achieving significant market penetration and expansion;" "Although the FDA-approved PF708 product has obtained regulatory approval from the FDA, PF708 may not be approved by other regulatory authorities and even if PF708 or our other product candidates obtain additional regulatory approvals, they may never achieve market acceptance or commercial success.;"* and *"If the FDA-approved PF708 product does not receive an "A" therapeutic equivalence designation from the FDA, our business may suffer."* Alvogen may experience significant fluctuations in sales of the FDA-approved PF708 product from period to period and, ultimately, we may never generate sufficient revenue from our agreement with Alvogen to reach or maintain profitability or sustain anticipated levels of operation. Any inability on the part of Alvogen to successfully commercialize the FDA-approved PF708 product in the U.S. and to successfully commercialize PF708 in any significant international markets where PF708 may be subsequently approved, or any significant delay, could have a material effect on our financial condition and results of operations. We have also entered into an agreement with China NT Pharma Group Company Ltd. (NT Pharma) to develop and commercialize PF708 in certain territories. The prospects for the FDA-approved PF708 product and PF708 depend on the expertise, development and commercial skills, and financial strength of Alvogen and NT Pharma.

In addition to our reliance on the commercial success of the FDA-approved PF708 product and PF708, two third parties accounted for more than 10% of our 2019, 2018 and 2017 revenue. For the year ended December 31, 2019, Jazz and Alvogen each accounted for more than 10% of our revenue. Jazz and BARDA each accounted for more than 10% of our revenue in 2018 and 2017.

The loss of any key collaboration partner, especially Alvogen and/or Jazz, or any significant adverse change in the size or terms of a contract with a key third party could significantly reduce our revenue over the short term. Moreover, having our revenue concentrated among a limited number of entities creates a concentration of financial risk for us, and in the event that any significant third party is unable to fulfill its payment obligations to us, our operating results and cash position would suffer. See *"Risks Relating to our Reliance on Third Parties—We are substantially dependent on the expertise of Alvogen, Jazz, and NT Pharma to develop and commercialize the FDA-approved PF708 product, and PF708 and certain other product candidates, if approved. If we fail to maintain our current strategic relationship with Alvogen, Jazz, NT Pharma, or with any future collaboration partner, our business, commercialization prospects and financial condition may be materially adversely affected.*"

We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.

We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons. For example, in 2017 we decided to pause development activities on PF582 and PF529 and focus development efforts elsewhere within the product portfolio while we continue to engage potential strategic partners for PF582 and PF529 to advance the programs and maximize value. As a result of changes in our strategy, we have and may in the future change or refocus our existing product development, commercialization and manufacturing strategies. This could require changes in our facilities and our personnel. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. Our decisions to allocate our research and development, management and financial resources toward particular product candidates may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also prove to be incorrect and could cause us to miss valuable opportunities.

We currently have limited marketing capabilities and no sales organization.

We currently have limited sales and marketing capabilities. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team.

To commercialize and manufacture the FDA-approved PF708 product and PF708, we have entered into collaboration agreements with Alvogen and NT Pharma and the prospects for the FDA-approved PF708 product and PF708 depend on the expertise, development and commercial skills, and financial strength of Alvogen and NT Pharma. Under the Alvogen agreements, Alvogen has the exclusive right to commercialize and manufacture PF708 in the United States, European Union, Middle East, North Africa, and the rest of the world not covered by the NT Pharma territory. The loss for any reason of Alvogen as a key partner could have a significant and adverse impact on our business. If we are unable to retain Alvogen as a partner on commercially acceptable terms, we may not be able to commercialize the FDA-approved PF708 product and PF708, if approved, as planned and we could experience delays in or suspension of the U.S. commercial launch of the FDA-approved PF708 product. Under the NT Pharma agreement, we granted an exclusive license to NT Pharma to commercialize PF708 in certain Asian countries and a non-exclusive license to conduct development activities in such territories with respect to PF708. For our other product candidates, if approved, we will need to identify potential sales, marketing and distribution partners or establish our own internal sales force. In the future, we may choose to collaborate with other third parties that have direct sales forces and established distribution systems, either to augment our own sales force or in lieu of our own sales force. If we are unable to maintain and/or enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize the FDA-approved PF708 product or our other product candidates. If we are not successful in commercializing the FDA-approved PF708 product, or PF708 or our other product candidates, if approved, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

We enter into various contracts in the normal course of our business that periodically incorporate provisions whereby we indemnify the other party to the contract. In the event we would have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial position and results of operations.

In the normal course of business, we periodically enter into academic, commercial and consulting agreements that contain indemnification provisions. With respect to our academic agreements, we may be required to indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to commercial agreements entered into with our protein production customers, we typically provide indemnification for claims from third parties arising out of any potential intellectual property infringement associated with our *Pf*ēnex Expression Technology® in the course of performing our services. With respect to our commercial agreements, the bulk of which are with contract manufacturers, we indemnify our vendors from third-party product liability claims which result from the production, use or consumption of the product, as well as for certain alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services. In all of the above cases, we do not indemnify the parties for claims resulting from the negligence or willful misconduct of the indemnified party.

In certain circumstances, we maintain insurance coverage which we believe may limit our obligations under certain of these indemnification provisions. However, we do not carry insurance for all risks that our business may encounter, including our obligations under certain indemnification provisions. To the extent we do not have insurance to cover certain indemnification obligations, we are denied insurance coverage, or our obligation under an indemnification provision exceeds applicable insurance coverage, any significant, uninsured liability may require us to pay substantial amounts, which would adversely affect our working capital and results of operations.

We may have difficulty expanding our operations successfully.

As we advance our product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaboration partners, suppliers and other organizations, including with respect to the commercialization of the FDA-approved PF708 product and PF708.

As of December 31, 2019, we had 81 full-time employees, including a total of 21 employees who hold Ph.D. or other doctoral degrees. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Therefore, we will need to continue to expand our managerial, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and potentially commercialize our current product candidates, if approved. In order to effectively execute our growth strategy, we will be required to:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- establish and maintain collaborations with third parties for the development and commercialization of the FDA-approved PF708 product, PF708 and our product candidates, or otherwise build and maintain a sales, marketing and distribution infrastructure to commercialize PF708 or any other products for which we may obtain marketing approval;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, this expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue, and operating results.

The U.S. government holds certain intellectual property rights related to our Anthrax vaccines, Px563L and RPA563.

Although we have intellectual property related to expression of recombinant protective antigen in *P. fluorescens*, the U.S. government holds certain patents related to the recombinant protective antigen in Px563L and RPA563, as well as certain license rights to intellectual property related to other Px563L components used to produce the final vaccine, which, if exercised, could materially impact our business, revenue and operating results. We have rights to utilize this intellectual property held by the U.S. government by virtue of the Authorization and Consent clauses of our contracts with the U.S. government.

Our contracts with the U.S. government, and our subcontracts with U.S. government contractors, require ongoing funding decisions by the U.S. government; reduced or discontinued funding of these contracts could cause our financial condition and operating results to suffer.

Development of our anthrax vaccines, Px563L and RPA563, is funded by BARDA. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, on March 29, 2019, we received notice from BARDA informing us of BARDA's decision to not exercise development options for cGMP manufacturing and potential Phase 1/2b study readiness for Px563L and RPA563. Following the receipts of the notice from BARDA and pursuant to ongoing discussions with BARDA, we deprioritized this program in our portfolio. Additionally, our government-funded development contracts give the U.S. government the right, exercisable in its sole discretion, to extend this contract for successive options following a base period of performance. The value of the services to be performed during these options may constitute the majority of the total value of the underlying contract. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under its contracts with us, our business, revenue and operating results would suffer.

Our current contract with BARDA is a cost-plus fixed fee contract and potential future contracts with the U.S. government may also be structured this way. Under our cost-plus fixed fee contracts, we are allowed to recover our approved costs plus a fixed fee. The total price on a cost-plus fixed fee contract is based primarily on allowable costs incurred, but generally is subject to contract funding limitations. U.S. government regulations require us to notify our customer of any cost overruns or underruns on a cost-plus fixed fee contract. If we incur costs in excess of the funding limitation specified in the contract, we may not be able to recover those cost overruns.

Moreover, changes in U.S. government contracting policies could directly affect our financial performance. Factors that could materially adversely affect our U.S. government contracting business include:

- budgetary constraints affecting U.S. government spending generally, or specific departments or agencies in particular;
- changes in U.S. government fiscal policies or available funding;
- changes in U.S. government defense and homeland security priorities;
- changes in U.S. government programs or requirements;
- adoption of new laws or regulations;
- technological developments;
- U.S. government shutdowns, threatened shutdowns or budget delays;
- competition and consolidation in our industry; and
- general economic conditions.

These or other factors could cause U.S. government departments or agencies to reduce their development funding or future purchases under contracts, to exercise their right to terminate contracts or fail to exercise their options to extend our contracts, any of which could have a material adverse effect on our business, financial condition, operating results and ability to meet our financial obligations.

Unfavorable provisions in government contracts, some of which are customary, may subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on our financial condition and operating results.

Government contracts contain provisions that give the U.S. government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the U.S. government to:

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify the government's obligations under such contracts or subcontracts, without the contractor's consent, including by imposing equitable price adjustments;
- audit contract-related costs and fees, including allocated indirect costs;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- under certain circumstances involving public health and safety, license inventions made under such agreements to third parties;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such contracts;
- suspend or debar the contractor from doing future business with the government;
- decline to exercise an option to continue a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;

- change the course of a development program in a manner that differs from the contract's original terms or from our desired development plan, including decisions regarding our partners in the program;
- pursue civil or criminal remedies under the False Claims Act (FCA) and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our contract with BARDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. In addition, government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program;
- mandatory internal control systems and policies; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential contract or FCA liability and to termination of our contracts.

Furthermore, we are required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors in order to satisfy our contractual obligations pursuant to our agreements with the United States government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our government contract. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our contract.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

Most U.S. government contracts grant the U.S. government the right to use on a royalty free basis, for or on behalf of the U.S. government, any technologies developed and data first produced by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the U.S. government.

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Department of Health and Human Services (HHS) and the Defense Contract Audit Agency (DCAA) routinely audit and investigate government contractors and recipients of federal grants and contracts. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The HHS and the DCAA also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's accounting, purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

The United States government's determination to award a future contract may be challenged by an interested party, such as another bidder, at the United States Government Accountability Office (GAO) or in federal court. If such a challenge is successful, any future contract we may be awarded may be terminated.

The laws and regulations governing the procurement of goods and services by the U.S. government provide procedures by which other bidders and interested parties may challenge the award of a government contract. If we are awarded a government contract, such challenges or protests could be filed even if there are not any valid legal grounds on which to base the protest. If any such protests are filed, the government agency may decide to suspend our performance under the contract while such protests are being considered by the GAO or the applicable federal court, thus potentially delaying delivery of payment. In addition, we could be forced to expend considerable funds to defend any potential award. If a protest is successful, the government may be ordered to terminate the contract and resolicit proposals. The government agencies with which we have contracts could even be directed to award a potential contract to one of the other bidders.

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government contracts, including our contract with BARDA. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations (FAR) and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the Truth in Negotiations Act, which requires certification and disclosure of cost or pricing data in connection with contract negotiations;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the Anti-Kickback Statute and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Any material changes in applicable laws and regulations could restrict our ability to maintain our existing BARDA contract and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of products we develop.

We face a risk of product liability as a result of the clinical testing of our product candidates and may face an even greater risk in connection with the commercialization of the FDA-approved PF708 product in addition to any other of our products that may be approved. For example, we may incur liability if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for the FDA-approved PF708 product, PF708 or any other product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could impact the commercialization of PF708 and any other products we develop. We currently carry product liability insurance in the amount of $10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Since we have received FDA approval for the PF708 product in the United States and if we obtain approval for marketing any of our product candidates, we may expand our insurance coverage to include the sale of such products; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

Our employees, independent contractors, principal investigators, CROs, CMOs, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, third-party clinical research organizations (CROs) and contract manufacturing organizations (CMOs), consultants and collaboration partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) regulations of the FDA and comparable foreign authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics and Conduct, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any

such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our cash and cash equivalents and short-term investments could be adversely affected if the financial institutions in which we hold our cash and cash equivalents and short-term investments fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation (FDIC) insurance limit. While we monitor the cash balances in our accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

We may be subject to information technology failures, including data protection breaches and cyber-attacks, that could disrupt our operations, damage our reputation and adversely affect our business, operations, and financial results.

We rely on our information technology systems for the effective operation of our business and for the secure maintenance and storage of confidential data relating to our business and third-party businesses. Although we have implemented certain security controls to protect our information technology systems, experienced programmers or hackers may be able to penetrate our security controls, and develop and deploy viruses, worms and other malicious software programs that compromise our confidential information or that of third parties and cause a disruption or failure of our information technology systems. Any such compromise of our information technology systems could result in the unauthorized publication of our confidential business or proprietary information, result in the unauthorized release of customer, supplier or employee data, result in a violation of privacy or other laws, expose us to a risk of litigation, or damage our reputation. The cost and operational consequences of implementing further data protection measures either as a response to specific breaches or as a result of evolving risks, could be significant. In addition, our inability to use or access our information systems at critical points in time could adversely affect the timely and efficient operation of our business. Any delayed sales, significant costs or lost customers resulting from these technology failures could adversely affect our business, operations and financial results.

Third parties with which we conduct business have access to certain portions of our sensitive data. In the event that these third parties do not properly safeguard our data that they hold, security breaches could result and negatively impact our business, operations and financial results.

Our business involves the use of hazardous materials and we, our collaboration partners, and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including small quantities of acetonitrile, methanol, ethanol, ethidium bromide and compressed gases, and other hazardous compounds. We and our collaboration partners, manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations.

We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, and the handling of biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. For claims not covered by workers' compensation insurance, we also maintain an employer's liability insurance policy in the amount of $1.0 million per occurrence and in the aggregate. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

Environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Any inability to comply with environmental laws and regulations may adversely affect our business and operating results.

Changes in accounting principles, or interpretations thereof, could have a significant impact on our financial position and results of operations.

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, referred to as GAAP. These principles are subject to interpretation by the Securities and Exchange Commission (SEC) and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Additionally, the adoption of new or revised accounting principles may require that we make significant changes to our systems, processes and controls.

It is not clear if or when these potential changes in accounting principles may become effective, whether we have the proper systems and controls in place to accommodate such changes and the impact that any such changes may have on our financial position and results of operations.

Although the FDA-approved PF708 product has obtained regulatory approval from the FDA, PF708 may not be approved by other regulatory authorities and even if PF708 or our other product candidates obtain additional regulatory approvals, they may never achieve market acceptance or commercial success.

Although the FDA-approved PF708 product has obtained regulatory approval from the FDA, and even if we obtain other regulatory approvals, the FDA-approved PF708 product or any of our other product candidates, if approved, may not achieve market acceptance among physicians and patients and may not be commercially successful. The degree and rate of market acceptance of the FDA-approved PF708 product, PF708, or any of our other product candidates for which we receive approval depends on a number of factors, including:

- the performance of our collaboration partners, including Alvogen, Jazz, and NT Pharma;
- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- whether we obtain an "A" therapeutic equivalence designation for the FDA-approved PF708 product, which may allow the product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states;
- whether we or Alvogen are able to obtain timely and adequate coverage and reimbursement for our products by key payors, such as Medicare Part D for the FDA-approved PF708 product in the United States;
- proper training and administration of our products by physicians, medical staff, and patients;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for the FDA-approved PF708 product, PF708 and our other product candidates, if approved, on the part of physicians and patients;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

Any failure by the FDA-approved PF708 product or product candidates that obtain regulatory approval to achieve market acceptance or commercial success would materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue and continue our business.

Risks Relating to our Reliance on Third Parties

We are substantially dependent on the expertise of Alvogen, Jazz, and NT Pharma to develop and commercialize the FDA-approved PF708 product, and PF708 and certain other product candidates, if approved. If we fail to maintain our current strategic relationship with Alvogen, Jazz, NT Pharma, or with any future collaboration partner, our business, commercialization prospects and financial condition may be materially adversely affected.

Because we have limited or no capabilities for commercial, manufacturing, sales, marketing and distribution, we have entered into alliances and may need to enter into additional alliances with other companies to develop and commercialize our products that we have developed and our product candidates. For example, to commercialize the FDA-approved PF708 product and PF708 if approved in other territories, we have entered into collaboration agreements with Alvogen and NT Pharma and the prospects for the FDA-approved PF708 product and PF708 if approved outside the U.S., depends in part on the expertise, commercial skills, and financial strength of Alvogen and NT Pharma. Under the Alvogen agreement, Alvogen has the exclusive right to commercialize and manufacture the FDA-approved PF708 product in the United States, and PF708 in the European Union, Middle East, North Africa, and the rest of the world not covered by the NT Pharma agreement. We may be unable to establish or maintain this relationship with Alvogen on a commercially reasonable basis, if at all. In addition, Alvogen may have similar or more established relationships with our competitors. Moreover, the loss for any reason of Alvogen as a key partner could have a significant and adverse impact on our business. If we are unable to retain Alvogen as a partner on commercially acceptable terms, the commercialization of PF708 may not occur as planned and there could be delays in or suspension of the commercial launch of the FDA-approved PF708 product in the U.S. Under the NT Pharma agreement, we granted an exclusive license to NT Pharma to commercialize PF708 in certain Asian countries, if approved, and a non-exclusive license to conduct development activities in such territories with respect to PF708. In addition, we entered into an agreement with Jazz, pursuant to which we have transferred the development, manufacturing and commercialization of certain product candidates.

In July 2016, we entered into a license and option agreement with Jazz, pursuant to which we and Jazz are collaboratively developing hematology/oncology products, including PF743 (JZP-458), a recombinant *Erwinia* asparaginase, and PF745 (JZP-341), a long-acting *Erwinia* asparaginase, and Jazz has the exclusive right to manufacture and commercialize such products throughout the world. In December 2017, we amended the agreement. As of December 31, 2019, we may be eligible to receive additional payments under the amended agreement of up to $162.5 million based on achievement of certain research and development, regulatory and sales-related milestones, bringing the total value of payments and potential payments associated with the collaboration to $224.5 million. In addition, we may be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from those under the 2016 agreement.

The prospects for the FDA-approved PF708 product, and PF708 and the other product candidates developed under these collaborations depend on the expertise, development and commercial skills, and financial strength of Alvogen, Jazz, and NT Pharma. Our collaborations with Alvogen, Jazz, NT Pharma or any future collaboration partner may not be successful, and we may not realize the expected benefits from such collaborations, due to a number of important factors, including but not limited to the following:

- Alvogen, Jazz, NT Pharma, or any future collaboration partner may terminate their agreements with us prior to completing development or commercialization of the FDA-approved PF708 product, PF708 or the other product candidates under the collaboration, in whole or in part, adversely impacting the potential approval and our revenue from licensed products;
- the timing and amount of any payments we may receive under these agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of the FDA-approved PF708 product and PF708 by Alvogen or the relevant product candidates by Jazz, NT Pharma, or any future collaboration partner, as applicable, under our agreements;
- the timing and amounts of expense reimbursement that we may receive are uncertain; or
- Alvogen, Jazz, NT Pharma, or any future collaboration partner may change the focus of their development or commercialization efforts or pursue or emphasize higher priority programs.

A failure of Alvogen, Jazz, NT Pharma or any future collaboration partner to successfully develop our product candidates which are covered by the collaboration, or to commercialize the PF708 product, PF708 or such other product candidates, or the termination of our agreements with Alvogen, Jazz, NT Pharma, or any future collaboration partner, as applicable, may have a material adverse effect on our business, results of operations and financial condition.

We are dependent on Alvogen for the commercial manufacture and supply of the FDA-approved PF708 product. The manufacture of the FDA-approved PF708 product is complex and Alvogen may encounter difficulties in production, particularly with respect to scaling up Alvogen's manufacturing capabilities of the FDA-approved PF708 product.

The process of manufacturing the FDA-approved PF708 product is complex, highly-regulated and subject to multiple risks. The manufacture of the FDA-approved PF708 product, PF708, and our product candidates involves complex processes and is subject to the risks more fully described in the risk factor entitled *"We rely on our collaboration partners, and other third parties, and in some cases a single third party, to manufacture commercial, nonclinical and clinical supplies of our product candidates, supply key materials to manufacture our other product candidates, and to store critical components of our other product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our other product candidates or fail to do so at acceptable quality levels or prices."*

We have transferred our manufacturing processes for the FDA-approved PF708 product to Alvogen. The transfer of process to Alvogen, or to CMOs selected by Alvogen, and the actual manufacture of the FDA-approved PF708 product by Alvogen or its selected CMOs, is subject to risk and may not ultimately be successful or may take longer to succeed than expected, which could delay or impair commercialization activities in the U.S., which would have an adverse effect on our business.

Reliance on Alvogen and third-party manufacturers entails risks to which we would not be subject if we manufactured the FDA-approved PF708 product ourselves, including reliance on Alvogen or the third-party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by Alvogen or the third-party because of factors beyond our control, including a failure to manufacture the FDA-approved PF708 product in accordance with specifications, and the possibility of termination or nonrenewal of the agreement by Alvogen, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA requires that the FDA-approved PF708 product be manufactured according to cGMP. Any failure by Alvogen to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of the FDA-approved PF708 product or PF708 in a timely manner, could lead to delay in, or failure to obtain, regulatory approval of PF708 in territories outside the U.S. In addition, failure to comply with cGMP could be the basis for the FDA to issue a warning letter, withdraw approvals previously granted to us or our collaboration partners, or take other regulatory or legal action, including recall or seizure of the FDA-approved PF708 product, PF708 or other product candidate, total or partial suspension of production, suspension of on-going clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Because we have received FDA approval for PF708, Alvogen is obligated to use diligent efforts to continue to develop, manufacture and commercialize the FDA-approved PF708 product at Alvogen's cost and expense. We and Alvogen have not yet identified alternate suppliers for the FDA-approved PF708 product, nor have we identified alternate suppliers for any other product candidate, in the event the current CMOs we utilize are unable to scale to commercial production, pass required preapproval inspections, or if we otherwise experience any problems with them. Although we believe alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it would be expensive and take a significant amount of time to arrange for, and qualify, alternative suppliers. Furthermore, if Alvogen is required to identify, qualify and contract with new manufacturing suppliers of the FDA-approved PF708 product or PF708, Alvogen would need to demonstrate to the satisfaction of the FDA in a bridging study that any new supply of the FDA-approved PF708 product is substantially the same as the previous supply of FDA-approved PF708 product. A bridging study may require further clinical testing, including testing in patients. We cannot assure you that we can arrange for alternative third-party manufacturing sources for the FDA-approved PF708 product on commercially reasonable terms or in a timely manner, or that such manufacturers or collaboration partners will be capable of manufacturing the FDA-approved PF708 product in compliance with cGMP and to FDA's satisfaction.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If Alvogen, our manufacturers or we are unable to purchase these key materials for the PF708 product, the commercial launch of the FDA-approved PF708 product could be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of the FDA-approved PF708 product.

We rely on our collaboration partners, and other third parties, and in some cases a single third party, to manufacture commercial, nonclinical and clinical supplies our product candidates, supply key materials to manufacture our other product candidates, and to store critical components of our other product candidates for us. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our other product candidates or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture supplies of our product candidates for use in clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on Alvogen, our collaboration partners, and other third-party manufacturers, including with respect to PF708, to manufacture PF708 or our product candidates for preclinical and clinical studies, and commercial supply. In addition, following FDA approval of PF708, Alvogen will also supply NT Pharma with PF708 if requested by NT Pharma. We have transferred the manufacturing techniques related to PF708 to Alvogen. Moreover, the market for contract manufacturing services for protein therapeutics is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Although we generally do not begin a clinical study unless we believe we have a sufficient supply of a product or product candidate to complete such study, any significant delay or discontinuation in the supply of a product or product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing, and potential regulatory approval of our current product candidates, which could harm our business and results of operations.

Reliance on Alvogen, our collaboration partners, and other third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, Alvogen, our collaboration partners, and other third-party manufacturers may not be able to comply with cGMP, or similar regulatory requirements outside the United States. Our failure, or the failure of Alvogen, our collaboration partners, or other third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions, untitled or warning letters, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and criminal prosecutions, any of which could significantly and adversely affect supplies of PF708 or any other product candidates or products that we may develop. Any failure or refusal to supply the components for PF708 or our other product candidates that are being developed could delay, prevent or impair clinical development or commercialization efforts. If our manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

In order to produce the quantities of the FDA-approved PF708 product necessary to meet anticipated market demand, Alvogen or any manufacturer that we and our collaboration partners engage may need to increase manufacturing capacity. If we, Alvogen, our collaboration partners, or our manufacturers are unable to produce the FDA-approved PF708 product, PF708 for commercial sales or for clinical studies, or any of our product candidates in sufficient quantities to meet the requirements for the launch of these products or to meet future demand, our revenue and gross margins could be adversely affected. Although we currently believe that we, Alvogen, our collaboration partners, and our manufacturers will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for PF708 or any of our other product candidates or materials used to produce such product candidate on acceptable terms, if at all. If we, Alvogen, or our collaboration partners are unable to arrange for manufacturing, either through a third party or Alvogen, or to do so on commercially reasonable terms, we may not be able to market the FDA-approved PF708 product or complete development of or market any of our other product candidates.

Any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our product candidates. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidate. If Alvogen, our manufacturers, collaboration partners, or we are unable to purchase these key materials for PF708 our other product candidates after regulatory approval, the commercial launch of our product candidates, if approved, could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from their sale.

We also rely on third parties to store master and working cell banks for PF708 and our other product candidates. We have master and working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks, which could materially and adversely affect our business, financial condition and results of operations.

Our existing product development and/or commercialization arrangements, and any that we may enter into in the future, may not be successful, which could adversely affect our ability to generate revenues from the FDA-approved PF708 product and develop and commercialize PF708 and our other product candidates.

We are a party to collaboration arrangements with other pharmaceutical companies for the development and/or commercialization of the FDA-approved PF708 product, PF708 and our current and future product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing, both in the United States and internationally. For example, to commercialize the FDA-approved PF708 product and PF708, we have entered into collaboration agreements with Alvogen and NT Pharma and the prospects for the FDA-approved PF708 product and PF708 depend in part on the expertise, development and commercial skills, and financial strength of Alvogen and NT Pharma. Under the Alvogen agreement, Alvogen has the exclusive right to commercialize and manufacture PF708 in the United States, European Union, Middle East, North Africa, and the rest of the world not covered by the NT Pharma agreement. Under the NT Pharma agreement, we granted an exclusive license to NT Pharma to commercialize PF708 in certain Asian countries and a non-exclusive license to conduct development activities in such territories with respect to PF708.

To the extent that we decide to enter into additional collaboration agreements, we will face significant competition in seeking appropriate collaboration partners. Any failure to meet our clinical milestones with respect to an unpartnered product candidate would make finding a collaboration partner more difficult. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement, and we cannot guarantee that we can successfully maintain such relationships or that the terms of such arrangements will be favorable to us. If we fail to maintain, establish and implement collaboration or other alternative arrangements, the value of our business and operating results will be adversely affected.

We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. The terms of any collaboration or other arrangements that we may establish may not be favorable to us. The management of collaborations may take significant time and resources that distract our management from other matters. Our ability to successfully collaborate with any current or future collaboration partners may be impaired by multiple factors including:

- a collaboration partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaboration partner may cease development in therapeutic areas which are the subject of alliances with us;
- a collaboration partner may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payments tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaboration partner may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaboration partner concerning the commercialization of the FDA-approved PF708 product or PF708 or the research, development, or commercialization of another product candidate resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;

- the results of our clinical trials may not match our collaboration partners' expectations, even if statistically significant;
- a collaboration partner may not adequately protect or enforce the intellectual property rights associated with a product or product candidate; and
- a collaboration partner may use our proprietary information or intellectual property in such a way as to invite litigation from a third party.

Any such activities by our current or future collaboration partners could adversely affect us financially and could harm our business reputation.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and commercialization of the FDA-approved PF708 product, and PF708 and other product candidates, if approved. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally, or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

We rely on CROs to conduct and oversee our planned clinical trials for our product candidates and other clinical trials for product candidates we are developing or may develop in the future. If our CROs do not successfully carry out their contractual duties, meet expected deadlines, or otherwise conduct the trials as required or comply with regulatory requirements, or if our relationship with our CRO terminates, we and our collaboration partners may not be able to seek or obtain regulatory approval for or commercialize our product candidates when expected or at all, and our business could be substantially harmed.

We will continue to rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and in accordance with applicable legal and regulatory requirements. These third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, there is no guarantee that any such third party will devote adequate time and resources to our clinical trial. If our CRO or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of, seek or obtain regulatory approval for, or successfully commercialize our product candidates. We plan to rely heavily on these third parties for the execution of clinical trials for products we are developing or may develop in the future and will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on our CRO does not relieve us of our regulatory responsibilities.

We, our CRO and our collaboration partners are required to comply with current Good Clinical Practice (cGCP), which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we, our CRO or our collaboration partners fail to comply with applicable cGCP regulations, the clinical data generated in clinical trials may be deemed unreliable and submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before accepting our applications for review or approving marketing applications. We cannot assure that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable cGCP regulations. In addition, clinical trials must be conducted with product produced under current Good Manufacturing Practices (cGMP) regulations, which are enforced by regulatory authorities. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if our CRO violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Comparative clinical trials require a substantial number of patients that can form the basis for generating statistically significant results. Delays in site initiation or unexpectedly low patient enrollment rates may delay the results of the clinical trial. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. Further, if our relationship with our CRO is terminated, we may be unable to enter into arrangements with an alternative CRO on commercially reasonable terms, or at all. Switching or adding CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition or results of operations.

We rely on third-party suppliers, and in some instances a single third-party supplier, for the manufacture and supply of certain materials in our protein production services, and these suppliers could cease to manufacture the materials, go out of business or otherwise not perform as anticipated.

We rely on third-party suppliers for our protein production services and, in some instances, a single third-party supplier, for the manufacture and supply of certain materials. For example, we currently rely, and expect to continue to rely, on a single-source supplier for the manufacture and supply of CRM197. To meet these demands, our supplier is in the process of increasing production capacity, and we also have established a repository in the United States that is capable of storing a safety stock of CRM197 and the CRM197 cell bank. Furthermore, we have taken steps to identify alternate sources of supply sufficient to support future needs and have several supply agreements in place with other vendors; however, there may be delays in switching to these alternative suppliers if our contract with primary sources are terminated without notice. Regardless of the foregoing alternative measures, we cannot guarantee that we will have an adequate supply of CRM197. If we are unable to secure adequate quantities of CRM197 from our primary supplier, from potential secondary suppliers or from our safety stock, we may be required to identify additional suppliers. If we are required to engage additional suppliers, we may not be able to enter into an alternative supply arrangement on commercially reasonable terms, or at all. Even if we are able to identify additional suppliers and enter into agreements on commercially reasonable terms, we may incur delays associated with identifying and qualifying additional suppliers and negotiating the terms of any supply contracts. These delays could adversely impact our business and negatively affect profitability of our protein production services.

We have entered into collaborations with third parties in connection with the development of PF708 and certain of our other product candidates. Even if we believe that the development of our technology, PF708 and other product candidates is promising, our partners may choose not to proceed with such development.

Our existing agreements with our collaboration partners, Alvogen, Jazz, and NT Pharma, and any future collaboration agreements we may enter into, are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances. Accordingly, even if we believe that the development of product candidates is worth pursuing, our partners may choose not to continue with such development. If any of our collaborations are terminated, such as the termination of our collaboration with Pfizer in August 2016, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner on short notice, and the terms of any additional collaboration or other arrangements that we establish may not be favorable to us.

We are also at risk that our current and any potential collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial and cash flow difficulties that force them to limit or reduce their participation in our joint projects;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate their collaboration with us, which could make it difficult for us to attract new partners or adversely affect perception of us in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition and operating results may be adversely affected.

If we are unable to maintain our commercial supply agreements with key customers purchasing CRM197, sales revenue could decline.

We primarily sell CRM197 directly to biopharmaceutical companies and currently have several supply agreements in place for supply of CRM197, although we currently rely, and expect to continue to rely, on a single-source supplier for the manufacture and supply of CRM197. To establish and maintain relationships with customers, we believe we need to maintain adequate supplies of CRM197, remain price competitive, comply with regulatory regulations and provide high quality products. If we are unable to establish and maintain arrangements for the sale of CRM197, our revenue and profits would decline.

Risks Relating to Our Intellectual Property

Our collaboration partners and other third parties may assert ownership or commercial rights to inventions we develop from our use of the materials which they provide to us, or otherwise arising from our collaboration.

We collaborate with other companies and institutions with respect to research and development matters. Also, we rely on numerous third parties to provide us with materials that we use to develop our technology. If we cannot successfully negotiate sufficient ownership, licensing and/or commercial rights to any inventions that result from our use of any third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's materials, or data developed in a collaborator's study, our ability to capitalize on the market potential of these inventions or developments may be limited or precluded altogether.

If our efforts to protect our intellectual property related to our platform technology, PF708 and our current or future product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to PF708 and our current product candidates and our development programs. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform, PF708 and product candidates. However, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patentability of inventions, and the validity, enforceability and scope of patents in the biotechnology and pharmaceutical industry involve complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the United States or foreign countries. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We may be unaware of certain prior art relating to our patent applications and patents, which could prevent a patent from issuing from a pending patent application or result in an issued patent being invalidated. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize PF708 or our product candidates. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to PF708, our current or future product candidates is challenged, then it could threaten our ability to commercialize PF708, our current or future

product candidates and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market our current or future product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates, or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the United States Patent and Trademark Office (USPTO), to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act (Leahy-Smith Act) signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

Although the PF708 product has been approved by the FDA and even if PF708 is approved in the EU, we or our collaboration partner may be delayed in selling the FDA-approved PF708 product or PF708 due to direct or indirect legal challenges.

Although the PF708 product has received marketing approval in the U.S. and even if PF708 receives marketing approval in the EU, we may also be subject to direct legal challenges from Eli Lilly and Company, the manufacturer of Forteo, and we could be delayed or prevented from launching PF708 as a result of court orders, regulatory stays, or the time necessary to resolve such challenges. For instance, we are aware of at least two instances of a third party being subject to litigation initiated by Eli Lilly and Company on a product purporting to be a generic version of Eli Lilly's Forteo (teriparatide [rDNA origin] injection) product. In accordance with regulatory requirements we provided notice of Paragraph IV certification (Notice Letter) to Eli Lilly and Company (Lilly) on February 19, 2019 that PF708 does not infringe any valid claim of the '334 patent. Under the Hatch-Waxman Act, Lilly had 45 days from the receipt of the Notice Letter to file a patent infringement lawsuit against Pfenex that would cause a 30-month litigation stay of approval for PF708. On April 11, 2019 we 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. Lilly did not file a lawsuit within this time period, and there was no 30-month litigation stay delaying FDA approval of PF708.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

As part of our efforts to protect our trade secrets and other confidential information, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. We also note in this respect that trade secret protection in foreign countries may not provide protection to the same extent as federal and state laws in the United States. A breach of

confidentiality could significantly affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Also, third parties, including our competitors, may independently develop substantially equivalent proprietary information and technologies or otherwise lawfully gain access to our trade secrets and other confidential information. In such a case, we would have no right to prevent such third parties from using such proprietary information or technologies to compete with us, which could harm our competitive position.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Our competitors have developed large portfolios of patents and patent applications in fields relating to our business and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. For example, on May 6, 2019, Pfenex filed two petitions for *inter partes* review of U.S. Patent No. 9,422,345 ("the '345 patent", entitled "Expression System"), which is owned by GlaxoSmithKline Biologicals S.A., with the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office. The '345 patent relates to polynucleotides that express diphtheria toxins, including the diphtheria toxin mutant CRM197. These two petitions, IPR2019-01027 and IPR2019-01028, seek, *inter alia*, a determination that certain claims in the '345 patent are invalid. Institution decisions by the PTAB for IPR2019-01027 and IPR2019-01028 are expected within the 2019 calendar year, and final written decisions on the validity of the challenged claims of the '345 patent, if these two petitions are instituted by the PTAB, by the end of 2020. On August 9, 2019, Pfenex filed a third petition for *inter partes* review of the '345 patent with the PTAB of the U.S. Patent and Trademark Office. The third petition, IPR2019-01478, seeks, *inter alia*, a determination that certain claims in the '345 patent are invalid. An institution decision by the PTAB for IPR2019-01478 is expected within the first quarter of 2020, and a final written decision on the validity of the challenged claims of the '345 patent, if the third petition is instituted by the PTAB, by the end of the first quarter of 2021. On November 14, 2019, the Board instituted trial on the invalidity grounds in IPR2019-01028, but exercised its discretion not to institute trial on IPR2019-01027 under its rules for multiple petitions. We cannot predict the ultimate outcome of our invalidity claims related to the '345 patent. If the claims of the '345 patent are upheld as valid and we are unable to enter into licenses on commercially acceptable terms, we could be prevented from commercializing a product or be forced to cease some aspects of our business operations. Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the EU member States seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our biosimilar or vaccine products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third-party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third-party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We may not be able to globally protect our intellectual property rights.

Filing, prosecuting and defending patents on products and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases, may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets of former or other employers.

Many of our employees and consultants, including our senior management, have been employed or retained by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or consultant's former or other employer. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Government Regulation

The approval processes of the FDA, EMA, and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we and our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting, and export and import of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the EMA and Competent Authorities of the Member States of the EEA, and by other regulatory authorities in other countries, and regulations differ from country to country. Neither we nor any collaboration partner is permitted to market any product candidate in the United States until approval from the FDA is received, or in the EEA until we receive European Commission authorization or approval from one or more Competent Authorities of the Member States of the EEA, as applicable. The time required to obtain approval from regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of such regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the filing of an application and/or the approval or the decision not to approve an application. In May 2019, Alvogen, our collaboration partner, submitted a centralized application to the EMA for PF708, and the application was accepted for review. In October 2019, Alvogen submitted a Marketing Authorization Application (MAA) to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). We received approval from the FDA for the PF708 product in October 2019. Other than the PF708 product NDA and the applications submitted to the EMA and SFDA for PF708, we and our collaboration partners have not submitted any marketing applications to regulatory authorities and, other than receipt of regulatory approval from the FDA for the PF708 product, neither we nor our collaboration partners have obtained regulatory approval for any other product candidate and it is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Applications for our product candidates could fail to receive regulatory approval or their regulatory approval could be delayed for many reasons, including but not limited to the following:

- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a Biologics License Application (BLA) under the section 351(a) pathway of the PHSA; an NDA under the section 505(b)(2) of the Food, Drug, and Cosmetic Act; a BLA for a biosimilar product application under the section 351(k) pathway of the PHSA, a marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 8(3), 10(1), 10(3) or 10a of Directive 2001/83/EC in the EEA, a biosimilar marketing authorization under Article 6 of Regulation (EC) No. 726/2004 and/or Article 10(4) of Directive 2001/83/EC in the EEA, or other submission or to obtain regulatory approval in the United States, the EEA, or elsewhere;
- regulatory authorities may disagree with the design (including the duration) or implementation of our clinical trials and may, at any time, determine that the regulatory pathway that we have committed to for any product candidate is inappropriate;
- the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- the approval policies or regulations of regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to seek or obtain regulatory approval to market any other product candidates, which would significantly harm our business, results of operations and prospects. Moreover, any delays in the commencement or completion of clinical testing could significantly impact our product development costs and could result in the need for additional financing.

In addition, even if we or our collaboration partners were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than requested, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we fail to obtain approval for our most advanced product candidates or if the FDA-approved PF708 product, PF708 or our most advanced product candidates are not commercially successful, we may have to curtail our product development programs and our business would be materially harmed.

We have invested a significant portion of our time, financial resources and efforts in the development of PF708 and our other product candidates. The clinical and commercial success of our product candidates and the commercial success of the FDA-approved PF708 product will depend on a number of factors, including our and our collaboration partners' ability to assure the following:

- timely and successful completion of all necessary clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third-party contractors;
- whether we obtain an "A" therapeutic equivalence designation for the FDA-approved PF708 product, which may allow the product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states;
- our ability to find suitable collaboration partners to develop our current product candidates or our ability to obtain substantial additional sources of funding to develop our current product candidates;
- timely receipt of necessary marketing approvals from the FDA, the European Commission, and similar foreign regulatory authorities;

- maintaining an acceptable safety and adverse event profile of the FDA-approved PF708 product, PF708 and any other product candidates following approval;
- achieving and maintaining compliance with all regulatory requirements applicable to our product candidates, including PF708, and the FDA approved PF708 product, or any other approved products;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- commercial sales of the FDA-approved PF708 product, PF708 and our other product candidates, if and when approved, whether alone or in collaboration with others;
- whether we or our collaboration partners are able to obtain timely and adequate coverage and reimbursement for our newly approved products by key payors, such as Medicare Part D for the FDA-approved PF708 product in the United States;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, where available, for our current product candidates;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- acceptance of the FDA-approved PF708 product, or our products candidates, if approved, by patients, the medical community and third-party payors; and
- the ability to raise additional capital on acceptable terms to achieve our goals.

If we and our collaboration partners are unable to seek and obtain regulatory approval or adequate coverage and reimbursement for the FDA-approved PF708 product or of our product candidates in a timely manner or at all, we may never realize revenue from these products and we may have to curtail our other product development programs. As a result, our business, financial condition and results of operations would be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on our collaboration partners, CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials for our product candidates. While we have agreements governing the committed activities of our collaboration partners and CROs, we have limited influence over their actual performance. A failure of one or more clinical trials can occur at any time during the trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates that have shown promising results in early studies may still suffer significant setbacks in subsequent clinical studies. There is a high failure rate for drugs and biologics proceeding through clinical studies, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if the clinical trials for our product candidates are completed, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past and may in the future experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement or completion of clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of human clinical studies;
- raise sufficient capital to fund a trial;
- obtain regulatory approval, or feedback on trial design, necessary to commence a trial;
- identify, recruit and train suitable clinical investigators;

- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board (IRB) approval or Ethics Committee (EC) positive opinion, as applicable at each site;
- identify, recruit, and enroll suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities of product candidate for use in clinical trials; and
- avoid delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies, or the inability to do any of the foregoing.

Patient enrollment is a significant factor in the completion of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or the ECs of the institutions in which such trials are being conducted, by the data safety monitoring board, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we or our collaboration partners experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from any of these product candidates will be delayed. In addition, any delays in completing clinical trials for our product candidates will increase our costs, slow down our product candidate development and approval process and jeopardize our or our collaboration partners' ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The development, manufacture and commercialization of therapeutic equivalent and vaccine products pose unique risks, and our failure to successfully introduce therapeutic equivalent and vaccine products could have a negative impact on our business and future operating results.

We are actively working to develop multiple therapeutic equivalent products and vaccines. The cost to develop each proposed therapeutic equivalent drug, and vaccine product candidate could vary significantly and is highly dependent on the specific compound and the amount and type of clinical work that will be necessary for regulatory approval. There can be no assurance that our clinical work will be successful, or that regulatory authorities will not require additional clinical development beyond that which we have planned. Additionally, we may enter into alliances and collaborations to fund biosimilar and therapeutic equivalent product research and development activities, and our ability to realize the benefits of such arrangements may depend on the success of any such biosimilar or therapeutic equivalent product program. Due to events beyond our control or the risks identified herein, we may be unable to fund all or some of our internal biosimilar, therapeutic equivalent, and vaccine product research and development initiatives, which would have an adverse impact on our strategy and growth initiatives.

If the FDA approves other therapeutic equivalent or generic products with Forteo as the reference drug and these drug products are successfully commercialized, the FDA-approved PF708 product may face additional competition and our business could suffer.

Other companies may seek FDA approval to manufacture and market therapeutic equivalent or generic product versions of Forteo. In October 2017, the FDA issued a draft guidance document that identified standards by which chemically manufactured, or synthetic, versions of Forteo may be approved under the 505(j), or Abbreviated New Drug Application (ANDA), regulatory pathway, which would not require the conduct of a comparative clinical trial in patients for approval of the product. Teva Pharmaceuticals USA, Inc. has filed an ANDA referencing Forteo that, if approved, could compete with the FDA-approved PF708 product. Apotex Corp. also has submitted an ANDA for a generic version of Forteo and other generic drug manufacturers may have filed and/or in the future may file ANDAs referencing Forteo. Products approved under the ANDA pathway are considered generic drugs, and generally are approved as therapeutic equivalents to the reference product, and therefore may be automatically substituted for the reference listed drug, depending on health care statutes and policies within each of the 50 states. The potential automatic substitution of these generic products may adversely affect our collaboration partner's ability to generate revenue with the FDA-approved PF708 product. If other therapeutic equivalent or generic product versions of Forteo are approved and successfully commercialized, Alvogen may never achieve significant market share for the FDA-approved PF708 product, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

If the FDA-approved PF708 product does not receive an "A" therapeutic equivalence designation from the FDA, our business may suffer.

In addition to obtaining FDA approval of our PF708 NDA, we and Alvogen have been seeking an "A" therapeutic equivalence designation for the FDA-approved PF708 product relative to the reference drug Forteo, which may permit the FDA-approved PF708 product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states. Consistent with our interactions with the FDA and its draft guidance document on demonstrating the therapeutic equivalence of drug-device combination products, we have completed a comparative human factors study comparing the FDA-approved PF708 product and Forteo. The human factors study was designed to further support a finding that the PF708 product is therapeutically equivalent to Forteo. On October 14, 2019, we announced the successful completion of our PF708 comparative use human factors study and our submission of the final study report to the FDA. The study data demonstrate that the user interface of the FDA-approved PF708 product was noninferior to that of Forteo® for each critical user task evaluated in the study based on a pre-specified statistical analysis of critical patient and caregiver tasks. We submitted the study results to the FDA in October 2019 for the FDA's consideration of a therapeutic equivalence designation for the FDA-approved PF708 product. While we believe this submission completes the information package required by the FDA to evaluate the therapeutic equivalence of the FDA-approved PF708 product, we cannot assure you that FDA will grant an "A" therapeutic equivalence designation to the FDA-approved PF708 product relative to Forteo, or that the FDA will make a timely decision regarding therapeutic equivalence. In addition, if we do not receive an "A" therapeutic equivalence designation, this may significantly impact Alvogen's ability to maximize revenues in the marketplace and could have a material adverse effect on our royalty revenues.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the Agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Failure to obtain regulatory approval in each regulatory jurisdiction would prevent us and our collaboration partners from marketing our products to a larger patient population and reduce our commercial opportunities.

In order to market our products in the EU, the United States and other jurisdictions, we or our collaboration partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. For example, in the EU, the EMA is responsible for the assessment of centralized marketing authorization applications for human medicines. This procedure results in a single marketing authorization granted by the European Commission that is valid in all EU Member States, as well as in EEA States Iceland, Liechtenstein and Norway. The time required to obtain approval abroad may differ from that required to obtain FDA approval. When a marketing authorization application is submitted to the EMA, a related scientific evaluation is conducted by the EMA's Committee for Medicinal Products for Human Use (CHMP), and a scientific opinion is prepared concerning the suitability of the product for authorization. This scientific opinion is sent to the European Commission which decides on the grant of marketing authorization. In accordance with the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days. This excludes clock stops during which additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as additional or different risks and we or our collaboration partners may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We or our collaboration partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products within the United States or in any market outside the United States. Failure to obtain these approvals would materially and adversely affect our business, financial condition and results of operations.

The United Kingdom's departure from the European Union results in uncertainty regarding regulatory requirements.

The United Kingdom left the EU on 31 January 2020, after which the UK has ceased to be an EU Member State. The EU and the UK have reached an agreement which will govern the UK's relation with the EU until the end of 2020. It is uncertain how the legal relation between the UK and the EU will be governed after 2020. The legal frameworks and regulatory requirements applicable to medicinal products may diverge and separate marketing authorizations and other regulatory approvals may be required to place medicinal products on the market and to manufacture, distribute, import and export medicinal products in the UK and in the EU.

The FDA-approved PF708 product, PF708, and any of our other product candidates, if approved, will be subject to ongoing regulatory review.

The FDA-approved PF708 product, PF708 and any of our other product candidates, if approved, and any products we develop will be subject to ongoing regulatory review with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we, our collaboration partners, and our contract manufacturers will be subject to continual and unannounced review and inspections by the regulatory authorities governing the markets in which we wish to sell our products. Accordingly, we, our collaboration partners and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

The PF708 product NDA and any regulatory approvals that we and our collaboration partners may receive for PF708 or any of our other product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or on other conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the safety and efficacy or the safety, purity, and potency of the product candidate. We and our collaboration partners will be required to promptly report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities, as well as submit other periodic reports. Any new legislation addressing drug or biologic product safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We and our collaboration partners will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug and biologic products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, 351(k) application or marketing authorization application must submit new or supplemental applications and obtain prior approval for certain

changes to the approved product, product labeling, or manufacturing process. We or our collaboration partners could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in penalties or other adverse consequences, up to and including potential withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, or if we or our collaboration partners fail to comply with applicable regulatory requirements, such regulatory agency may impose restrictions on that product or us or our collaboration partners, including requiring withdrawal of the product from the market. If we or our collaboration partners fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may subject us to administrative or judicially imposed sanctions or other actions, including, among other things:

- adverse publicity, fines or untitled or warning letters;
- mandated modifications to promotional materials or requirements to provide corrective information to healthcare practitioners;
- a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- civil or criminal penalties;
- injunctions;
- suspending or withdrawing regulatory approval;
- suspending any of our ongoing clinical studies;
- refusing to approve pending applications or supplements to approved applications submitted by us;
- imposing restrictions on our operations, including suspending or closing our contract manufacturers' facilities; or
- seizing or detaining products or requiring a product recall.

Any government investigation of alleged violations of law could require us or our collaboration partners to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our or our collaboration partners' ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

We or our collaboration partners will also be subject to various health care fraud and abuse laws, including anti-kickback, false claims and fraud laws, and physician payment transparency laws, and any violations by us of such laws could result in fines or other penalties.

We received FDA approval for the FDA-approved PF708 product in October 2019. Because Alvogen is commercializing the FDA-approved PF708 product, Alvogen will be subject to healthcare regulation and enforcement by the U.S. federal government and the states related to the FDA-approved PF708 product. If we or our collaboration partners commercialize PF708 or our other product candidates, we or they will be subject to analogous healthcare regulation and enforcement in the applicable jurisdictions in which we or they commercialize our product candidates. These laws include anti-kickback, fraud and abuse, false claims, and physician sunshine laws and regulations. In the United States, for example, the federal Anti-Kickback Statute (AKS) prohibits, among other things, knowing and willful solicitation, offer, receipt, or payment of remuneration, directly or indirectly, by persons and entities in exchange for or to induce either the referral of patients for, or the purchase, order, arrangement or recommendation of any good or service that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Violations of the AKS may also result civil and criminal penalties, including criminal fines and imprisonment, or exclusion from federal healthcare programs. Liability under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it, and a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The federal civil False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment of government funds. Actions under the FCA may be brought by as qui tam actions by private individuals in the name of the government.

Violations of the FCA can result in significant mandatory monetary penalties per false claim or statement, treble damages and exclusion from federal health care programs. The federal Physician Payments Sunshine Act requires, among other parties, certain manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value made to physicians, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our or our collaborators' operations are found to be in violation of any of such laws or any other governmental regulations that apply, we or our collaborators may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, and exclusion from participation in federal and state healthcare programs, any of which could adversely affect our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us or our collaboration partners for violation of these laws, even if successfully defended against, could cause us or our collaboration partners to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure investors that our or our collaborators' internal control policies and procedures will prevent violations of these laws, or allegations of such violations, which could result in fines, penalties or prosecution and/or otherwise have a negative impact on our business, results of operations and reputation.

We also may be subject to healthcare privacy and data privacy laws and regulations, and violations of these laws could result in government enforcement actions and create liability for us, private litigation and/or adverse publicity that could negatively affect our business.

We may be subject to laws and regulations covering data privacy and security of health information, and the collection, use, disclosure, and the protection of health-related and other personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, state genetic privacy laws, and federal and state consumer protection and privacy laws (including, for example, Section 5 of the FTC Act and the California Consumer Privacy Act (CCPA)), govern the collection, use, disclosure, and protection of personal information. Compliance with these laws is difficult, constantly evolving, and time consuming. These laws may differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. In addition, healthcare providers who prescribe our products and research institutions we collaborate with are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than potentially with respect to providing certain employee benefits, we potentially could be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In California, CCPA took effect on January 1, 2020. The CCPA establishes certain requirements for data use and sharing transparency and creates new data privacy rights for consumers. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are a number of legislative proposals in the European Union, the United States, at both the federal and state level, as well as other jurisdictions that could impose new obligations or limitations in areas affecting our business. In addition, some countries are considering or have passed legislation implementing data protection requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities. These laws and regulations, as well as any associated claims, inquiries, or investigations or any other government actions may lead to unfavorable outcomes including increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, and remedies that harm our business, including fines or demands or orders that we modify or cease existing business practices.

EU member states, Switzerland and other countries have also adopted data protection laws and regulations that impose significant compliance obligations. In the EU, the collection and use of personal health data is governed by the provisions of the General Data Protection Regulation (GDPR). The GDPR entered into application on 25 May 2018, repealing the Data Protection Directive and increasing our responsibility and liability in relation to the processing of personal data of EU subjects. The GDPR imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

These obligations and restrictions concern, in particular, the legal basis for processing personal data, which may include the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data outside the EU, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations. Data protection authorities from the different EU member states may interpret the GDPR slightly differently, which adds to the complexity of processing personal data of EU subjects.

With respect to the transfer of personal data out of the EU, the GDPR provides that the transfer of personal data to countries that the European Commission does not consider to provide an adequate level of data protection, including the United States, is permitted only on specific legal bases.

Our failure to comply with these laws, or changes in the way in which these laws are implemented, could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us or our collaboration partners to obtain regulatory approval of our product candidates and to produce, market, and distribute our products after approval is obtained, if any.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacturing, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could require substantial time and impose significant costs and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

If efforts by manufacturers of reference products to delay or limit the use of therapeutic equivalent products are successful, sales of therapeutic equivalent products may suffer.

Many manufacturers of reference products have increasingly used legislative, regulatory and other means in attempts to delay regulatory approval of and competition from therapeutic equivalent products. If these or other efforts to delay or block competition are successful, we or our collaboration partners may be unable to sell our therapeutic equivalent product candidates, which could have a material adverse effect on our sales and profitability.

Our and our collaboration partners' sales are dependent on the availability and level of coverage and reimbursement from third-party payors who continue to implement cost-cutting measures and more stringent reimbursement standards.

In the United States and internationally, our and our collaboration partners' ability to generate revenue on sales of our products are dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payors, such as state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. In addition, particularly in the U.S. and increasingly in other countries, we will be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities.

As Alvogen commercializes the FDA-approved PF708 product, a significant portion of the product's revenue may be obtained through government payors, such as Medicare and Medicaid. For example, we expect that a substantial proportion of the U.S. market for the FDA-approved PF708 product could be subject to coverage and reimbursement under the federal healthcare program Medicare Part D. Any delay or failure by Alvogen to obtain adequate coverage for the FDA-approved PF708 product or to qualify for or receive adequate reimbursement under these programs could impact Alvogen's ability to maximize revenues in the marketplace and could have a material adverse effect on revenues from such products.

In March 2010, the ACA was enacted with a goal of reducing the cost of healthcare, improving quality, and expanding access to care. The ACA has substantially changed the way healthcare is financed by both government and private insurers and has significantly affected the pharmaceutical industry. The ACA, among other things, implemented new price reporting requirements for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, added new entity types eligible for participation in the Public Health Service's 340B drug pricing program, established annual fees and taxes on manufacturers of certain prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts (as of January 1, 2019) off negotiated prices.

In addition, legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% per fiscal year under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction to 2029. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in reduced demand for the FDA-approved PF708 product or our product candidates, if approved, or additional pricing pressures. Certain provisions of the ACA have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate". In December 2018, the District Court for the Northern District of Texas ruled (i) that the "individual mandate" is unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act; and (ii) the individual mandate is not severable from the rest of the ACA, and as a result the entire ACA is invalid. In December 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, which is now pending before the Supreme Court, or other efforts to repeal, replace, or invalidate the ACA or its implementing regulations, or portions thereof, will affect our business.

With the approval of the FDA-approved PF708 product, we anticipate that Alvogen will need to participate in the Medicaid Drug Rebate program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we or our collaboration partners would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD

Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The requirements under the Medicaid Drug Rebate, 340B, FSS, and TRICARE programs could reduce the revenue we or our collaboration partners may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

If we or our collaboration partners successfully commercialize the FDA-approved PF708 product, PF708 or any of our product candidates and if we or our collaboration partners participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to various government agencies. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non-federal average manufacturer price for the VA FSS pricing program. If we or our collaborators successfully commercialize the FDA-approved PF708 product, PF708 or any of our other product candidates and participate in such governmental pricing programs, we or our collaboration partners will be liable for errors associated with submission of pricing data. That liability could be significant. For example, knowing submission of false average manufacturer price, average sales price, best price, or non-federal average manufacturer price information to the government, or failure to timely submit such information, could result in liability for significant civil monetary penalties. The foregoing also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program.

Foreign governments tend to impose strict price controls, which may adversely affect our revenue, if any.

In some foreign countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Our existing or future collaboration partners, if any, may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals which could adversely affect our revenues and profits. To obtain reimbursement or pricing approval in some countries, we or our collaboration partners may also be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

If in the future we and our collaboration partners are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of regulatory authorities, those partners will not obtain regulatory approval for commercial sale of our biosimilar product candidates and our future results of operations would be adversely affected.

Our future results of operations depend on our future collaboration partners' ability to obtain regulatory approval for and commercialize our proposed biosimilar products. To obtain regulatory approval for the commercial sale of these product candidates, those partners will be required to demonstrate to the satisfaction of regulatory authorities that, among other things, our proposed biosimilar products are highly similar to biological products already licensed by the FDA pursuant to BLAs, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. In the EEA, the similar nature of a biosimilar and a reference product is demonstrated by comprehensive comparability studies covering quality, biological activity, safety and efficacy.

To make a final determination of biosimilarity or interchangeability, regulatory authorities may require additional confirmatory information beyond what our collaboration partners plan to initially submit in applications for approval, such as more in-depth analytical characterization, animal testing, or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive. We cannot predict whether any of our biosimilar product candidates will meet regulatory authority requirements for approval as a biosimilar or interchangeable product. To date, the FDA has not approved a biosimilar product as being interchangeable to the reference drug.

We and our collaboration partners intend to market our products outside of the United States, and we will be subject to the risks of doing business outside of the United States.

Because we and our collaboration partners intend to market PF708 and our product candidates, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in foreign laws and regulatory requirements;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in foreign countries;
- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of product candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates.

Moreover, our partners and third-party contractors located outside the U.S. may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

Risks Relating to Owning Our Common Stock

The market price of our stock may fluctuate significantly, and investors may have difficulty selling their shares.

Our stock is currently traded on NYSE American, but we can provide no assurance that we will be able to maintain an active trading market on NYSE American or any other exchange in the future. The trading volume of our stock tends to be low relative to our total outstanding shares, and we have several stockholders who hold substantial blocks of our stock. As of December 31, 2019, we had 32,266,708 shares of common stock outstanding, and stockholders holding at least 5% of our stock, individually or with affiliated persons or entities, collectively beneficially owned or controlled approximately 48% of such shares. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our relatively small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline.

Since shares of our common stock were sold in our initial public offering in July 2014 at a price of $6.00 per share, our stock price has ranged from $2.07 to $24.41 through December 31, 2019. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report on Form 10-K, factors that may cause volatility in our share price include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- changes to our organization and management;
- commencement of, or our involvement in, litigation;

- market conditions in the relevant market;
- reimbursement or legislative changes in the relevant market;
- failure to complete significant sales;
- regulatory developments that may impact the FDA-approved PF708 product, PF708 and our product candidates;
- any future sales of our common stock or other securities;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general and market prices for the securities of biopharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock regardless of operating performance.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been and will likely continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If securities or industry analysts publish unfavorable research about our business or cease to cover our business, our stock price and/or trading volume could decline.

The trading market for our common stock may rely, in part, on the research and reports that equity research analysts publish about us and our business. We do not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, the market price of our common stock may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. Any such future issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could reduce the price that our common stock might otherwise attain and may dilute your voting power and your ownership interest in us.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. We also register the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

The 2019 net operating loss carryforwards are available to offset future taxable income until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We may have experienced an ownership change in connection with sale of securities pursuant to a predecessor registration statement or otherwise and we may experience ownership changes in the future as a result of shifts in our stock ownership, including as a result of the sale of securities. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs to offset such taxable income may be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

We are incurring increased costs as a result of operating as a public company and our management is required to devote substantial time to new compliance initiatives and corporate governance practices including maintaining an effective system of internal control over financial reporting.

As a public company, we are incurring significant legal, accounting and other expenses that we did not incur as a private company. We ceased to be an "emerging growth company" on December 31, 2019 and are no longer eligible for reduced disclosure requirements and exemptions applicable to "emerging growth companies." As such, we will be required to hold a say-on-pay vote and a say-on-frequency vote at our 2020 annual meeting of stockholders. We expect that our loss of "emerging growth company" status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC, and the NYSE American impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934 (Exchange Act), as amended, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel devote a substantial amount of time to comply with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and changing governance practices.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes-Oxley Act requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act (Section 404(b)) also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. As an "emerging growth company," we availed ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b). However, we may no longer avail ourselves of this exemption since we ceased to be an "emerging growth company" on December 31, 2019. As a result, our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting and the cost of our compliance with Section 404(b) will correspondingly increase. Our compliance with applicable provisions of Section 404 requires us and will continue to require us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of any required compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

If we fail to maintain effective internal control over financial reporting in the future, the accuracy and timing of our financial reporting may be impaired, which could adversely affect our business and our stock price.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management time on compliance-related issues. We currently do not have an internal audit group, and we continue to evaluate our need for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we do not comply with the requirements of Section 404, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the NYSE American, the SEC, or other regulatory authorities, which would require additional financial and management resources.

Our directors, executive officers and principal stockholders will continue to have substantial control over us and could limit investors' ability to influence the outcome of key transactions, including transactions that would cause a change of control.

As of December 31, 2019, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates beneficially owned or controlled approximately 50% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and stockholders and their respective affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may therefore delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of the board of directors, or the chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

We do not anticipate paying any cash dividends in the foreseeable future.

At the closing of our initial public offering, our board of directors issued shares of common stock to pay all accrued but unpaid dividends on our convertible preferred stock. With the exception of this dividend, we do not anticipate paying cash dividends on any classes of our capital stock in the foreseeable future. We currently intend to retain our future earnings for the foreseeable future to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our common stock for the foreseeable future.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

As of December 31, 2019, we leased a total of approximately 46,959 square feet of office and laboratory space located at 10790 and 10788 Roselle Street, San Diego, CA 92121. The lease expires on March 31, 2024. We believe that our existing facilities are adequate to meet our business requirements for the foreseeable future and that additional space will be available on commercially reasonable terms, if required.

Item 3. ***Legal Proceedings***

On May 6, 2019, Pfenex filed two petitions for inter partes review of U.S. Patent No. 9,422,345 ("the '345 patent"; entitled "Expression System"), which is owned by GlaxoSmithKline Biologicals S.A., with the Patent Trial and Appeal Board ("PTAB") of the U.S. Patent and Trademark Office. The '345 patent relates to polynucleotides that express diphtheria toxin mutants, including the diphtheria toxin mutant CRM197. These two petitions, IPR2019-01027 and IPR2019-01028, seek, inter alia, a determination that certain claims in the '345 patent are invalid. Institution decisions by the PTAB for IPR2019-01027 and IPR2019-01028 are expected within the 2019 calendar year, and a final written decision determining the validity of the challenged claims of the '345 patent, if these two petitions are instituted by the PTAB, by the end of 2020. On August 9, 2019, Pfenex filed a third petition for inter partes review of the '345 patent with the PTAB of the U.S. Patent and Trademark Office. The third petition, IPR2019-01478, seeks, inter alia, a determination that certain claims in the '345 patent are invalid. An institution decision by the PTAB for IPR2019-01478 is expected within the first quarter of 2020, and a final written decision on the validity of the challenged claims of the '345 patent, if the third petition is instituted by the PTAB, by the end of the first quarter of 2021. On November 14, 2019, the Board instituted trial on the invalidity grounds in IPR2019-01028, but exercised its discretion not to institute trial on IPR2019-01027 under its rules for multiple petitions.

Item 4. ***Mine Safety Disclosures.***

Not applicable.

PART II

Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Market Information and Holders of Record

Our common stock has been listed on the NYSE American under the symbol "PFNX" since July 24, 2014. Prior to that date, there was no public trading market for our common stock. As of March 2, 2020, we had 20 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

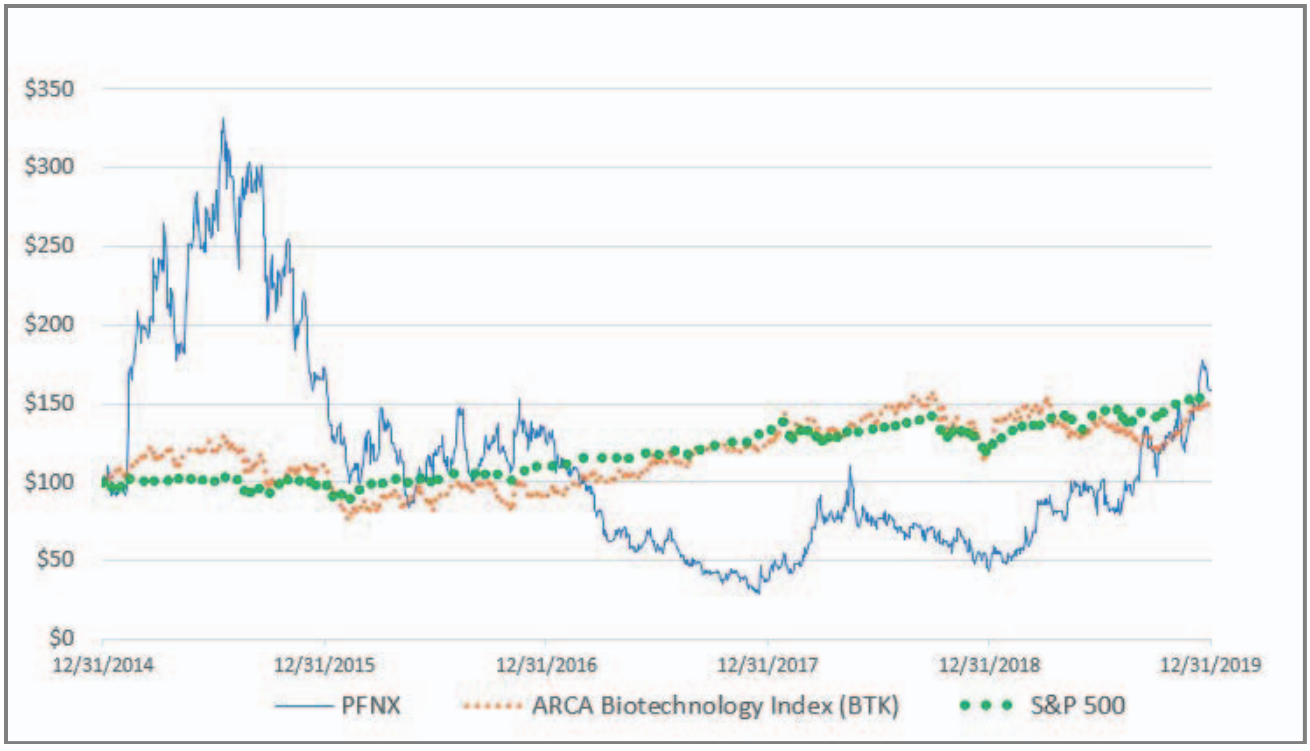
Dividends

With the exception of common stock issued in connection with the payment of all accrued but unpaid dividends upon the conversion of all preferred stock upon the completion of our initial public offering, we have not made any distributions on our common stock and do not intend to make any distributions on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or incorporated by reference into any filing of Pfenex Inc. under the Securities Act of 1933, as amended, or the Exchange Act.

The graph below shows the cumulative total stockholder return assuming the investment of $100 as of the close on December 31, 2014, and the reinvestment of dividends thereafter in each of (i) Pfenex Inc.'s common stock, (ii) the ARCA Biotechnology Index and, (iii) the S&P 500 Index. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or the index. The prices are as of December 31, 2014 to the close at December 31, 2019.



Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities and Issuer Purchases of Equity Securities

(a) Sales of Unregistered Securities

None.

(b) Issuer Purchases of Equity Securities

None.

Item 6. *Selected Financial Data*

The following selected historical financial data below should be read in conjunction with Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations,*" our financial statements, and the related notes appearing in Item 8, "*Financial Statements and Supplementary Data*", of this Annual Report on Form 10-K to fully understand factors that may affect the comparability of the information presented below.

The consolidated statements of operations data for the years ended December 31, 2019, 2018 and 2017and the consolidated balance sheet data as of December 31, 2019 and 2018 are derived from our audited financial statements appearing in Item 8, "*Financial Statements and Supplementary Data*," of this Annual Report on Form 10-K. The consolidated statements of operations data for the year ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 are derived from audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results to be expected in the future.

	Years Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except for per share data)				
Revenues	$ 50,326	$ 14,857	$ 28,780	$ 60,194	$ 9,583
Expense:					
Cost of revenue [(1)]	4,891	5,022	5,156	5,313	4,640
Research and development [(1)]	25,533	33,854	31,925	32,418	18,183
Selling, general and administrative	19,078	15,832	17,674	17,340	14,598
Total expense	49,502	54,708	54,755	55,071	37,421
Income (loss) from operations	824	(39,851)	(25,975)	5,123	(27,838)
Other income (expense), net	235	258	119	149	74
Income (loss) before income taxes	1,059	(39,593)	(25,856)	5,272	(27,764)
Income tax (provision) benefit	(1)	—	172	209	(452)
Net income (loss)	$ 1,058	$ (39,593)	$ (25,684)	$ 5,481	$ (28,216)
Net income (loss) attributable to common stockholders	$ 1,058	$ (39,593)	$ (25,684)	$ 5,481	$ (28,216)
Basic and diluted net income (loss) per share attributable to common stockholders	$ 0.03	$ (1.40)	$ (1.09)	$ 0.23	$ (1.26)
Basic weighted-average shares used to compute net income (loss) per share attributable to common stockholders	31,602	28,340	23,503	23,389	22,376
Diluted weighted-average shares used to compute net income (loss) per share attributable to common stockholders	32,373	28,340	23,503	23,688	22,376

(1) Please refer to Note 1 of our consolidated financial statements for an explanation of the method used to recognize cost of revenue and research and development expense.

Other Financial Data

	As of December 31,				
	2019	2018	2017	2016	2015
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents and short-term investments	$ 55,624	$ 56,220	$ 57,664	$ 81,501	$ 106,162
Restricted cash	200	200	200	—	3,959
Accounts and unbilled receivables, net	5,628	5,171	1,306	2,822	2,683
Inventory	—	—	—	—	24
Property and equipment, net	7,744	7,671	7,397	5,246	3,179
Right-of-use asset	3,903	—	—	—	—
Goodwill and intangibles	9,310	9,825	10,348	10,878	11,409
Other	2,478	2,191	2,476	2,675	4,278
Total assets	$ 84,887	$ 81,278	$ 79,391	$ 103,122	$ 131,694
Current liabilities	$ 9,666	$ 12,133	$ 11,046	$ 10,696	$ 6,883
Deferred revenue	—	7,817	10,163	12,255	48,095
Debt	—	—	—	—	3,813
Lease liabilities – long-term	2,896	—	—	—	—
Other	26	191	419	26	1,722
Total liabilities	12,588	20,141	21,628	22,977	60,513
Stockholders' equity	72,299	61,137	57,763	80,145	71,181
Total liabilities and stockholders' equity	$ 84,887	$ 81,278	$ 79,391	$ 103,122	$ 131,694

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "projections," "business outlook," "estimate," or similar expressions constitute forward-looking statements. Our actual results could differ materially from those contained in or implied by any forward-looking statements. Factors that could cause or contribute to these differences include those discussed below, in the section captioned "Risk Factors," and elsewhere in this Annual Report on Form 10-K.

Overview

We are a development and licensing biotechnology company focused on leveraging our proprietary protein production platform, *Pf*ēnex Expression Technology®, to develop next generation and novel protein therapeutics to meaningfully improve existing therapies and create novel therapies for some of the biological targets linked to critical diseases still waiting to successfully be addressed. We have extensive experience in protein therapeutic development and our proven platform enables deliberate and rapid candidate selection, fast drug development, and potentially higher success rates for a wide range of complex modalities. We aim to leverage existing drug development successes into a broad pipeline that is diversified across multiple assets, including U.S. Food and Drug Administration (FDA) approved, next generation and novel biopharmaceutical products.

In October 2019, the FDA approved the new drug application (NDA) for PF708 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 for fracture. Marketing authorization applications are pending in other jurisdictions. This FDA-approved PF708 product will be commercialized and manufactured in the U.S. by our collaboration partner, Alvogen. In November of 2019, in accordance with the Development and License Agreement, (US Alvogen Agreement), we transferred the NDA to Alvogen. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product.

Our other products and collaborations include PF743 (JZP-458), which we are developing in collaboration with Jazz Pharmaceuticals for the treatment of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma and which commenced a pivotal Phase 2/3 clinical study in December 2019. We also have collaborations based on CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates, with Merck & Co Inc. (Merck) and Serum Institute of India Private Limited (SIIPL). Both Merck and SIIPL have licenses to the Pfēnex Expression Technology for the production of CRM197 for use in conjugate vaccine products. Merck's V114, a 15-valent Pneumococcal conjugate vaccine is currently in 15 Phase 3 clinical trials, and SIIPL's Pneumosil®, a 10-valent Pneumococcal vaccine designed for the developing world, recently achieved World Health Organization (WHO) Prequalification allowing the product to be procured by United Nations agencies and Gavi, the Vaccine Alliance. In addition, a Phase 3, randomized, double-blind study to evaluate the immunogenicity, safety and tolerability of Pneumosil in healthy Indian infants has been completed and SIIPL is currently in the process of submitting the data from the Phase 3 trial to the Drug Controller General of India (DCGI) in support of India marketing authorization.

In the third quarter of 2019, we added PF810, a peptide based next generation therapeutic, to our wholly owned pipeline. PF810 is currently in preclinical development. In addition, we have established a strategic collaboration with Arcellx, Inc. (Arcellx) to advance multiple proprietary sparX proteins that activate, silence and reprogram Antigen-Receptor Complex T cell based therapies based on the Arcellx product platform.

Our FDA-Approved Product, Our Product Candidates and Collaborations

The following summarizes certain information about the FDA-approved product that we developed, our pipeline candidates, and collaborations:

Our FDA-Approved Product, Product Candidates and Collaborations	Branded Reference Drug	Program
FDA-Approved PF708 Product	Forteo®	• Approved in the United States; licensed to Alvogen
PF708	Forteo®	• Product candidate in EU, MENA, and Rest of World licensed to Alvogen (excluding areas licensed to NT Pharma) • Product candidate in Mainland China, Hong Kong, Singapore, Malaysia, Thailand licensed to NT Pharma
Multiple Hematologic Oncology Product Candidates	N/A	• PF743 (JZP-458) – Recombinant Erwinia asparaginase • PF745 (JZP-341) – Long-acting recombinant Erwinia asparaginase • PF690* – pegaspargase
Peptide based next generation therapeutic	N/A	• PF810
Arcellx sparX programs	N/A	• PF753 • PF754

*Jazz retains an exclusive option to license this product pursuant to certain option triggers.

In pursuit of novel wholly-owned product candidates, we have also established a collaboration with a third-party technology platform company who is screening our selected, validated biological targets with its novel binding modality library in an effort to identify potential lead product candidates. Those candidates will be transferred to us and could become wholly owned product candidates developed by us.

FDA-Approved PF708 Product

In October 2019, the FDA approved the NDA for PF708 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 for fracture. The FDA-approved PF708 product will be commercialized and manufactured in the U.S. by our collaboration partner, Alvogen. In November of 2019, we transferred the NDA to Alvogen pursuant to our collaboration agreement. Forteo (marketed by Eli Lilly and Company) achieved $1.4 billion in global product sales in 2019. Almost half of these product sales came from the United States alone. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product.

The FDA approval of the FDA-approved PF708 product was supported by data from Study PF708-301, which compared the effect of PF708 and Forteo in osteoporosis patients. The PF708-301 study enrolled a total of 181 patients, with 90 patients receiving PF708 and 91 patients receiving Forteo. Eighty-two patients completed the study in the FDA-approved PF708 product treatment group, compared with 81 patients in the Forteo treatment group. The primary study endpoint was anti-drug antibody (ADA) incidence after 24 weeks of drug treatment. 2.2% (2/90) of patients who received PF708 and 2.2% (2/91) of patients who received Forteo had detectable antibodies to teriparatide, and one of the two patients who received PF708 developed neutralizing antibodies to teriparatide. The secondary study endpoints included mean percentage changes in lumbar-spine bone mineral density (BMD) and median percentage changes in bone turnover markers (BTM) after 24 weeks of drug treatment, as well as pharmacokinetic (PK) parameters for up to four hours after the first dose. Safety endpoints were incidences of adverse events (AE) and serious adverse events (SAE).

The PF708-301 study showed comparable overall profiles between PF708 and Forteo across multiple endpoints. These results from the PF708-301 study, along with bioequivalence findings from Study PF708-101 in healthy subjects, supported the PF708 NDA submitted in December 2018 pursuant to the 505(b)(2) pathway. On October 4, 2019 the NDA was approved by the FDA.

In addition to obtaining FDA approval of PF708, we have been continuing our efforts to obtain an "A" therapeutic equivalence designation for the product relative to its reference drug, Forteo. A determination of therapeutic equivalence (as shown by an "A" rating) may permit the FDA-approved PF708 product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the U.S. Consistent with our interactions with the FDA and the agency's draft guidance document on comparative use human factors studies for demonstrating the therapeutic equivalence of drug-device combination products, we successfully completed the PF708 comparative use human factors (HF) study and submitted the final study report to the FDA in October 2019. The study data demonstrate that the user interface of the FDA-approved PF708 product was noninferior to that of Forteo for each critical user task evaluated in the study based on a pre-specified statistical analysis of critical patient and caregiver tasks.

The comparative use HF study was a simulated use study intended to evaluate the effect of each product's delivery device and user interface on critical task performance by untrained osteoporosis patients and caregivers. The study used a paired design of the FDA-approved PF708 and the Forteo products.

A total of 102 untrained participants, 52 osteoporosis patients and 50 caregivers, completed the study. For 67% (12 of 18) of critical tasks performed in the patient user group, and 83% (15 of 18) performed in the caregiver group, PF708 had fewer or equal user errors when compared to Forteo. Importantly, in each of the instances where PF708 had marginally higher user error rates 33% (6/18) of critical tasks performed in the patient user group, and 17% (3/18) of critical tasks performed in the caregiver user group, the magnitude of the differences (≤ 2 UEs and ≤ 3 UEs, respectively) did not exceed the predetermined maximum allowable difference in either user group. For these reasons, we believe the study data demonstrate that the user interface of the FDA-approved PF708 product is noninferior to that of Forteo based on pre-specified statistical analysis of critical patient and caregiver tasks. With submission of the final study report to FDA, we believe this completes the information package required by the FDA to evaluate the therapeutic equivalence of the PF708 product. For a discussion of certain significant risks relating to the FDA-approved PF708 product, please see the following Risk Factors: "*The FDA-approved PF708 product, PF708 and our other product candidates, if approved, face significant competition from the reference products and from therapeutic equivalent products of the reference products, and from other products. Our or our collaboration partners' failure to effectively compete may prevent us from achieving significant market penetration and expansion.*" and "*If the FDA-approved PF708 product does not receive an "A" therapeutic equivalence designation from the FDA, our business may suffer.*"

In June 2018, we and Alvogen entered into the US Alvogen Agreement pursuant to which Alvogen received the exclusive right to commercialize and manufacture PF708 in the United States. Alvogen intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. In February 2019 we and Alvogen expanded our collaboration, granting Alvogen exclusive rights to commercialize and manufacture PF708 in the EU, certain countries in the Middle East and North Africa (MENA), and the rest of the world (ROW) territories (the latter defined as all countries outside of the EU, US and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). We believe this collaboration leverages Alvogen's established international experience and expertise in regulatory, IP and supply chain activities, as well as its established network of specialty pharmaceutical companies to conduct sales and marketing activities in these regions.

Alvogen submitted a centralized application to the European Medicines Agency (EMA) for PF708 on May 6, 2019, and the filing was accepted by the EMA on May 23, 2019. We believe that PF708 could be approved in the EU as early as the second half of 2020, pending marketing authorization by the European Commission under the EU centralized procedure and other factors. In October 2019, Alvogen's partner SAJA, submitted a Marketing Authorization Application (MAA) for PF708 to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). Subject to applicable regulatory approvals, PF708 will be commercialized in Europe and other jurisdictions by Alvogen's current and/or future commercialization partners including Theramex in Europe, SAJA, a Tamer Group company in MENA, JAMP Pharma in Canada, Kamada Ltd. in Israel, and Pharmbio Korea, Inc. in South Korea. Alvogen is responsible for overseeing any clinical development, regulatory, litigation, commercial manufacturing or commercialization activities of its partners in these jurisdictions. We are eligible to receive additional upfront and milestone payments of $1.5 million for the EU, MENA and ROW agreements, and we may also be eligible to receive up to 60% of Alvogen's gross profit derived from product sales, if approved, depending on geography and cost of goods sold. In connection with the October 2019 FDA approval of PF708, we earned a $2.5 million milestone payment under our collaboration with Alvogen payable upon Alvogen's receipt of notice of NDA approval.

In April 2018, we and China NT Pharma Group Company Ltd. (NT Pharma) entered into a Development and License Agreement (NT Pharma Agreement), pursuant to which 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. In accordance with the agreement, we received a payment of $2.5 million upon signing the NT Pharma Agreement and may be eligible to receive additional payments of up to $22.5 million based on the achievement of certain development, regulatory, and sales-related milestones. We may also be eligible to receive double-digit royalties on net sales of PF708. NT Pharma is responsible for any further development required to achieve regulatory approval as well as commercialization activities in the applicable territories.

In accordance with regulatory requirements we provided notice of Paragraph IV certification (Notice Letter) to Eli Lilly and Company (Lilly) on February 19, 2019 that PF708 does not infringe any valid claim of the ’334 patent. Under the Hatch-Waxman Act, Lilly had 45 days from the receipt of the Notice Letter to file a patent infringement lawsuit against us that would cause a 30-month litigation stay of approval for PF708. On April 11, 2019 we 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. Lilly did not file a lawsuit within this time period, and there was no 30-month litigation stay that delayed approval of the FDA-approved PF708 product.

In May 2019, we entered into an agreement with Alvogen for us to provide PF708 drug substance batches and pen components in exchange for $2.3 million. This product sold to Alvogen was initially manufactured by our CMO for manufacturing process validation purposes as part of the PF708 NDA submission to the FDA for approval. We do not expect to have similar transactions with our collaboration partners in the future.

Jazz Collaboration—multiple hematologic oncology product candidates- In July 2016, we entered into a license and option agreement with Jazz, pursuant to which we and Jazz are developing hematologic oncology products, including PF743 (JZP-458), a recombinant Erwinia asparaginase, and PF745 (JZP-341), a long-acting recombinant Erwinia asparaginase, and Jazz will have the exclusive right to manufacture and commercialize such products throughout the world. In addition, pursuant to the agreement, we have granted Jazz certain other rights to negotiate the exclusive right to develop, manufacture and commercialize throughout the world other hematologic oncology products that are currently or in the future may be developed by us. Both PF743 (JZP-458) and PF745 (JZP-341) are being developed for the treatment of ALL and other hematological malignancies. In the third quarter of 2017, we achieved a process development milestone associated with this collaboration. In December 2017, we and Jazz signed an amended and restated agreement under which we will be eligible to receive an additional $43.5 million in amendment fee and development milestone payments as compared to the 2016 agreement, increasing the total value of upfront, option and amendment fee payments and potential payments for the achievement of development, regulatory and sales-related milestones associated with the collaboration to an aggregate of $224.5 million. We will also continue to be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from those under the 2016 agreement. In December 2017, as part of the amended and restated agreement, we received a total payment of $18.5 million, consisting of an upfront payment of $5.0 million and a payment of $13.5 million for development achievement. In the second quarter of 2018, we achieved two development milestones and received $0.8 million for successful achievement of process development milestones for PF745. In August 2019, Jazz reported that they completed a Phase 1 study for PF743 (JZP-458). After receiving Fast Track designation from the U.S. Food and Drug Administration in October 2019, Jazz announced the initiation of a Phase 2/3 pivotal study for PF743(JZP-458) in December 2019 and recently announced their intent to file a Biologics License Application (BLA) with the US FDA as early as the fourth quarter of 2020. In September and December 2019, we achieved development milestones and received $11 million and $15 million, respectively, in connection with process development activities for PF745 (JZP-341).

CRM197 — We have both licenses and supply agreements in place for CRM197, which is a non-toxic mutant of diphtheria toxin. CRM197 is a well-characterized protein and functions as a carrier for polysaccharides and haptens, making them immunogenic. We have developed unique CRM197 production strains based on our *Pf*ēnex Expression Technology platform. As a result of our development efforts, we previously entered into commercial licenses for production strains capable of producing CRM197 with both Merck and SIIPL. Merck and SIIPL are using the CRM197 produced via the licensed production strain in multiple clinical stage and pre-clinical products. The clinical stage products currently include Merck’s 15-valent pneumococcal conjugate vaccine, PCV-15 (V114), currently in several ongoing Phase 3 clinical studies, and SIIPL’s 10-valent pneumococcal conjugate vaccine, Pneumosil®, which achieved WHO Prequalification in December 2019, and a pentavalent meningococcal conjugate vaccine currently in a Phase 3 clinical study. The CRM197 production strains utilized by both Merck and SIIPL are unique and exclusively licensed to each party. The commercial license agreements with Merck and SIIPL contemplate potential maintenance and milestone fees as well as royalties on net sales. Additionally, as part of the SIIPL commercial license agreement, SIIPL supplies both reagent grade and cGMP CRM197 to Pfenex, which supplies the product to vaccine development-focused pharmaceutical partners.

Arcellx Development, Evaluation and License Agreement - We previously 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, we are 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 a production strain based on the Pfēnex Expression Technology, as well as royalties on worldwide sales of any such products. We have completed the development of both sparX 1 and sparX 2 and Arcellx has opted into the commercial license for both production strains. As of December 31, 2019, we have earned $2.4 million in development funding from Arcellx.

Additional Biosimilar, Novel Vaccine and Other Pipeline Products — Our pipeline includes biosimilar candidates to certain reference products, including biosimilar candidates to Lucentis (PF582) and Neulasta (PF529) and two novel anthrax vaccine candidates, Px563L and RPA563, which are funded by the Biomedical Advanced Research and Development Authority (BARDA). In November of 2017, we paused development on both PF582 and PF529. We do not intend to advance PF582 or PF529 without development and commercial collaboration partners. In March 2019 we received a notice from BARDA advising us of BARDA's decision not to exercise development options for cGMP manufacturing, preclinical studies and Phase 1/2b study readiness in connection with our Px563L and RPA563 novel anthrax vaccine program. Following the receipt of the notice from BARDA and pursuant to discussions with BARDA, we deprioritized this program in our portfolio.

To date, PF708 is our only FDA approved product under the 505(b)(2) regulatory pathway, with Forteo as the reference drug. Our product candidates are enabled by our patented protein production platform, *Pf*ēnex Expression Technology, which we believe confers several important competitive advantages compared to traditional techniques for protein production, including the ability to produce complex proteins with higher accuracy and greater degree of protein purity, as well as speed and cost advantages. The development of proteins requires several competencies which represent both challenges and barriers to entry. Due to their inherent complexity, proteins require the use of living organisms to efficiently produce them at a large scale. Traditional techniques for protein production employ a trial and error approach to production organism, or strain, selection and process optimization, which is inherently inefficient and typically produces suboptimal results. This historically inefficient process provides barriers to creating or replicating complex proteins, adds significant time to market and results in the high cost of goods typical of biologic therapeutics. Together, these limitations pose significant hurdles for companies interested in entering the market with novel biologics, biosimilars and therapeutic equivalents. Our platform utilizes a proprietary high throughput fully automated parallel approach, which allows the construction and testing of thousands of unique protein production strains in parallel, thereby allowing us to produce and characterize complex proteins while reducing the time and cost of development and long-term production.

The potential market opportunities for our most advanced product candidate, PF708, are substantial. We have developed PF708 as a therapeutic equivalent candidate to Forteo, which achieved product sales of approximately $1.4 billion in 2019. Approximately 46% of these product sales came from the U.S. alone. In 2019, Forteo lost patent protection with respect to claims of patents listed in the Orange Book related to compounds, methods of treatment, and formulations in the U.S. An additional Orange Book listed patent, which has claims relating to the delivery system, expires in 2025. In accordance with regulatory requirements, we provided notice of Paragraph IV certification (Notice Letter) to Eli Lilly and Company (Lilly) on February 19, 2019 that PF708 does not infringe any valid claim of the '334 patent. Under the Hatch-Waxman Act, Lilly had 45 days from the receipt of the Notice Letter to file a patent infringement lawsuit against us that would cause a 30-month litigation stay of approval for PF708. On April 11, 2019 we 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. Lilly did not file a lawsuit within this time period, and there was no 30-month litigation stay that delayed approval of the FDA-approved PF708 product.

Our revenue for the three months ended December 31, 2019 and 2018 was $24.4 million and $3.4 million, respectively, and was $50.3 million and $14.9 million for the twelve months ended December 31, 2019 and 2018, respectively. Our historical revenue has been primarily derived from monetizing our *Pf*ēnex Expression Technology through collaboration agreements, service agreements, government contracts and reagent protein product sales, which provide for various types of payments, including upfront payments, funding of research and development, milestone payments, intellectual property access fees and licensing fees.

As of December 31, 2019, we had an accumulated deficit of $197.7 million, of which $89.8 million was attributable to recognizing the accretion in the redemption value of our convertible preferred stock. We recognized net income of $11.6 million and net loss of $6.8 million for the three months ended December 31, 2019 and 2018, respectively, and net income of $1.1 million and net loss of $39.6 million for the twelve months ended December 31, 2019 and 2018, respectively.

As we continue to develop and invest more resources into the development and commercialization of our product candidates, our net operating losses may increase over the next several years. Research and development expenses will continue to be material as we incur further costs of development. We are currently developing our wholly owned therapeutics, establishing additional product development partnerships, and investigating and targeting novel modalities for possible future lead candidates, and we do not yet have an extensive sales organization. We will need substantial additional funding to support our operating activities, especially as we approach anticipated regulatory approval in the United States, Europe and other territories, and begin to establish our commercialization capabilities. Adequate funding may not be available to us on commercially reasonable terms, or at all. Since our inception, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. We have devoted substantially all of our capital resources to the research and development of our product candidates and working capital requirements.

Recent Developments

In January and February 2020, we sold approximately 1.8 million shares of our common stock through an "at-the-market" equity offering program, for aggregate gross proceeds of approximately $20.0 million.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. Historical results are not necessarily indicative of future results.

We believe the following critical accounting policies involve significant judgements and estimates used in the preparation of our consolidated financial statements (see also Note 1 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K).

Revenues

Our revenues to date have been generated primarily through collaboration and license agreements. Our collaboration and license agreements frequently contain multiple elements including (i) intellectual property licenses, and (ii) product research and development services. Consideration received under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments. Our customers include Alvogen, NT Pharma, Jazz, Arcellx, and BARDA.

Effective January 1, 2019 (Adoption Date), we adopted ASC 606, *Revenue from Contracts with Customers* (ASC 606). ASC 606 supersedes prior revenue recognition guidance and establishes a comprehensive revenue recognition model with a broad principle that requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this principle, an entity identifies the contract with a customer, identifies the separate performance obligations in the contract, determines the transaction price, allocates the transaction price to the separate performance obligations and recognizes revenue when each separate performance obligation is satisfied. The standard allows for two methods of adoption: (a) "full retrospective" adoption, meaning the standard is applied to all periods presented, or (b) "modified retrospective" adoption, meaning the cumulative effect of applying the new guidance is recognized as an adjustment to the opening retained earnings balance for the year of implementation. We have adopted this standard as of January 1, 2019 using the modified retrospective method for those contracts which were not substantially completed as of the transition date. As a result, we have changed our accounting policy for revenue recognition as detailed below. The cumulative impact to our accumulated deficit balance at the Adoption Date as a result of the adoption of ASC 606 was a decrease of $2.5 million. The decrease relates to a reduction of deferred revenue associated to an upfront payment received from NT Pharma in 2018. The comparative information prior to the Adoption Date has not been restated and continues to be reported under the accounting standards in effect for the periods presented.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (ASC 808): Clarifying the Interaction between ASC 808 and ASC 606*. The amendments in ASU No. 2018-18 make targeted improvements to generally accepted accounting principles for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in ASC 808 was aligned with the guidance in ASC 606 when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. ASU No. 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments in ASU No. 2018-18 are required to be applied retrospectively to the date of initial application of ASC 606. We have adopted this standard concurrently with ASC 606 and did not materially impact on our financials upon adoption.

The following table summarizes the impacts of adopting ASC 606 on our consolidated financial statements, in thousands.

	Impact of Changes in Accounting Policies *($ thousands)*		
Three months ended December 31, 2019 (unaudited)	**As reported**	**Adjustments**	**Balances without adoption of ASC 606**
License and service revenue	$ 23,413	$ —	$ 23,413
Product revenue	992	—	992
Total revenues	24,405	—	24,405
Income from operations	11,595	—	11,595
Net income	$ 11,634.30	—	$ 11,634.30
Year ended December 31, 2019			
License and service revenue	$ 44,497	$ 2,500	$ 46,997
Product revenue	5,829	—	5,829
Total revenues	50,326	2,500	52,826
Income from operations	824	2,500	3,324
Net income	$ 1,058.00	2,500	$ 3,558.00

ASC 606 did not have an aggregate impact on our net cash used in operating activities but resulted in offsetting certain assets and liabilities presented within net cash used in operating activities in our consolidated statements of cash flows.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to be entitled to receive in exchange for goods or services and excludes sales incentives and amounts collected on behalf of third parties. We analyze the nature of these performance obligations in the context of individual agreements in order to assess the distinct performance obligations.

We apply the following five-step model to recognize revenue: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

i) Identify the contract with a customer. We consider the terms and conditions of our agreements to identify contracts within the scope of ASC 606. We conclude we have a contract with a customer when the contract is approved, each party's rights regarding the goods and services to be transferred can be identified, the payment terms for the goods and services can be identified, it has been determined that the customer has the ability and intent to pay and the contract has commercial substance. We use judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) Identify the performance obligations in the contract. Performance obligations in the agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from us, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. Our performance obligations generally consist of intellectual property licenses and research and development services with respect to license and service agreements, and the manufacture and supply of product for product sales agreements.

iii) Determine the transaction price. We determine the transaction price based on the consideration to which we expect to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from our customers. None of our revenue generating contracts contain consideration payable to our customer or a significant financing component.

iv) Allocate the transaction price to performance obligations in the contract. If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) Recognize revenue when or as we satisfy a performance obligation. Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. We recognize revenue when control of the goods or services is transferred to the customers for an amount that reflects the consideration that we expect to receive in exchange for those goods or services.

Performance Obligations.

The following is a general description of principal goods and services from which we generate revenue.

License to intellectual property

We generate revenue from licensing our intellectual property including know-how and development and commercialization rights. These licenses provide customers with the right to further research, develop and commercialize internally discovered or collaborated drug candidates, or the right to use our P*f*ēnex Expression Technology platform to further research, develop and commercialize customer drug candidates. The consideration we receive is in the form of nonrefundable upfront consideration related to the functional intellectual property licenses and is recognized when we transfer such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on the estimated pattern in which we satisfy the combined performance obligation. Our licensing agreements are generally cancelable. Customers have the right to terminate the contracts between a range of 30 days and 12 months with written notice. We have the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

Research and development services

We generate revenue from research and development services we provide to our customers and primarily includes scientific research activities, preparation for clinical trials, and assistance during regulatory approval application process. Revenue associated with these services is recognized based on our estimate of total consideration to be received for such services and the pattern in which we perform the services. The pattern of performance is generally determined to be the amount of incurred costs related to the service portion of the contract with the customer as a percentage of total expected costs associated with the service portion of the contract.

Product Revenue

We generate revenue from product sales and recognize revenue when control of the products is transferred to customers, typically upon shipment, in an amount that reflects the consideration we expect to receive in exchange for those products. Our principle product sales relate to the sales of our product, CRM 197. Our product sales agreements are not subject to rebates or discounts. Product replacement or refund is available at our discretion if the product is found to be defective or nonconforming. Historically, product returns have been immaterial.

Contracts with Multiple Performance Obligations.

Most of our collaboration and license agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services, we analyzed whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The estimated standalone selling price is based on the adjusted market assessment approach including estimated present value of future cash flows and cost-plus margin approach, taking into consideration the type of services, estimates of hourly market rates, and stage of the development.

Variable Consideration.

Our contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to us upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until we conclude it is probable that reversal of such milestone revenue will not occur. As part of our evaluation of the constraint, we consider numerous factors, including whether the achievement of the milestone is outside of our control, contingent upon regulatory approval or dependent on licensee efforts.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. We recognize revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

The transaction price is reevaluated each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Disaggregation of Revenue.

We operate in one reportable business segment. We provide goods and services to our customers through collaboration and license agreements pursuant to various geographical markets. In the following table, revenue is disaggregated by major customers, timing of revenue recognition and revenue classification:

	Year ended December 31, 2019			
Customers	License and service	Product	Total	
Alvogen	$ 11,133	$ 2,334	$ 13,467	*(w)*
Jazz	28,742	—	$ 28,742	*(x)*
Arcellx	2,231	—	$ 2,231	*(y)*
BARDA	1,541	—	$ 1,541	*(y)*
Other	850	3,495	$ 4,345	*(z)*
Total	44,497	5,829	$ 50,326	

(w) - Revenue recognized at point in time except for immaterial portion of the $2.5 million upfront payment that was constrained until FDA approval of PF708.

(x) - $26 million recognized at a point-in-time and $2.7 million recognized over time

(y) - Revenue recognized over time

(z) - Revenue recognized at point in time

Contract Assets and Contract Liabilities.

We receive payments from customers based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, we generally bill our customers monthly or quarterly as the services are performed. We satisfy our performance obligation on product sales when the products are shipped. Payment terms on invoiced amounts are typically 30 days.

Contract assets include amounts related to our contractual right to consideration for both completed and partially completed performance obligations that have not been invoiced and for which we do not yet have the right to payment. As of

the Adoption Date, our contract asset balance was $3.7 million, consisting of $1.6 million related to partially completed performance obligations from the BARDA contract, and $2.1 million of unbilled receivables from Alvogen related to cost sharing activities for the development of PF708 and recorded net against research and development expenses as of December 31, 2018. Under our arrangement with Alvogen, these cost sharing activities were only billable upon approval from Alvogen. During 2019, we invoiced and collected the total $3.7 million balance of contract assets.

As of December 31, 2019, we had a contract assets balance of $0.2 million related to partially completed performance obligations associated to the BARDA contract. The decrease in contract assets during the year relates to decreased activity related to the BARDA agreement as we deprioritized this program in our portfolio during the year and obtained approval from Alvogen on cost sharing activities.

As of the Adoption Date, we had an accounts receivable balance of $1.5 million related to contracts with customers. As of December 31, 2019, we had an accounts receivable balance of $5.4 million related to contracts with customers. The increase in the accounts receivable balance during the year primarily relates to Alvogen executing sublicense agreements in Europe and the Middle East in December 2019.

Contract liabilities consist of deferred revenue and include payments received in advance of performance under the contract. As of the Adoption Date, we had a contract liability balance of $2.8 million all of which was deferred revenue, and all of this $2.8 million balance was recognized as revenue in 2019.

As of December 31, 2019, we have a contract liability balance of $0.7 million, consisting of $0.1 million related to deferred revenue and $0.6 million recorded to other current liabilities related to a payment received in 2019 from Alvogen in connection to us acting as the liaison between Alvogen and our established raw materials supplier/manufacturer.

Cost to Obtain and Fulfill a Contract.

We generally do not incur costs to obtain new contracts. Costs to fulfill contracts are expensed as incurred.

Remaining Performance Obligations.

The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to our existing collaboration and license agreements as of December 31, 2019 is immaterial.

Preclinical and Clinical Trial Accruals

Our clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related series are recorded as prepaid expenses until the services are rendered.

Other Information

Income Tax Matters

On December 22, 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (the "Tax Act"). Shortly after the Tax Act was enacted, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which provides guidance on accounting for the Tax Act's impact. SAB 118 provides a measurement period, which should not extend beyond one year from the Tax Act enactment date, during which a company acting in good faith may complete the accounting for the impacts of the Tax Act under ASC Topic 740. In accordance with SAB 118, the Company must reflect the income tax effects of the Tax Act in the reporting period in which the accounting under ASC Topic 740 is complete.

To the extent that our accounting for certain income tax effects of the Tax Act is incomplete, we can determine a reasonable estimate for those effects and record a provisional estimate in the consolidated financial statements in the first reporting period in which a reasonable estimate can be determined. If we cannot determine a provisional estimate to be included in the consolidated financial statements, we should continue to apply ASC 740 based on the provisions of the tax laws that were in effect immediately prior to the Tax Act being enacted. If we are unable to provide a reasonable estimate of the impacts of the Tax Act in a reporting period, a provisional amount must be recorded in the first reporting period in which a reasonable estimate can be determined. For further information, see Note 11 "Income Taxes" to our consolidated financial statements included in Item 8 of this Form 10-K.

During the year ended December 31, 2019 we recorded a tax provision of $1 thousand. During the years ended 2018, no tax provision was recorded. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our consolidated balance sheets at December 31, 2018 and 2017. We are subject to taxation in the United States and various state jurisdictions. Our tax years 2014 and forward are subject to examination by the United States and tax years 2010 and forward in California and various state tax authorities.

As of December 31, 2019, we had federal and state research and development credits carryforwards of approximately $7.5 million and $4.2 million, respectively, to offset potential tax liabilities. The federal research and development credits have a 20-year carryforward period and begin to expire in 2030 unless utilized. California research and development tax credits have no expiration. We have $82.7 million of federal net operating loss carryforwards and $32.9 million of state net operating loss carryforwards as of December 31, 2019. Of the total federal net operating loss carryforwards, we have $41.2 million with no expiration dates. The remaining federal and state net operating losses can be carried forward until 2036 unless utilized.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. If an ownership change has occurred, our ability to use our NOLs or tax credit carryforwards may be restricted, which could require us to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

Results of Operations

Comparison of the years ended December 31, 2019, 2018, and 2017

The following table summarizes our net income (loss) during the periods indicated.

	Years Ended December 31,			% change from 2018 to 2019	% change from 2017 to 2018
	2019	2018	2017		
	(in thousands)				
Revenues	$ 50,326	$ 14,857	$ 28,780	239%	(48)%
Cost of revenue	4,891	5,022	5,156	(3)%	(3)%
Gross profit	45,435	9,835	23,624	362%	(58)%
Operating expenses					
Research and development	25,533	33,854	31,925	(25)%	6%
Selling, general and administrative	19,078	15,832	17,674	21%	(10)%
Total operating expense	44,611	49,686	49,599	(10)%	0%
Income (loss) from operations	824	(39,851)	(25,975)	(102)%	53%
Other income	235	258	119	(9)%	117%
Net income (loss) before income taxes	1,059	(39,593)	(25,856)	(103)%	53%
Income tax (provision) benefit	(1)	—	172	(100)%	(100)%
Net income (loss)	$ 1,058	$ (39,593)	$ (25,684)	(103)%	54%

Revenues

Revenue increased by $35.4 million, or 239%, from $14.9 million in 2018 to $50.3 million in 2019. The increase in revenue primarily resulted from $26 million in development milestones achieved from the collaboration agreement with Jazz, Alvogen milestone and sublicensing revenue of $11 million, and revenue from Arcellx and CRM197 product sales. The increase was partially offset by a decrease in revenue from BARDA and recognized revenue from Jazz that was previously deferred, as the upfront payment from Jazz was fully amortized in mid-2019.

Revenue decreased by $13.9 million, or 48%, from $28.8 million in 2017 to $14.9 million in 2018. The change in revenue primarily resulted from $13.5 million in revenue recognized from a milestone payment from Jazz in 2017. Additionally, our government contract with NIAID was completed at the end of 2017, contributing a further decrease in revenue.

Given the nature of the development process, revenue will fluctuate depending on stage of development.

Cost of Revenue

Cost of revenue decreased by $0.1 million, or 3%, to $4.9 million in 2019 compared to $5.0 million in 2018. The change was driven by a decline in BARDA activity, offset by increases resulting from work on Arcellx, as well as greater CRM197 product sales.

Cost of revenue decreased by $0.2 million, or 3%, to $5.0 million in 2018 compared to $5.2 million in 2017. The change was due primarily to a net decrease in costs related to our government contract with NIAID, as the program was completed at the end of 2017.

Research and Development

Research and development expenses decreased by approximately $8.4 million, or 25%, to $25.5 million in 2019 compared to $33.9 million 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.

Research and development expenses increased by approximately $2.0 million, or 6%, to $33.9 million in 2018 compared to $31.9 million in 2017. The increase was primarily due to increased activity for PF708 to satisfy the clinical and manufacturing filing requirements for an NDA, which we submitted to the FDA in December of 2018. These increased costs were partially offset by a decrease in expenses due to our decision to pause our development activities on certain product candidates in the first half of 2017.

We expect research and development expenses to increase as we advance our lead candidates and pipeline product candidates. The funding necessary to bring a drug candidate to market is subject to numerous uncertainties. Once a drug candidate is identified, the further development of that drug candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand. For each of our drug candidate programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. Certain of our programs may be terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization.

Selling, General and Administrative

Selling, general and administrative expenses increased by $3.3 million, or 21% to $19.1 million in 2019 compared to $15.8 million in 2018. The increase was primarily due to higher legal and audit fees, employee costs and the expansion of business development efforts.

Selling, general and administrative expenses decreased by $1.8 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 for former officers in the first half of 2017.

Liquidity and Capital Resources

To date, we have funded our operations primarily through the sale and issuance of common stock in our public offerings, revenue from our collaboration agreements, government contracts, service agreements, and reagent protein product sales, our prior credit facility and the private placement of equity securities. At December 31, 2019, we had $55.6 million in cash and cash equivalents and $0.2 million in restricted cash compared to $56.2 million in cash and cash equivalents and $0.2 million in restricted cash as of December 31, 2018. We believe we have sufficient cash resources to meet our working capital and capital expenditures needs for the next 12 months from the date this Annual Report is filed with the SEC.

In July 2016, we entered into a development and license agreement with Jazz Pharmaceuticals for the development and commercialization of multiple early stage hematology/oncology product candidates, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, and in the third quarter of 2017, achieved a process development milestone. The agreement also includes an option for Jazz to negotiate a license for a recombinant pegaspargase (PF690) product candidate with us. Under the terms of the agreement, we received an upfront and option payment totaling $15.0 million in July 2016 and may be eligible to receive additional payments based on the achievement of certain research and development, regulatory, and sales-related milestones.

In December 2017, we and Jazz entered into an amended and restated agreement, bringing the total value of payments and potential payments associated with the collaboration to $224.5 million. In addition, we may be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from those under the 2016 agreement. Under the amended and restated agreement, in the second quarter of 2018, we achieved two process development milestones for PF745. In September and December 2019, we achieved development milestones and recognized $11.0 million and $15 million in revenue for successful achievement of process development milestones for PF745, and we received cash payment for these milestones in the fourth quarter of 2019.

In March 2018, we entered into an equity sales agreement (Sales Agreement) with William Blair & Company, L.L.C. (William Blair) to sell shares of our common stock having aggregate sales proceeds of up to $20.0 million, from time to time, through an “at the market” equity offering program under which William Blair would act as sales agent. Under the Sales Agreement, we set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. The Sales Agreement provided that William Blair would be entitled to compensation for its services equal to 3.0% of the gross sales price per share of all shares sold through William Blair under the Sales Agreement. In January and February 2020, we sold a total of 1.8 million shares of our common stock through the “at-the-market” equity offering program for aggregate gross proceeds of approximately $20.0 million, at which point the Sales Agreement automatically terminated.

On May 25, 2018, we closed an underwritten public offering of 7,820,000 shares of our common stock at a price of $5.50 per share, which included the full exercise by the underwriters of their option to purchase an additional 1,020,000 shares of our common stock, pursuant to our existing shelf registration statement. Net proceeds from this offering were approximately $39.5 million.

We believe that our existing cash and cash equivalents and our cash inflow from operations will be sufficient to meet our anticipated cash needs for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital although we may receive milestone and other contingent payments under our current license and collaboration agreements. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional agreements with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the timing and extent of spending on our research and development efforts;
- our ability to enter into and maintain collaboration, licensing, commercialization and other arrangements and the terms and timing of such arrangements;
- our ability to retain Alvogen as a collaboration partner for the FDA-approved PF708 product and PF708 on commercially acceptable terms;
- the timing of the marketing approval for PF708, if any;

- whether we and Alvogen obtain, in a timely manner or at all, an "A" therapeutic equivalence designation for the FDA-approved PF708 product that may allow such product to be automatically substituted for Forteo depending on applicable laws and policies within each of the 50 states;
- the cost to us of development, manufacturing and commercialization activities for PF708 and our other product candidates, if any;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the receipt of any collaboration or milestone payments;
- the scope, rate of progress, results and FDA acceptance of the results, and cost of our clinical trials, preclinical testing and other related activities for our product candidates;
- the emergence of competing technologies or other adverse market developments;
- the time and costs involved in seeking and obtaining regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical trials;
- the introduction of new product candidates and the number and characteristics of product candidates that we pursue;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from the FDA-approved PF708 product, PF708, and any other potential products;
- the degree and rate of market acceptance and coverage and reimbursement by payors of the FDA-approved PF708 product, PF708 and any of our other product candidates launched by us or our collaboration partners;
- the potential expansion of our sales and marketing activities; and
- the potential acquisition and in-licensing of other technologies, products or assets.

In October 2019, the FDA approved the NDA for PF708 submitted under the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. Our collaboration partner, Alvogen, intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product. In consideration for the licenses and other rights granted to Alvogen under the agreement, we received an upfront payment of $2.5 million, achieved two development milestones for $2.5 million each, and will be eligible to receive an additional $20 million in support and regulatory milestone payments. We are also eligible to receive a 50% gross profit split on sales if the product is rated as Therapeutically Equivalent (AP) to Forteo and up to 40% if rated differently.

If we were to experience any delays or encounter issues with any of the above, including with respect to obtaining an "A" therapeutic equivalence designation for the FDA-approved PF708 product, Alvogen's commercial launch of the FDA-approved PF708 product in the U.S., clinical holds, failed studies, inconclusive or hard-to-interpret results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional major studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above and delay or suspend revenues.

We may need to raise additional capital to fund our operations in the near future. Funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents and restricted cash for each of the periods presented below.

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Net cash (used in) provided by:			
Operating activities	$ (4,128)	$ (39,428)	$ (21,510)
Investing activities	(845)	(1,472)	(2,197)
Financing activities	4,377	39,456	70
Net decrease in cash, cash equivalents and restricted cash	$ (596)	$ (1,444)	$ (23,637)

Net cash used in operating activities

Net cash used in operating activities was $4.1 million for 2019, $39.4 million for 2018 and $21.5 million for 2017. The decrease in cash used from 2018 to 2019 was primarily driven by a decrease in spending on our lead product candidate, PF708, after we filed the NDA with the FDA in late 2018, as well as achievement of development milestones from Jazz and FDA acceptance and approval from Alvogen. The increase in cash used in operating activities from 2017 to 2018 was primarily attributable to our research and development activities associated with PF708 and our other product candidates.

Net cash used in operating activities was $21.5 million for the year ended December 31, 2017. Net cash used was primarily attributable to our research and development activities associated with PF708 and our other product candidates, partially offset by $18.5 million of payments received pursuant to our agreement with Jazz.

Net cash used in investing activities

Net cash used in investing activities was $0.8 million, $1.5 million and $2.2 million for the years ended December 31, 2019, 2018 and 2017, respectively, and was due primarily to the purchase of lab equipment.

Net cash provided by financing activities

Net cash provided by financing activities in 2019 was primarily related to the net proceeds of approximately $4.7 million in proceeds from exercise of stock options and Employee Stock Purchase Plan (ESPP) purchases.

Net cash provided by financing activities in 2018 was primarily related to the net proceeds of approximately $39.5 million from the issuance of our common stock in connection with our follow-on offering after deducting offering expenses.

Net cash provided by financing activities was $0.1 million for the year ended December 31, 2017, which was primarily due to $0.2 million in proceeds from the issuance of common stock in connection with our ESPP and exercises of stock options. This was partially offset by $0.1 million used to repay capital lease obligations.

Off-Balance Sheet Arrangements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. Our exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. As of December 31, 2019, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations.

Contractual Obligations and Commitments

The following summarizes our contractual obligations and commitments as of December 31, 2019:

		Payments due by period			
Contractual Obligations (in thousands)	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Purchase obligations	$ 2,258	$ 2,258	$ —	$ —	$ —
Operating lease liability [1]	4,074	927	1,908	1,239	—
Finance lease liability[2]	199	198	1	—	—
	$ 6,531	$ 3,383	$ 1,909	$ 1,239	$ —

(1) - *Operating lease liabilities are primarily rent payments on our facility leases*

(2) - *Finance lease liabilities consist mainly of capital leases on lab equipment.*

In June 2010, we entered into an operating lease agreement (Lease) with a landlord for an initial term of 10 years, for our corporate headquarters comprised of one building located in San Diego, California. Occupation of the premises under the Lease began in April 2011. Under the terms of the Lease, we pay annual base rent, subject to an annual fixed percentage increase, plus our share of common operating expenses and tax obligations. The annual base rent was subject to abatement of 50% for the first year of the Lease.

In September 2014, we amended the Lease to extend the term for an additional three years through March 31, 2024 and to an additional 7,315 square feet of leased space. The extended term on the existing space increased total estimated rent payments by approximately $1.4 million. Base rent payments for the new space commenced in December 2014 and increased total estimated rent payments over the life of the Lease by approximately $1.5 million. In November 2015, we further amended the Lease to add facilities consisting of 16,811 square feet. Base rent payments for the new space commenced in March 2016 and June 2016 and increased total estimated rent payments over the life of the Lease by approximately $2.3 million.

In June 2017, we signed master lease agreements for the purchase of specialized equipment totaling approximately $0.8 million. The finance leases each have a term of 36 months and commenced during the quarter ending September 30, 2017.

We enter into contracts in the normal course of business with contract research organizations and subcontractors to further develop our products. The contracts are cancellable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for products or services that we had received as of the effective date of the termination and any applicable cancellation fees.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This new guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for us beginning in the first quarter of fiscal year 2020, with early adoption permitted. We are currently evaluating this guidance to determine the impact on our financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption of the standard is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. We have not early adopted this ASU for 2019. The ASU is currently not expected to have a material impact on our consolidated financial statements.

Item 7A. *Quantitative and Qualitative Disclosures about Market Risk*

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. As of December 31, 2019, we did not hold or issue financial instruments for trading purposes.

Interest rate fluctuation risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds, treasury obligations, short term certificates of deposit and high-grade corporate securities, directly or through managed funds, with maturities of six months or less. As of December 31, 2019, we had cash and cash equivalents of $55.6 million consisting of cash of $13.2 million and investments of $42.4 million in highly liquid U.S. money market funds. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 100 basis point movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

Foreign currency exchange risk

We contract with clinical research organizations, investigational sites and suppliers in foreign countries. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We have not entered into any material foreign currency hedging contracts although we may do so in the future. To date we have not incurred any material effects from foreign currency changes on these contracts. The effect of a 10% adverse change in exchange rates on foreign currency denominated cash and payables as of December 31, 2019 would not have been material. However, fluctuations in currency exchange rates could harm our business in the future.

Inflation risk

Inflation may affect us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations for any period presented herein.

Item 8. ***Financial Statements and Supplementary Data***

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Pfenex Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Pfenex Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and financial statement schedule II (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 11, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Changes in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method of accounting for revenue as of January 1, 2019 due to the adoption of Accounting Standards Codification 606, *Revenue from Contracts with Customers,* and for leases as of January 1, 2019 due to the adoption of Accounting Standards Codification 842, *Leases.*

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2016.

San Diego, California
March 11, 2020

PFENEX INC.

Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
	(in thousands)	
Assets		
Current assets		
Cash and cash equivalents	$ 55,624	$ 56,220
Restricted cash	200	200
Accounts and unbilled receivables, net	5,628	5,171
Other current assets	2,308	2,058
Total current assets	63,760	63,649
Property and equipment, net	7,744	7,671
Right-of-use asset	3,903	—
Other long-term assets	170	133
Intangible assets, net	3,733	4,248
Goodwill	5,577	5,577
Total assets	$ 84,887	$ 81,278
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 673	$ 2,005
Accrued liabilities	7,351	9,812
Current portion of deferred revenue	75	5,317
Lease liabilities – short-term	951	—
Current portion of capital lease obligations	—	316
Other current liabilities	616	—
Total current liabilities	9,666	17,450
Deferred revenue, less current portion	—	2,500
Lease liabilities – long-term	2,896	—
Capital lease obligations, less current portion	—	191
Other non-current liabilities	26	—
Total liabilities	12,588	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 at December 31, 2019 and 2018, respectively, 32,266,708 and 31,467,580 shares issued and outstanding at December 31, 2019 and 2018, respectively	33	32
Additional paid-in capital	270,008	262,405
Accumulated deficit	(197,742)	(201,300)
Total stockholders' equity	72,299	61,137
Total liabilities and stockholders' equity	84,887	$ 81,278

The accompanying notes are an integral part of these consolidated financial statements.

PFENEX INC.

Consolidated Statements of Operations

	Years Ended December 31,		
	2019	2018	2017
	(in thousands except for per share data)		
Revenue			
License and service revenue	$ 44,497	$ 13,762	$ 27,578
Product revenue	5,829	1,095	1,202
Total revenue	50,326	14,857	28,780
Cost of revenue			
License and service	$ 3,042	$ 4,454	$ 4,524
Product	1,849	568	632
Total cost of revenue	4,891	5,022	5,156
Gross profit	45,435	9,835	23,624
Operating expense			
Research and development	25,533	33,854	31,925
Selling, general and administrative	19,078	15,832	17,674
Total operating expense	44,611	49,686	49,599
Income (loss) from operations	824	(39,851)	(25,975)
Other income, net	235	258	119
Net income (loss) before income taxes	1,059	(39,593)	(25,856)
Income tax (provision) benefit	(1)	—	172
Net income (loss)	$ 1,058	$ (39,593)	$ (25,684)
Net income (loss) per common share, basic and diluted	$ 0.03	$ (1.40)	$ (1.09)
Weighted-average common shares used to compute net income (loss) per share			
Basic	31,602	28,340	23,503
Diluted	32,373	28,340	23,503

The accompanying notes are an integral part of these consolidated financial statements

PFENEX INC.

Consolidated Statements of Changes in Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2016	23,430	$ 24	$ 216,144	$ (136,023)	$ 80,145
Exercise of stock options	85	—	26	—	26
Issuance of common stock under employee stock purchase plan	33	—	153	—	153
Stock-based compensation expense	—	—	3,123	—	3,123
Net loss	—	—	—	(25,684)	(25,684)
Balance at December 31, 2017	23,548	$ 24	$ 219,446	$ (161,707)	$ 57,763
Restricted stock units	17	—	57	—	57
Exercise of stock options	44	—	94	—	94
Issuance of common stock under employee stock purchase plan	39	—	115	—	115
Stock-based compensation expense	—	—	3,179	—	3,179
Issuance of common stock, net of discount and offering costs	7,820	8	39,514	—	39,522
Net loss	—	—	—	(39,593)	(39,593)
Balance at December 31, 2018	31,468	$ 32	$ 262,405	$ (201,300)	$ 61,137
Adoption of ASC 606 (Note 7)	—	—	—	2,500	2,500
Exercise of stock options	764	1	4,597	—	4,598
Issuance of common stock under employee stock purchase plan	35	—	109	—	109
Stock-based compensation expense	—	—	2,897	—	2,897
Net income	—	—	—	1,058	1,058
Balance at December 31, 2019	32,267	$ 33	$ 270,008	(197,742)	$ 72,299

The accompanying notes are an integral part of these consolidated financial statements

PFENEX INC.

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Cash flows from operating activities			
Net income (loss)	$ 1,058	$ (39,593)	$ (25,684)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	1,294	1,148	876
Amortization of intangible assets	515	532	530
Stock-based compensation expense	2,897	3,179	3,123
(Gain)/Loss on disposal of property and equipment	(97)	8	(20)
Changes in operating assets and liabilities			
Accounts and unbilled receivables	(457)	(3,865)	1,516
Other current assets	(198)	284	251
Other long-term assets	(90)	—	(53)
Accounts payable	(1,354)	68	628
Accrued liabilities	(2,454)	1,157	(585)
Deferred revenue	(5,242)	(2,346)	(2,092)
Net cash used in operating activities	(4,128)	(39,428)	(21,510)
Cash flows from investing activities			
Acquisitions of property and equipment	(1,442)	(1,472)	(2,242)
Proceeds from sales of equipment	597	—	45
Net cash used in investing activities	(845)	(1,472)	(2,197)
Cash flows from financing activities			
Proceeds from issuance of common stock, net of underwriters' fees	—	39,999	—
Payments for offering costs	—	(477)	—
Repayments of financial lease obligation	(330)	—	—
Repayments of capital lease obligations	—	(238)	(109)
Proceeds from exercise of stock options and other stock issuances	4,707	210	179
Payment for taxes related to net share settlement of equity awards	—	(38)	—
Net cash provided by financing activities	4,377	39,456	70
Net decrease in cash, cash equivalents and restricted cash	(596)	(1,444)	(23,637)
Cash, cash equivalents and restricted cash			
Beginning of year	56,420	57,864	81,501
End of year	$ 55,824	$ 56,420	$ 57,864
Supplemental schedule of cash flow information			
Cash paid for interest	$ 22	$ 41	$ 22
Cash paid for taxes	$ 2	$ 48	$ —
Adoption of ASC 606 - impact on deferred revenue	$ (2,500)	$ —	$ —
Adoption of ASC 842 - ROU assets	$ 4,540	$ —	$ —
Adoption of ASC 842 - lease liabilities	$ (4,755)	$ —	$ —
Non-cash financing and investing transactions			
Acquisitions under finance lease obligations or capital lease obligations (Note 4 and Note 8)	$ —	$ 98	$ 676
Restricted stock issuance for bonus payment	$ —	$ 57	$ —
Asset acquisitions in accounts payable and accrued expenses	$ 603	$ 210	$ 361

The accompanying notes are an integral part of these consolidated financial statements

Notes to Consolidated Financial Statements

1. Organization and Summary of Significant Accounting Policies

Business Activities and Organization

Pfenex Inc. (the Company or 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, the Company has created an advanced pipeline of potential therapeutic equivalents, and novel and next generation therapeutics. On October 4, 2019, the U.S. Food and Drug Administration (FDA) approved the new drug application (NDA) for PF708 submitted in accordance with the 505(b)(2) regulatory pathway, with Forteo® (teriparatide injection) as the reference drug. Like Forteo, this FDA-approved PF708 product is indicated for the treatment of osteoporosis in certain patients at high risk for fracture. Marketing authorization applications are pending in other jurisdictions. In addition, the Company is developing hematologic oncology products in collaboration with Jazz Pharmaceuticals Ireland Limited (Jazz) including PF743 (JZP-458), a recombinant *Erwinia* asparaginase, and PF745 (JZP-341), a long-acting *Erwinia* asparaginase. Both PF743 and PF745 are being developed for the treatment of Acute Lymphoblastic Leukemia (ALL) and other hematological malignancies. The Company also uses its *Pf*ēnex Expression Technology platform to produce CRM197, a diphtheria toxoid carrier protein used in prophylactic and therapeutic vaccine candidates under development by Merck & Co, Inc. (Merck) and Serum Institute of India Private Ltd. (SIIPL). Both have licenses to the Pfēnex Expression Technology for the production of CRM197 for use in conjugate vaccine products. The Company also provides services related to its technology to express difficult-to-produce proteins and other biologic products using its proprietary *Pseudomonas fluorescens* expression platform. The Company is focused on developing its portfolio of partnered as well as wholly-owned peptides and complex proteins. Currently, the Company is exploring opportunities to develop novel modalities through an assessment program designed to evaluate and pursue validated biologic pathways that are differentially druggable via a selected modality in specific diseases. In addition, the Company is exploring a range of platform partnerships with third parties who have products and/or platforms that are compatible with its *Pf*ēnex Expression Technology platform.

FDA-Approved PF708 Product

On October 4, 2019, the FDA approved the NDA for PF708 submitted in accordance with 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 for fracture. In November 2019, the Company transferred the NDA to Alvogen pursuant to the License and Development Agreement, described below, between the companies. In addition, the Company has been continuing its efforts to obtain an "A" therapeutic equivalence designation for the product relative to its reference drug, Forteo. A determination of therapeutic equivalence may permit the FDA-approved PF708 product to be automatically substituted for Forteo, depending on applicable laws and policies within each of the 50 states in the United States. Consistent with the Company's interactions with the FDA and the agency's draft guidance document on demonstrating the therapeutic equivalence of drug-device combination products, the Company has completed a comparative human factors study comparing the FDA-approved PF708 product and Forteo. The human factors study was designed to further support a finding that the FDA-approved PF708 product is therapeutically equivalent to Forteo. On October 14, 2019, the Company announced the successful completion of its PF708 comparative use human factors study and its submission of the final study report to the FDA. The study data demonstrate that the user interface of the FDA-approved PF708 product was noninferior to that of Forteo for each critical user task evaluated in the study based on pre-specified statistical analysis of critical patient and caregiver tasks. The Company believes this submission completes the information package required by the FDA to evaluate the therapeutic equivalence of the PF708 product. The Company's collaboration partner, Alvogen, intends to launch the FDA-approved PF708 product in the U.S. upon an FDA decision on the therapeutic equivalence evaluation of the product.

In April 2018, the Company and China NT Pharma Group Company Ltd. (NT Pharma) entered into a Development and License Agreement (NT Pharma Agreement), pursuant to which the Company 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. The Company will be responsible for commercial manufacturing and providing product for commercial sale to NT Pharma. The Company will facilitate this obligation via its commercial partner Alvogen. NT Pharma is responsible for all regulatory submissions, development costs and costs associated with regulatory approvals in such territories. The total value of payments and potential payments associated with the NT Pharma agreement is $25 million. In addition, the Company may be eligible to receive royalties on sales of the product in the territory.

In June 2018, the Company and Alvogen Malta Operations Ltd. (Alvogen) entered into a Development and License Agreement (Alvogen Agreement) pursuant to which Alvogen has the exclusive right to commercialize and manufacture PF708 in the United States. The Company expects Alvogen to launch FDA-approved PF708 in the U.S. upon an FDA rating decision on the therapeutic equivalence evaluation of the product. Following the FDA approval of the NDA for PF708, the FDA-approved PF708 product will be commercialized and manufactured in the U.S. by Alvogen. In November 2019 the Company transferred the NDA to Alvogen pursuant to the License and Development Agreement. The total value of payments and potential payments associated with the Alvogen agreement is $27.5 million. In addition, the Company may be eligible to receive royalties on sales of the product in the U.S.

In February 2019, the Company and Alvogen entered into additional agreements, extending Alvogen's rights to commercialize and manufacture PF708 to include the European Union (EU), certain countries in the Middle East and North Africa (MENA) and to the rest of world (ROW) territories (excluding certain Asian countries granted to NT Pharma). Alvogen is responsible for local activities and for overseeing any clinical development, regulatory, litigation, commercial manufacturing and commercialization activities in these jurisdictions. The total value of payments and potential payments associated with the Alvogen EU, MENA and ROW agreements is $3.8 million. In addition, the Company may be eligible to receive royalties on sales of the product in the EU and MENA territories.

Collaboration Partner: Jazz Pharmaceuticals Ireland Limited

In July 2016, the Company and Jazz announced an agreement under which the Company granted Jazz worldwide rights to develop and commercialize multiple early stage hematologic oncology product candidates, including PF743 (JZP-458), a recombinant *Erwinia* asparaginase, and PF745 (JZP-341), a long-acting *Erwinia* asparaginase. In December 2017, the parties amended the Jazz agreement, bringing the total value of payments and potential payments associated with the collaboration to $224.5 million. In addition, the Company may be eligible to receive tiered royalties on worldwide sales of any products resulting from the collaboration at rates reduced from those under the 2016 agreement.

Pfenex Expression Technology Licenses: CRM197

The Company has both licenses and supply agreements in place for CRM197, which is a non-toxic mutant of diphtheria toxin. CRM197 is a well-characterized protein and functions as a carrier for polysaccharides and haptens, making them immunogenic. The Company has developed unique CRM197 production strains based on its *Pf*ēnex Expression Technology platform. As a result of these development efforts, the Company previously entered into commercial licenses for production strains capable of producing CRM197 with both Merck & Co., Inc. (Merck) and Serum Institute of India Private Ltd. (SIIPL). Merck and SIIPL are using the CRM197 produced via the licensed production strain in multiple clinical stage products. Those products currently include Merck's 15-valent pneumococcal conjugate vaccine, PCV-15 (V114), currently in several ongoing Phase 3 clinical studies, and SIIPL's 10-valent pneumococcal conjugate vaccine Pneumosil®, which achieved WHO Prequalification in December 2019, and a pentavalent meningococcal conjugate vaccine currently in a Phase 3 clinical study. The CRM197 production strains utilized by both Merck and SIIPL are unique and exclusively licensed to each party. These commercial license agreements with Merck and SIIPL contemplate potential maintenance and milestone fees as well as royalties on net sales. Additionally, as part of the SIIPL commercial license agreement, SIIPL supplies both reagent grade and cGMP CRM197 to Pfenex, which supplies the product to vaccine development-focused pharmaceutical partners.

Arcellx Development, Evaluation and License Agreement

The Company previously 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 agreement, we are 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 a production strain based on the Pfēnex Expression Technology, as well as royalties on worldwide sales of any such products. We have completed the development of both sparX 1 and sparX 2 and Arcellx has opted into the commercial license for both production strains.

Other Pipeline Products

In the third quarter of 2019 we added PF810, a peptide based next generation therapeutic, to our wholly owned pipeline. PF810 is currently in preclinical development.

At the Market Offering Program

In March 2018, the Company entered into an equity sales agreement (Sales Agreement) with William Blair & Company, L.L.C. (William Blair) to sell shares of the Company's common stock having aggregate sales proceeds of up to $20.0 million, from time to time, through an "at the market" (ATM) equity offering program under which William Blair will act as sales agent. Under the Sales Agreement, the Company sets the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. As of December 31, 2019, the Company had not sold any shares under the Sales Agreement. In January 2020, the Company sold 500,000 shares for net proceeds of $6.2 million, and in February 2020, the Company sold an additional 1,253,443 shares for net proceeds of $13.2 million. As of February 2020, the ATM was fully utilized.

Follow-on Public Offering

In May 2018, the Company completed a public offering of common stock in which it sold 7,820,000 shares of its common stock at an offering price of $5.50 per share, which included the full exercise by the underwriters of their option to purchase an additional 1,020,000 shares, pursuant to the Company's existing shelf registration statement. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately $39.5 million.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP), and reflect all of the Company's activities, including those of its wholly-owned subsidiary. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, all adjustments considered necessary for a fair presentation have been included. These adjustments consist of normal and recurring accruals, as well as non-recurring charges.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Estimates have been prepared on the basis of the most current and best available information. However, actual results could differ from those estimates.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's product candidates, uncertainty of market acceptance of the Company's products if approved for sale, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals.

Products developed by the Company require clearances from international and domestic regulatory agencies prior to commercial sales in such jurisdictions. There can be no assurance that the products will receive the necessary clearances. If the Company was denied clearance, clearance was delayed or the Company was unable to maintain clearance, it could have a materially adverse impact on the Company.

As of December 31, 2019, the Company had an accumulated deficit of $197.7 million and expects to incur substantial operating losses for the next several years. 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 from the date these consolidated financial statements are issued.

The Company will require substantial cash to achieve its objectives of discovering, developing and commercializing drugs, as this process typically takes many years and potentially hundreds of millions of dollars for an individual drug. The Company may not have adequate available cash, or assets that could be readily turned into cash, to meet these objectives in the long term. It will need to obtain significant funds under its existing collaborations and license agreements, under new collaboration, licensing or other commercial agreements for one or more of its drug candidates and programs or patent

portfolios, or from other potential sources of liquidity, which may include the sale of equity, issuance of debt or other transactions. However, there can be no assurance that any additional financing or strategic investments will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that it does not obtain additional funding, the Company will most likely be required to reduce its plans and/or certain discretionary spending, which could have a material adverse effect on its ability to achieve its intended business objectives.

Cash and Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash amounts that are restricted as to withdrawal or usage are presented as restricted cash. In January 2017, the Company entered into a Borrower's Pledge Agreement, which required $0.2 million in restricted cash to be provided as security for its commercial credit card arrangement with one of the Company's banks.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and accounts and unbilled receivables. The Company has established guidelines intended to limit its exposure to credit risk by placing cash and cash equivalents with high credit quality financial institutions and diversifying its portfolio. All cash and cash equivalents were held at three major financial institutions as of December 31, 2019. For the Company's cash position of $55.8 million as of December 31, 2019, which included restricted cash of $0.2 million, the Company has exposure to credit loss for amounts in excess of insured limits in the event of non-performance by the institutions; however, the Company does not anticipate non-performance.

Additional credit risk is related to the Company's concentration of receivables. As of December 31, 2019 and 2018, receivables were concentrated among two and three customers representing 90% and 87% of total net receivables, respectively. No allowance for doubtful accounts was recorded at December 31, 2019 or 2018. For the years ended December 31, 2019, 2018 and 2017 revenue was concentrated among two customers and/or collaboration partners representing 84%, 87%, and 94% of total revenues, respectively.

A portion of revenue is earned from sales outside the United States. Non-U.S. revenue is denominated in U.S. dollars and includes revenue generated from customers with headquarters outside of the U.S. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the years ended December 31, 2019, 2018 and 2017 is as follows:

	Years Ended December 31,		
	2019	2018	2017
	(in thousands)		
US revenue	$ 6,055	$ 5,083	$ 6,477
Non-US revenue	44,271	9,774	22,303
Total revenue	$ 50,326	$ 14,857	$ 28,780

During the year ended December 31, 2019, Ireland accounted for $28.7 million, or 57%, of the Company's revenue and Malta accounted for $13.5 million, or 27% of the Company's revenue. During the year ended December 31, 2018, Ireland accounted for $8.1 million, or 54%, of the Company's revenue. During the year ended December 31, 2017, Ireland accounted for $21.5 million, or 75%, of the Company's revenue.

Fair Value of Financial Instruments

Financial instruments, including cash, cash equivalents, restricted cash, lines of credit, and accounts and unbilled receivables are carried at cost, which management believes approximates fair value because of the short-term maturity of these instruments.

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities. Level 1 assets at December 31, 2019 and December 31, 2018 included the Company's cash, cash equivalents and restricted cash. There were no Level 1 liabilities;
- Level 2—Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly. The Company had no Level 2 assets or liabilities at December 31, 2019 or December 31, 2018; and
- Level 3—Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of assets or liabilities in which there is little or no market data. The Company had no Level 3 assets or liabilities at December 31, 2019 or December 31, 2018.

Accounts and Unbilled Receivables

Accounts receivable represent primarily commercial receivables associated with the Company's service fees, license fees, product sales and receivables from U.S. government contracts. Accounts receivable amounted to $5.0 million and $1.5 million as of December 31, 2019 and 2018, respectively. Unbilled receivables represent reimbursable costs in excess of billings and, where applicable, accrued profit related to long-term government contracts for which revenue has been recognized, but the customer has not yet been billed. Unbilled receivables amounted to $0.6 million and $3.7 million as of December 31, 2019 and 2018, respectively.

The Company evaluates the collectability of its receivables based on a variety of factors, including the length of time the receivables are past due, the financial health of its customers and historical experience. Based upon the review of these factors, the Company recorded no allowance for doubtful accounts at December 31, 2019 and 2018.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from five to ten years with the exception of leasehold improvements which are amortized over the shorter of the lease term or their estimated useful life.

Leases

Effective January 1, 2019, the Company adopted Accounting Standards Codification (ASC) 842, *Leases* (ASC 842). This standard increases transparency and comparability by recognizing a lessee's rights and obligations resulting from leases by recording them on the balance sheet as right-of-use assets and lease liabilities. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification dictates whether lease expense is to be recognized based on an effective interest method or on a straight-line basis over the term of the lease. Additional qualitative and quantitative disclosures will be required to give financial statement users information on the amount, timing and judgments related to a reporting entity's cash flows arising from leases. The Company adopted the standard effective January 1, 2019 using the effective date transition method. This transition method allowed the Company to initially apply the requirements of the standard at the adoption date, versus at the beginning of the earliest period presented.

As of January 1, 2019, the Company recorded an operating lease right-of-use assets of $3.7 million and corresponding net operating lease liability of $4.2 million at that date. In addition, effective January 1, 2019, the Company recorded a financial lease right-of-use assets of $0.9 million and corresponding net financial lease liability of $0.5 million. In calculating the right of use asset and lease liability, the Company elects to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election and recognizes lease costs on a straight-line basis over the lease term for these arrangements. Adoption of the standard did not have an effect on retained earnings. The Company availed itself of the practical expedients provided under the standard and its subsequent amendments regarding identification of leases, lease classification, indirect costs, and the combination of lease and non-lease components. The Company continues to account for leases in the prior period financials statements under ASC 840. Variable lease expenses are recorded when incurred.

Intangible Assets

Intangible assets include customer relationships, developed technology and trade names related to the Company's asset acquisition and have been capitalized and amortized over the estimated useful life of 15 years, 20 years and 15 years, respectively.

Impairment of Long-Lived Assets Other Than Goodwill

The Company assesses potential impairments to its long-lived assets, including property, plant and equipment, right-of-use assets and intangibles other than goodwill, whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flow expected to result from the use of the assets. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset. No impairment was noted for the years ended December 31, 2019, 2018 or 2017.

Goodwill

Effective January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2017-04 *Intangibles – Goodwill and Other: Simplifying the Test for Goodwill Impairment*. This updated guidance eliminates Step 2 from the current two-step quantitative model for goodwill impairment tests. Step 2 required an entity to calculate an implied fair value, which included a hypothetical purchase price allocation requirement, for reporting units that failed Step 1. Per this updated guidance, a goodwill impairment will instead be measured as the amount by which a reporting unit's carrying value exceeds its fair value as identified in Step 1. This guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that reporting period. The Company has adopted this standard as of December 31, 2019. The adoption of this guidance did not impact the consolidated financial statements for fiscal year 2019.

Goodwill is the excess of purchase price over the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed, in a business combination. The Company does not amortize goodwill. Instead, goodwill is tested for impairment annually and between annual tests if the Company becomes aware of an event or a change in circumstances that would indicate the carrying amount may be impaired. The Company performs its annual impairment testing as of December 31st of each year. The Company will first assess qualitative factors to determine whether the existence of events or circumstances suggests that goodwill is impaired. If the entity determines that there are not triggering events, the Company does not perform the quantitative impairment test. The Company's determination as to whether, and, if so, the extent to which goodwill becomes impaired is highly judgmental and include, but not limited to changes in the manner of its use of the acquired assets, changes in its overall business strategy, regulatory changes, market and economic environment trends, key personnel changes, negative trends in its overall financial performance, and sustained deceases in share-price. No impairment was noted as of December 31, 2019 or 2018.

Preclinical and Clinical Trial Accruals

The Company's clinical trial accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on the Company's behalf.

The Company estimates preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on its behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

Revenue

Company revenues to date have been generated primarily through collaboration and license agreements. The Company's collaboration and license agreements frequently contain multiple elements including (i) intellectual property licenses, and (ii) product research and development services. Consideration received under these arrangements may include upfront payments, research and development funding, cost reimbursements, milestone payments, payments for product sales and royalty payments. The Company's customers include Alvogen, NT Pharma, Jazz, Arcellx, and BARDA.

Effective January 1, 2019 (Adoption Date), the Company adopted ASC 606, *Revenue from Contracts with Customers* (ASC 606). ASC 606 supersedes prior revenue recognition guidance and establishes a comprehensive revenue recognition model with a broad principle that requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this principle, an entity identifies the contract with a customer, identifies the separate performance obligations in the contract, determines the transaction price, allocates the transaction price to the separate performance obligations and recognizes revenue when each separate performance obligation is satisfied. The standard allows for two methods of adoption: (a) "full retrospective" adoption, meaning the standard is applied to all periods presented, or (b) "modified retrospective" adoption, meaning the cumulative effect of applying the new guidance is recognized as an adjustment to the opening retained earnings balance for the year of implementation. The Company has adopted this standard as of January 1, 2019 using the modified retrospective method for those contracts which were not substantially completed as of the transition date. As a result, the Company has changed its accounting policy for revenue recognition as detailed below. The cumulative impact to the Company's accumulated deficit balance at the Adoption Date as a result of the adoption of ASC 606 was a decrease of $2.5 million. The decrease relates to a reduction of deferred revenue associated to an upfront payment received from NT Pharma in 2018. The comparative information prior to the Adoption Date has not been restated and continues to be reported under the accounting standards in effect for the periods presented.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (ASC 808): Clarifying the Interaction between ASC 808 and ASC 606*. The amendments in ASU No. 2018-18 make targeted improvements to generally accepted accounting principles for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in ASC 808 was aligned with the guidance in ASC 606 when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. ASU No. 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments in ASU No. 2018-18 are required to be applied retrospectively to the date of initial application of ASC 606. The Company adopted this standard concurrently with ASC 606 and did not materially impact on the Company's financials upon adoption.

The following table summarizes the impacts of adopting ASC 606 on the Company's consolidated financial statements, in thousands.

	Impact of Changes in Accounting Policies *($ thousands)*		
Three months ended December 31, 2019 (unaudited)	**As reported**	**Adjustments**	**Balances without adoption of ASC 606**
License and service revenue	$ 23,413	$ —	$ 23,413
Product revenue	992	—	992
Total revenues	24,405	—	24,405
Income from operations	11,595	—	11,595
Net income	$ 11,634.30	—	$ 11,634.30
Year ended December 31, 2019			
License and service revenue	$ 44,497	$ 2,500	$ 46,997
Product revenue	5,829	—	5,829
Total revenues	50,326	2,500	52,826
Income from operations	824	2,500	3,324
Net income	$ 1,058.00	2,500	$ 3,558.00

ASC 606 did not have an aggregate impact on the Company's net cash used in operating activities but resulted in offsetting certain assets and liabilities presented within net cash used in operating activities in the Company's consolidated statements of cash flows.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for goods or services and excludes sales incentives and amounts collected on behalf of third parties. The Company analyzes the nature of these performance obligations in the context of individual agreements in order to assess the distinct performance obligations.

The Company applies the following five-step model to recognize revenue: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

i) Identify the contract with a customer. The Company considers the terms and conditions of its agreements to identify contracts within the scope of ASC 606. The Company concludes it has a contract with a customer when the contract is approved, each party's rights regarding the goods and services to be transferred can be identified, the payment terms for the goods and services can be identified, it has been determined that the customer has the ability and intent to pay and the contract has commercial substance. The Company uses judgment in determining the customer's ability and intent to pay, which is based upon factors including the customer's historical payment experience or, for new customers, credit and financial information pertaining to the customers.

ii) Identify the performance obligations in the contract. Performance obligations in the agreements are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct, whereby the customer can benefit from the service either on its own or together with other resources that are readily available from third parties or from the Company, and are distinct in the context of the contract, whereby the transfer of the services is separately identifiable from other promises in the contract. The Company's performance obligations generally consist of intellectual property licenses and research and development services with respect to license and service agreements, and the manufacture and supply of product for product sales agreements.

iii) Determine the transaction price. The Company determines the transaction price based on the consideration to which the Company expects to be entitled in exchange for transferring goods and services to the customer. In determining the transaction price, any variable consideration would be considered, to the extent applicable, if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. In accordance with the royalty exception under ASC 606 for licenses of intellectual property, the transaction price excludes future royalty payments to be received from the Company's customers. None of the Company's revenue generating contracts contain consideration payable to its customer or a significant financing component.

iv) Allocate the transaction price to performance obligations in the contract. If the contract contains a single performance obligation, the entire transaction price is allocated to that performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation based on a relative standalone selling price.

v) Recognize revenue when or as we satisfy a performance obligation. Revenue is recognized at the time the related performance obligation is satisfied by transferring the promised goods or services to a customer. The Company recognizes revenue when control of the goods or services is transferred to the customers for an amount that reflects the consideration that the Company expect to receive in exchange for those goods or services.

Performance Obligations.

The following is a general description of principal goods and services from which the Company generates revenue.

License to intellectual property

The Company generates revenue from licensing its intellectual property including know-how and development and commercialization rights. These licenses provide customers with the right to further research, develop and commercialize internally-discovered or collaborated drug candidates, or the right to use the Company's P*f*enex Expression Technology platform to further research, develop and commercialize customer drug candidates. The consideration the Company receives is in the form of nonrefundable upfront consideration related to the functional intellectual property licenses and is recognized when the Company transfers such license to the customer unless the license is combined with other goods or services into one performance obligation, in which case the revenue is recognized over a period of time based on the estimated pattern in which the Company satisfies the combined performance obligation. The Company's licensing agreements are generally cancelable. Customers have the right to terminate the contracts between a range of 30 days and 12 months with written notice. The Company has the right to terminate the contracts generally only if the customer is in breach of the contract and fails to remedy the breach in accordance with the contractual terms.

Research and development services

The Company generates revenue from research and development services it provides to its customers and primarily includes scientific research activities, preparation for clinical trials, and assistance during regulatory approval application process. Revenue associated with these services is recognized based on the Company's estimate of total consideration to be received for such services and the pattern in which the Company perform the services. The pattern of performance is generally determined to be the amount of incurred costs related to the service portion of the contract with the customer as a percentage of total expected costs associated with the service portion of the contract.

Product Revenue

The Company generates revenue from product sales and recognizes revenue when control of the products is transferred to customers, typically upon shipment, in an amount that reflects the consideration the Company expects to receive in exchange for those products. The Company's principle product sales relate to the sales of its product, CRM 197. The Company's product sales agreements are not subject to rebates or discounts. Product replacement or refund is available at the Company's discretion if the product is found to be defective or nonconforming. Historically, product returns have been immaterial.

Contracts with Multiple Performance Obligations.

Most of the Company's collaboration and license agreements with customers contain multiple promised goods or services. Based on the characteristics of the promised goods and services the Company analyzes whether they are separate or combined performance obligations. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The estimated standalone selling price is based on the adjusted market assessment approach including estimated present value of future cash flows and cost plus margin approach, taking into consideration the type of services, estimates of hourly market rates, and stage of the development.

Variable Consideration.

The Company's contracts with customers primarily include two types of variable consideration: (i) development and regulatory milestone payments, which are due to the Company upon achievement of specific development and regulatory milestones and (ii) one-time sales-based payments and sales-based royalties associated with licensed intellectual property.

Due to uncertainty associated with achievement of the development and regulatory milestones, the related milestone payments are excluded from the contract consideration and the corresponding revenue is not recognized until we conclude it is probable that reversal of such milestone revenue will not occur. As part of the Company's evaluation of the constraint, the Company considers numerous factors, including whether the achievement of the milestone is outside of the Company's control, contingent upon regulatory approval or dependent on licensee efforts.

Product sales-based royalties under licensed intellectual property and one-time payments are accounted for under the royalty exception. The Company recognizes revenue for sales-based royalties under licensed intellectual property and one-time payments at the later of when the sales occur or the performance obligation is satisfied or partially satisfied.

The transaction price is reevaluated each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Disaggregation of Revenue.

We operate in one reportable business segment. We provide goods and services to our customers in collaboration and license agreements pursuant to various geographical markets. In the following table, revenue is disaggregated by major customers, timing of revenue recognition and revenue classification:

	Year ended December 31, 2019			
Customers	License and service	Product	Total	
Alvogen	$ 11,133	$ 2,334	$ 13,467	*(w)*
Jazz	28,742	—	$ 28,742	*(x)*
Arcellx	2,231	—	$ 2,231	*(y)*
BARDA	1,541	—	$ 1,541	*(y)*
Other	850	3,495	$ 4,345	*(z)*
Total	44,497	5,829	$ 50,326	

(w) - Revenue recognized at point in time except for immaterial portion of the $2.5 million upfront payment that was constrained until FDA approval of PF708.

(x) - $26 million recognized at a point-in-time and $2.7 million recognized over time

(y) - Revenue recognized over time

(z) - Revenue recognized at point in time

Contract Assets and Contract Liabilities.

The Company receives payments from customers based on contractual terms. Accounts receivable are recorded when the right to consideration becomes unconditional. For research and development services, the Company generally bills its customers monthly or quarterly as the services are performed. The Company satisfies its performance obligation on product sales when the products are shipped. Payment terms on invoiced amounts are typically 30 days.

Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance obligations that have not been invoiced and for which the Company does not yet have the right to payment. As of the Adoption Date, the Company's contract asset balance was $3.7 million, consisting of $1.6 million related to partially completed performance obligations from the BARDA contract, and $2.1 million of unbilled receivables from Alvogen related to cost sharing activities for the development of PF708 and recorded net against research and development expenses as of December 31, 2018. Under the Company's arrangement with Alvogen, these cost sharing activities were only billable upon approval from Alvogen. During 2019, the Company invoiced and collected the total $3.7 million balance of contract assets.

As of December 31, 2019, the Company had a contract assets balance of $0.2 million related to partially completed performance obligations associated to the BARDA contract. The decrease in contract assets during the year relates to decreased activity related to the BARDA agreement as the Company deprioritized this program in its portfolio during the year and obtaining approval from Alvogen on cost sharing activities.

As of the Adoption Date, the Company had an accounts receivable balance of $1.5 million related to contracts with customers. As of December 31, 2019, the Company had an accounts receivable balance of $5.4 million related to contracts with customers. The increase in the accounts receivable balance during the year primarily relates to Alvogen executing sublicense agreements in Europe and the Middle East in December 2019.

Contract liabilities consist of deferred revenue and include payments received in advance of performance under the contract. As of the Adoption Date, the Company had a contract liability balance of $2.8 million all of which was deferred revenue, and all of this $2.8 million balance was recognized as revenue in 2019.

As of December 31, 2019, the Company has a contract liability balance of $0.7 million, consisting of $0.1 million related to deferred revenue and $0.6 million recorded to other current liabilities related to a payment received in 2019 from Alvogen in connection to the Company acting as the liaison between Alvogen and the Company's established raw materials supplier/manufacturer.

Cost to Obtain and Fulfill a Contract.

The Company generally does not incur costs to obtain new contracts. Costs to fulfill contracts are expensed as incurred.

Remaining Performance Obligations.

The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to the Company's existing collaboration and license agreements as of December 31, 2019 is immaterial.

Cost of Revenue

Cost of revenue related to license and service revenue includes costs incurred in connection with the execution of license and service contracts. These are primarily costs incurred for third-party manufacturing, materials and internal labor. Costs related to government contract activities are generally recognized as incurred.

Cost of revenue related to products includes costs to manufacture or purchase, package and ship the Company's reagent products, and these costs are recognized upon shipment to the customer.

Research and Development Expenses

Research and development expenses, which consist primarily of salaries and other personnel costs, clinical trial costs and preclinical study fees, manufacturing costs for non-commercial products, and the development of earlier-stage programs and technologies, are expensed as incurred when these expenditures have no alternative future uses. Research and development expenses are recognized as incurred and amounted to $25.5 million, $33.9 million and $31.9 million for the years ending December 31, 2019, 2018 and 2017, respectively.

Stock-Based Compensation

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (ASC 718)*, which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company has adopted this standard as of January 1, 2019. The impact of adopting this standard to the Company's consolidated financial statements was immaterial.

Employee stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense, net of estimated forfeitures, over the requisite service period. As of January 1, 2019, consultant stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense, net of estimated forfeitures, over the requisite service period. Stock-based compensation expense is amortized on a straight-line basis over the requisite service period for the entire award, which is generally the vesting period of the award.

The Company estimates the fair value of stock options and other equity-based compensation using a Black-Scholes option pricing model on the date of grant. The Black-Scholes valuation model requires multiple subjective inputs, which are discussed further in Note 9 — Stock-Based Compensation. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally four years; however, certain provisions in the Company's equity compensation plan provides for shorter and longer vesting periods under certain circumstances.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive income (loss) and, therefore, for all periods presented, the Company's comprehensive income (loss) was the same as its reported net income (loss).

Income Taxes

The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities using enacted tax rates in effect for years in which the temporary differences are expected to reverse. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and income tax bases of assets and liabilities and for the expected future tax benefit, if any, to be derived from tax credits and loss carryforwards. Deferred income tax expense or benefit would represent the net change during the year in the deferred income tax asset or liability. Deferred tax assets, if any, are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Net Income (Loss) per Share of Common Stock

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding and potentially dilutive securities during the period under the treasury stock method. For purposes of the diluted net income (loss) per share calculation, stock options and employee purchase plan shares are considered to be potentially dilutive securities. Securities are excluded from the computation of diluted net income (loss) per share if their effect would be anti-dilutive to earnings per share. Because the Company has reported a net loss for the year ended December 31, 2018 and 2017, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recently Issued Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU No. 2018-15, Intangibles—*Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This new guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for the Company beginning in the first quarter of fiscal year 2020, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact on its financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption of the standard is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. The Company has not early adopted this ASU for 2019, and the ASU is currently not expected to have a material impact on the Company's consolidated financial statements.

2. Fair Value Measurements

The fair value measurements of the Company's cash equivalents and investments, which are measured at fair value on a recurring basis as of December 31, 2019 and 2018, were determined using the inputs described above and are as follows:

	Fair Value Measurements at Reporting Data Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(in thousands)			
December 31, 2019				
Cash and money market funds	$ 55,824	$ 55,824	$ —	$ —
Total assets measured at fair value	$ 55,824	$ 55,824	$ —	$ —
December 31, 2018				
Cash and money market funds	$ 56,420	$ 56,420	$ —	$ —
Total assets measured at fair value	$ 56,420	$ 56,420	$ —	$ —

Cash and money market funds at December 31, 2019 and 2018 include restricted cash, which is included in current assets on the balance sheet.

3. Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the statement of cash flows.

	December 31, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 55,624	$ 56,220
Restricted cash	200	200
Total cash, cash equivalents and restricted cash shown in statement of cash flows	$ 55,824	$ 56,420

4. Property and Equipment

Property and equipment consisted of the following:

	December 31, 2019	2018
	(in thousands)	
Furniture and equipment	$ 346	$ 367
Computers and IT equipment	498	451
Purchased software	434	375
Lab and research equipment	9,202	9,154
Leasehold improvements	959	876
Construction-in-progress	1,242	328
Other fixed assets	83	83
Total property and equipment, gross	12,764	11,634
Less: accumulated depreciation and amortization	(5,020)	(3,963)
Property and equipment, net	$ 7,744	$ 7,671

As of January 1, 2019, the Company adopted the new lease standards of ASC 842, reclassifying a net amount of $0.9 million of leased lab and research equipment and furniture and equipment out of property and equipment to finance lease right-of-use asset. No new finance leases were entered into during 2019. Total property and equipment assets under capital lease were $1.0 million as of December 31, 2018. Accumulated depreciation related to assets under capital lease as of December 31, 2018 was $137 thousand. As of December 31, 2019, there was no property and equipment assets under capital lease as these were reclassified to finance lease right-of-use assets as part of the adoption of ASC 842.

Property and equipment classified as construction-in-progress increased by $0.9 million as of December 31, 2019 compared to December 31, 2018. The change was primarily attributed to additional lab equipment that was being brought online for novel target identification purposes.

For the years ended December 31, 2019, 2018, and 2017, total depreciation and amortization expense was $1.3 million, $1.1 million, and $0.9 million, respectively, and is included in cost of revenue, research and development and selling, general and administrative expenses in the accompanying consolidated statements of operations as follows:

	Years ended December 31,		
	2019	2018	2017
	(in thousands)		
Cost of revenue	$ 194	$ 51	$ —
Research and development	897	938	549
Selling, general and administrative	203	159	327
Total depreciation and amortization expense	$ 1,294	$ 1,148	$ 876

5. Intangible Assets

Intangible assets consisted of the following:

	December 31,	
	2019	2018
	(in thousands)	
Customer relationships	$ 3,750	$ 3,750
Developed technology	4,400	4,400
Trade names	921	920
Gross intangible assets	9,071	9,070
Less: Accumulated amortization	(5,338)	(4,822)
Total intangible assets, net	$ 3,733	$ 4,248

Amortization expense related to intangible assets was $0.5 million for each of the years ended December 31, 2019, 2018 and 2017, respectively. Amortization expense is included within selling, general and administrative expense in the accompanying consolidated statements of operations. As of December 31, 2019, estimated amortization expense for the next five years amounts to approximately $0.5 million per year. As of December 31, 2019, the weighted average amortization period for the net intangible assets balance is 8.2 years.

6. Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31,	
	2019	2018
	(in thousands)	
Accrued vacation	$ 547	$ 493
Deferred rent	—	589
Accrued bonuses	2,657	1,748
Other accrued employee-related liabilities	905	302
Accrued professional fees	755	1,524
Accrued supplier liability	917	387
Accrued subcontractor costs	750	4,265
Other accrued liabilities	821	504
Total accrued liabilities	$ 7,351	$ 9,812

As of January 1, 2019, the Company adopted ASC 842 and as such, reclassified the $0.6 million deferred rent liability to operating lease right-of-use asset.

7. Significant Revenue Generating Contracts

The Company has three types of revenue generating contracts (i) those for which the Company co-develops or assists customers in developing their products (Collaboration Agreements), (ii) those for which the Company receives funding to advance its own products (Funding Agreements), and (iii) those for which the Company sells its reagent protein and other products.

Collaboration and License Agreements

Alvogen

In June 2018, the Company entered into an agreement with Alvogen in which the Company has granted Alvogen exclusive rights to commercialize PF708 in the United States. The Company will continue to be responsible for development and registration of PF708, while Alvogen is providing additional regulatory and development expertise. Alvogen has assumed responsibility for costs related to litigation, commercial manufacturing and supply chain, and commercialization of PF708. In consideration for the licenses and other rights granted in the development and license agreement, the Company received an upfront payment of $2.5 million, which was recorded to deferred revenue as of December 31, 2018. The original contract included an additional $25 million in support and regulatory milestone payments.

In February 2019, the Company and Alvogen entered into agreements expanding the Company's and Alvogen's collaboration to develop and commercialize PF708 to the European Union (EU), to certain countries in the Middle East and North Africa (MENA) and to the ROW territories (the latter defined as all countries outside of the EU, US and MENA, excluding Mainland China, Hong Kong, Singapore, Malaysia and Thailand). The EU and MENA agreements allows for Alvogen to sublicense the license rights to a third party in exchange for consideration to the Company, payable upon Alvogen executing a sublicense agreement with a third party.

During 2019, Pfenex received upfront payments from the EU, MENA and ROW agreements totaling $1.1 million, a milestone payment of $0.3 million from the EU agreement, and sublicense consideration of $2.2 million for the EU and MENA agreements.

As of December 31, 2019, the Company will be eligible to receive an additional $20 million in support and regulatory milestone payments and receive a 50% gross profit split related to the US agreement, an additional $250 thousand in support and regulatory milestone payments and 50% gross profit split on sales related to the EU agreement, approximately $240 thousand in support and regulatory milestone payments and 60% gross profit split on sales related to the ROW agreement, and 60% gross profit split on sales related to the MENA agreement

Accounting for Alvogen Agreement under ASC 606

The Company assessed this arrangement in accordance with ASC 606 and identified the following performance obligations: 1) license to intellectual property, PF708, 2) development services, including preparing and submitting an NDA for PF708, manufacturing process quality services and support FDA pre-approval inspections for the facilities named in the NDA application 3) COGS reduction activities related to PF708 manufacturing. The Company concluded that each of these performance obligations were distinct because Alvogen can benefit from the good or service either on its own or together with other resources that are readily available, and each performance obligation is separately identifiable from other promises within the contract. The performance obligations have not changed with the EU, MENA, and ROW agreements as Alvogen is receiving a license for substantially the same Pfenex technology in each respective geographic Territory (i.e., the EU, MENA, and ROW Territories defined in those Agreements) as the Pfenex technology in the US Agreement.

As noted above, in 2018, the Company received a $2.5 million upfront payment in connection with the Alvogen Agreement. This upfront payment was fully refundable if the Company did not obtain FDA approval of the PF708 NDA by June 2021. Due to the uncertainty associated with the FDA approval of the NDA, the Company determined that this amount should be fully constrained until FDA approval of the NDA, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The FDA approved the NDA in October 2019, at which time the upfront payment was included in the transaction price.

In February 2019, the Company received a $0.5 million nonrefundable upfront license fee for executing the EU agreement and a $0.3 million nonrefundable upfront license fee for executing the MENA agreement. These upfront payments were considered fixed and included in the transaction price at contract inception.

Also in February 2019, the Company achieved a development milestone of $2.5 million related to the acceptance of the PF708 NDA by the FDA. This milestone was constrained at the Adoption Date and not included in the transaction price until the date the FDA accepted the NDA, in February 2019.

In May 2019, the Company achieved a development milestone of $250 thousand for the EU agreement by submitting a Marketing Authorization Application (MAA) for PF708 to the Kingdom of Saudi Arabia's Saudi Food and Drug Authority (SFDA). This development milestone was constrained until the date the MAA was submitted, in May 2019.

In October 2019, the Company achieved a development milestone related to the original agreement of $2.5 million for the FDA approval of PF708 NDA, Due to the uncertainty associated with the FDA approval of the NDA, the Company determined that this amount should be fully constrained until FDA approval of the NDA. This amount is included in the transaction price at the date the FDA approved the NDA.

The Company received $1.0 million sublicense consideration related to the EU agreement and $1.2 million sublicense consideration related to the MENA agreement. These fees are considered variable consideration but are included in the transaction price at the date the sublicense contracts were executed by Alvogen to the third parties, in December 2019.

The estimated total transaction price was allocated between satisfied and unsatisfied performance obligations based on the relative standalone selling prices of the identified performance obligations. The Company uses an adjusted market assessment approach and an expected cost plus a margin approach to estimate the standalone selling price for the performance obligations. The Company allocated the $2.5 million transaction price of the original upfront payment, $0.8 million nonrefundable upfront license fee for the EU and MENA agreements, $5.0 million transaction price of the two milestone achievements of the original agreement, $250 thousand transaction price of the milestone achievement of the EU agreement, $2.2 million sublicense consideration for the EU and MENA agreements, $0.3 million of initial payments related to the ROW agreement, and $113 thousand of a milestone achievement of the EU agreement to the license to intellectual property and development services performance obligations. None of the transaction price was allocated to the COGS reduction activities performance obligation due to the immateriality in the valuation of the standalone selling price relative to the other two identified performance obligations.

In May 2019, the Company entered into a separate agreement with Alvogen for the Company to provide PF708 drug substance batches and pen components in exchange for $2.3 million. This product sold to Alvogen was initially manufactured by the Company's CMO for manufacturing process validation purposes as part of the PF708 NDA submission to the FDA for approval. The Company assessed this arrangement in accordance with ASC 606 and identified the deliverables, the drug substance and associated pen parts, as one performance obligation because they are highly interdependent in that the pen parts have been customized so that they only work in combination with the drug substance. The Agreement does not include any forms of variable consideration, noncash consideration, consideration payable to the customer, or a significant financing component, so the Company concluded that it is receiving a fixed price of $2.3 million and included in the transaction price at contract inception. The Company concluded that the product revenue should be recognized at the point in time that the Company's performance obligation to deliver the drug substance and pen parts is satisfied and recognized the $2.3 million in August 2019.

Accounting for Alvogen Agreement under previous revenue recognition policy

In accordance with ASC 605-25, the Company identified all of the deliverables at the inception of the Alvogen Agreement. The significant deliverables were determined to be the development and regulatory services up through the NDA filing and ultimate approval related to the PF708 product and the exclusive license granted to Alvogen to commercialize PF708 in the United States. The Company has determined that the license and the development and regulatory activities meet the separation criteria; therefore, they are each treated as separate units of accounting.

To determine the stand-alone value of the license, the Company considered our negotiation discussions with Alvogen that led to the final terms of the agreement and other information. The Company determined a selling price for the services by estimating costs expected to be incurred for internal labor, burden rates, internal margins, and subcontractors.

The upfront payment of $2.5 million received in 2018 was not fixed and determinable due to a contract clause that $2.5 million may be payable to Alvogen if the NDA approval is not transferred to Alvogen by a specified date; therefore, the upfront payment was recorded as deferred revenue in the accompanying consolidated balance sheet as of December 31, 2018.

NT Pharma

In April 2018, the Company entered into an agreement with NT Pharma under which the Company granted NT Pharma non-exclusive development and exclusive commercialization rights to PF708 in Mainland China, Hong Kong, Singapore, Malaysia and Thailand. NT Pharma will be responsible for any further development required to achieve regulatory approval as well as commercialization activities in the applicable territories.

As noted above, in 2018 the Company received $2.5 million upfront license fee in connection with the NT Pharma Agreement. This upfront payment was fully refundable if the Company did not submit the PF708 NDA to the FDA by the contractual deadline of December 31, 2018 or if the Company did not subsequently provide NT Pharma the associated documents related to the NDA filing.

As of December 31, 2019, the Company may be eligible to receive up to $22.5 million in payments based on the achievement of certain development, regulatory, and sales-related milestones. In addition, the Company is eligible to receive double-digit royalties on net product sales.

Accounting for NT Pharma Agreement under ASC 606

The Company assessed this arrangement in accordance with ASC 606 and identified the following performance obligations: 1) license to intellectual property, PF708, and 2) development services including preparing and submitting an NDA for PF708 and providing NT Pharma with documents related to the NDA submission. The Company concluded that each of these performance obligations were distinct because NT Pharma can benefit from the good or service either on its own or together with other resources that are readily available, and each performance obligation is separately identifiable from other promises within the contract.

The estimated total transaction price was allocated between satisfied and unsatisfied performance obligations based on the relative standalone selling prices of the identified performance obligations. The Company uses an adjusted market assessment approach and an expected cost plus a margin approach to estimate the standalone selling price for the performance obligations. The Company allocated the $2.5 million transaction price of the original upfront payment as such: $1.3 million to the development services performance obligation and $1.2 million to license to the intellectual property performance obligation.

The Company concluded that under ASC 606 the $2.5 million should be recognized as of the Adoption Date as the work was substantially complete (including the satisfaction of the performance obligations above) and a significant revenue reversal was not probable. However, under ASC 605, the Company concluded that the upfront payment of $2.5 million was not fixed and determinable, and that due to a contract clause, the $2.5 million could be payable to NT Pharma if the NDA was not filed by a specified date and additional deliverables were required after NDA submission. Therefore, under ASC 605 the upfront payment was recorded as deferred revenue in the accompanying consolidated balance sheet at December 31, 2018. As a result of the adoption of ASC 606, the Company adjusted its accumulated deficit balance at January 1, 2019 by decreasing the amount by $2.5 million.

Accounting for NT Pharma Agreement under previous revenue recognition policy

In accordance with ASC 605-25, the Company identified all of the deliverables at the inception of the NT Pharma Agreement. The significant deliverables were determined to be the license and research and development services up through the NDA filing related to the PF708 product. The Company has determined that these deliverables meet the separation criteria and therefore are each treated as separate units of accounting.

The upfront payment of $2.5 million was not fixed and determinable. Due to a contract clause, the $2.5 million could be payable to NT Pharma if the NDA was not filed by a specified date and additional deliverables were required after NDA submission. Therefore, the upfront payment was recorded as deferred revenue in the accompanying consolidated balance sheet at December 31, 2018. The NDA was filed in December 2018, and NT Pharma received the information contractually required in January 2019.

Jazz

In July 2016, the Company entered into a development and license agreement with Jazz Pharmaceuticals for the development and commercialization of multiple early stage hematology/oncology product candidates, including PF743, a recombinant crisantaspase, and PF745, a recombinant crisantaspase with half-life extension technology, and in the third quarter of 2017, achieved a process development milestone. The agreement also includes an option for Jazz to negotiate a license for a recombinant pegaspargase (PF690) product candidate with the Company. Under the agreement, the Company received an upfront payment of $5.0 million and an option payment of $10.0 million in July 2016 and may be eligible to receive additional payments based on achievement of certain research and development, regulatory and sales-related milestones.

In December 2017, the Company and Jazz entered into an amended and restated agreement. In connection with the amendment and restatement of the Jazz Agreement (as amended, the Amended Jazz Agreement), the Company received a total of $18.5 million, consisting of an upfront payment of $5.0 million and a payment of $13.5 million for development achievement.

As a result of the Amended Jazz Agreement, the total payments and potential payments to the Company is $224.5 million. The Company has received $62 million of upfront and milestone payment through December 31, 2019 and may be eligible to receive additional payments of up to $162.5 million based on achievement of certain research and development, regulatory and sales-related milestones. The total remaining milestones are categorized as follows: $3.5 million based on achievement of certain research and development milestones; $34.0 million for certain regulatory milestones; and $125.0 million for sales milestones.

Accounting for Jazz Agreement under ASC 606

Upon implementation of ASC 606 on January 1, 2019, the Company applied a practical expedient for contract modifications applicable to contracts that were modified before the implementation date. The Company assessed this arrangement in accordance with ASC 606 and identified the following performance obligations: 1) research and development services related to the Pegaspargase product candidate option ("Pegaspargase Data Package"), 2) license and research and development activities of the PF743 product, and 3) license and research and development activities of the PF745 product. The Company concluded that the development activities for PF743 and PF745 are highly interrelated and integrated with the license to intellectual property, so the research and development activities and license were combined into one performance obligation. The Company concluded that each of these performance obligations were distinct because Jazz can benefit from the good or service either on its own or together with other resources that are readily available, and each performance obligation is separately identifiable from other promises within the contract. The performance obligations have not changed under the amendment.

As noted above, in 2016, the Company received a $5.0 million upfront fee related to the PF743 and PF745 licenses and a $10 million upfront fee related to the Pegaspargase Data Package in connection with the original Jazz agreement. These payments were concluded to be fixed consideration as they were non-refundable, and therefore included in the transaction price at the inception of the original agreement. At contract inception of the original agreement, the first development milestone for $0.4 million was likely to occur at the inception of the agreement, so the payment was included in the transaction price at the inception of the agreement, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

In 2017, the Company received a $5.0 million upfront license fee in connection with the amended Jazz agreement. This upfront payment was concluded to be fixed consideration as it was non-refundable, and therefore and included in the transaction price at the inception of the amended agreement. At contract inception of the amended agreement, the first development milestone for $0.4 million was likely to occur at the inception of the amendment, so the payment was included in the transaction price at the inception of the amendment, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.

The remaining milestone payments within the original and amended agreements include a level of production/manufacturing that is unprecedented in the Company's history at contract inception, the development milestones were highly uncertain and the Company determined that they should not be included in the transaction price until the milestones are reached, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur. In addition, the future royalties related to licensed intellectual property were also excluded from the estimated total transaction price under the royalty exception in ASC 606. Between 2016 and 2018, the Company achieved multiple development milestones totaling $15.3 million in connection with the original agreement and amended agreement.

The $20 million received in upfront payments was allocated between satisfied and unsatisfied performance obligations based on the relative standalone selling price of the identified performance obligations. The Company uses an adjusted market assessment approach and an expected cost plus margin approach to estimating the standalone selling price for all three performance obligations. The Company allocated the $20 million transaction price of the upfront payments as such: $10 million to the Pegaspargase Data Package, $7.5 million to the license and research and development activities of the PF745 product, and $2.5 million to the license and research and development activities of the PF743 product. The milestone payments related to the PF743 product license and development services performance obligation and the PF745 product license and development services are allocated to each of those performance obligations because those performance obligations are each a series of distinct services.

The upfront payments allocated to the three performance obligations meet the criteria under ASC 606 to be recognized over time using an input method based on estimated costs. The Company concluded that this is the best method for measuring progress because the costs incurred by the Company enhances the assets over time. As of the Adoption Date the Company recognized license and service revenue for all of the $2.5 million allocated to the PF743 product license and research and development activities performance obligation, $5.7 million of the $7.5 million allocated to the PF745 product license and research and development activities performance obligation, and $9.1 million of the $10 million allocated to the Pegaspargase Data Package performance obligation. As of January 1, 2019, deferred revenue associated with the upfront payments of the Jazz collaboration was $2.7 million.

In 2019, the Company recognized the remaining $2.7 million of the upfront payments. In addition, the Company achieved two development milestones during 2019, and recognized $26 million in license and service revenue for successful achievement of process development milestones for the PF743 product and the PF745 product. During the years ended December 31, 2019 and 2018, the Company recorded license and service revenue of approximately $28.7 million and $8.1 million related to the Jazz Collaboration, respectively.

Accounting for Jazz Agreement under previous revenue recognition policy

In accordance with ASC 605-25, the Company identified all of the deliverables at the inception of the Jazz Agreement and again upon entering into the Amended Jazz Agreement. The deliverables have not changed under the amendment. The significant deliverables were determined to be the research and development services related to the Pegaspargase product candidate option and for license and research and development activities of the other hematology/oncology products. The Company has determined that the license, together with the research and development activities, represent one unit of accounting for each product under license, as the license does not have standalone value from the respective development activities. The research and development activities related to the Pegaspargase option were determined to have standalone value apart from the license and development activities for the other hematology/oncology products. The estimated selling price for the Pegaspargase product candidate and the hematology/oncology products was determined using an income approach. In determining the estimated selling price, the Company considered costs expected to be incurred for internal labor, burden rates, internal margins, and subcontractors. Based on the Company's considerations of estimated selling price, the Company allocated the original $15.0 million upfront and option payment as follows: $10.0 million to the Pegaspargase product candidate and $2.5 million to each of the hematology/oncology products. For the $5.0 million upfront payment received under the terms of the Amended Jazz Agreement, the Company determined that $0.8 million represented development services performed prior to the amendment, which had been reimbursable under the original agreement. The remaining $4.2 million of the upfront payment was allocated to the remaining hematology product; the amount was deferred and recognized over the period of performance. The Amended Jazz Agreement provisions allow for Jazz to halt the advancement of one of the products under development and replace with others wherein the Company could potentially earn milestone revenue on those products. However, the Company believes it is unlikely Jazz would halt the advancement of the product under development and replace with other products. Therefore, none of the upfront payments were allocated to this option.

The upfront and option payment for the original Jazz agreement and the amendment was deferred and recognized as revenue ratably over the period in which the Company expects services to be rendered for each respective unit of accounting. The estimated period of revenue recognition approximates a range of 15 to 32 months. Based on changes to this estimate that occurred during the quarter ended June 30, 2017, the Company modified the period of revenue recognition to range from 15 to 35 months. During the year ended December 31, 2017, the Company completed the service period related to one of the hematology products. In 2018, the Company achieved two development milestones and recognized $750 thousand in revenue for successful achievement of process development milestones for PF745. During the years ended December 31, 2018 and 2017, the Company recorded revenue of approximately $8.1 million and $21.6 million related to the Jazz Collaboration, respectively. As of December 31, 2018 and 2017, deferred revenue associated with the Jazz collaboration was $2.7 million and $10.1 million, respectively.

Arcellx

In December 2018, the Company entered into a development, evaluation and license agreement with Arcellx which provides access to the P*fē*nex 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, the Company 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 P*fē*nex Expression Technology, as well as royalties on worldwide sales of any such products. The Company currently has two sparX proteins in development with Arcellx.

Accounting for Arcellx Agreement under ASC 606

The Company assessed this arrangement in accordance with ASC 606 and identified one combined license and development performance obligation. The Company concluded that the development activities provided to Arcellx are highly interrelated and integrated with the license to intellectual property, so the research and development activities and license were combined into one performance obligation. The Company is receiving development fees for work performed over each Arcellx owned sparX protein. The development work is provided in stages and each stage includes fix development fees. The

upfront payments meet the criteria under ASC 606 to be recognized over time using an input method based on estimated costs. The Company concluded that this is the best method for measuring progress because the costs incurred by the Company in providing the development service reflect the pattern of the Company's performance in transferring control to Arcellx. As of December 31, 2019 there was no deferred revenue related to the Arcellx contract. During the year ended December 31, 2019, revenue from Arcellx was $2.2 million.

Funding Agreements

The U.S. Department of Health and Human Services

In August 2015, the Company completed a development contract with the BARDA within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services for Px563L and RPA563 as a novel vaccine candidate for the prevention of anthrax infection. The Company entered into a follow-on contract with BARDA in August 2015 for the advanced development of Px563L and RPA563. This agreement is a cost-plus fixed fee development contract valued at up to approximately $143.5 million, including a 30-month base period of performance of approximately $15.9 million, and eight option periods valued at a total of approximately $127.6 million. The base period of performance was initially from August 2015 through February 2018 and later extended through September 2018. BARDA exercised additional phases of the development contract effective January 2017, totaling $4.9 million and allowing for the continuing development of Px563L and RPA563. The period of performance for the two option periods was extended through September 2018 and December 2019. In May 2018, BARDA increased the funding for one of the option periods by approximately $1.7 million. On March 29, 2019, the Company received notice from BARDA advising the Company of its decision not to exercise development options for cGMP manufacturing and potential Phase 1/2b study readiness for Px563L and RPA563. Following the receipt of the notice from BARDA and pursuant to discussions with BARDA, the Company deprioritized this program in its portfolio. This agreement is subject to early termination and stop-work order in conformance with Federal Acquisition Regulations 52.249-6 and 52.242-15 whereupon BARDA may immediately terminate the agreement early for convenience or request the Company to stop all or any part of the work for a period of at least 90 days. If BARDA is not adequately funded, there is a potential that some or all of the follow-on options could be delayed or never elected.

Accounting for BARDA Agreement under ASC 606

The Company assessed this arrangement in accordance with ASC 606 and identified one performance obligation, research and development services. The performance obligations have not changed under the amendments. The Company is receiving fees from BARDA based on the costs the Company incurs with either a percentage markup or no markup, and reimbursable expenses, so the Company concluded that all of the consideration is variable. The Company also concluded that the contract with BARDA is a month-to-month contract and that it satisfies its performance obligation over time, and therefore, the Company includes the variable fees in the transaction price when the services are complete at the end of each month and the variable fees are known. The Company concluded that recognizing revenue over time is the best method for measuring progress because the costs incurred by the Company in providing the development service reflect the pattern of the Company's performance in transferring control to BARDA. During the year ended December 31, 2019, revenue from BARDA was $1.5 million.

Accounting for BARDA Agreement under previous revenue recognition policy

Revenue is recognized in accordance with the authoritative guidance for revenue recognition including the authoritative guidance specific to federal government contractors. Reimbursable costs under this government contract primarily include direct labor, materials, subcontracts, accountable property and indirect costs. In addition, the Company receives a fixed fee under the BARDA contract, which is unconditionally earned as allowable costs are incurred and is not contingent on success factors. Reimbursable costs under this BARDA contract, including the fixed fee, are generally recognized as revenue in the period the reimbursable costs are incurred and become billable. The Company recorded revenues of $4.8 million and $5.5 million for services performed in the years ended December 31, 2018 and 2017, respectively. Reimbursable costs related to fulfilling on this contract amounted to $3.7 million and $3.5 million for the years ended December 31, 2018 and 2017, respectively, and are reflected in cost of revenue in the accompanying consolidated statements of operations. The billing of any overage in indirect cost rates over the approved provisional rates in the contract is not allowed. Any such overage is expensed as incurred. When and if final rates with Defense Contract Audit Agency are approved, the Company will recognize any change in revenue resulting from the rate change in the period such revised rates are approved and as such this would be considered a change in estimate.

CRM197

The Company has several development and commercial partnerships in place for CRM197, which 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. The Company developed a unique CRM197 production strain based on its Pseudomonas fluorescens platform and sells non-GMP and cGMP CRM197 to vaccine development-focused pharmaceutical partners. As a result of those efforts, the Company previously entered into commercial licenses for production strains capable of producing CRM197 with both Merck & Co., Inc. (Merck) and Serum Institute of India Private, Ltd (SIIPL). These commercial license agreements with Merck and SIIPL contemplate potential maintenance and milestone fees as well as royalties on net sales. Merck and SIIPL are currently using the Company's CRM197 in multiple Phase 3 clinical trials for such diseases as pneumococcal and meningitis bacterial infections.

The Company generates revenue by selling bulk CRM197 product. If a customer purchases reagent grade CRM197, the Company can ship the product from its facilities to the customer from reagent stock that is ordered and received from SIIPL and kept in the Company's lab freezers. Any unsold reagent grade product is counted and included in inventory each quarter and has historically been immaterial. If a customer purchases GMP/human grade CRM197, SSIPL dropships the product directly to the Company's customers.

The Company assessed the purchase order arrangements in accordance with ASC 606. As the purchases are received for a specific quantity and type of CRM197 product, there is deemed to be just one performance obligation, delivery of such product. The transaction price is clearly identified on the purchase order and product quote information and allocated to the single performance obligation. The customer control and risk of loss is transferred upon shipment which results in the Company recognizing revenue at a point in time. During the year ended December 31, 2019, revenue from CRM197 was $3.5 million.

8. Commitments and Contingencies

Lease Agreements

The Company determines if an arrangement is, or contains, a lease at contract inception. These lease agreements have remaining lease terms of 1 to 5 years. The Company recognizes a right-of-use ("ROU") asset and a lease liability at the lease commencement date. The lease liability is initially measured at the present value of the unpaid future lease payments as of the lease commencement date. A key estimate includes how the Company determines the discount rate it uses to discount the unpaid lease payments to present value.

ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. Generally, the Company cannot determine the interest rate implicit in the lease because it does not have access to the lessor's estimated residual value or the amount of the lessor's deferred initial direct costs. Therefore, the Company generally uses its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. Because the Company does not generally borrow on a collateralized basis, it uses quoted interest rates obtained from financial institutions as an input to derive an appropriate incremental borrowing rate, adjusted for the amount of the lease payments, the lease term, and the effect on that rate of designating specific collateral with a value equal to the unpaid lease payments for that lease.

In June 2010, the Company entered into an operating lease agreement (Lease) with a landlord for an initial term of 10 years, for its corporate headquarters comprised of one building located in San Diego, California. Occupation of the premises under the Lease began in April 2011. Under the terms of the Lease, the Company pays annual base rent, subject to an annual fixed percentage increase, plus its share of common operating expenses and tax obligations. The annual base rent was subject to abatement of 50% for the first year of the Lease.

In September 2014, the Company amended the Lease to extend the term for an additional three years through March 31, 2024 and to an additional 7,315 square feet of leased space. The extended term on the existing space increased total estimated rent payments by approximately $1.4 million. Base rent payments for the new space commenced in December 2014 and increased total estimated rent payments over the life of the Lease by approximately $1.5 million. In November 2015, the Company further amended the Lease to add facilities consisting of 16,811 square feet. Base rent payments for the new space commenced in March 2016 and June 2016 and increased total estimated rent payments over the life of the Lease by approximately $2.3 million.

In February 2019, the Company entered into a sublease agreement with a tenant to lease a portion of its office space. The term of the lease agreement commenced on April 1, 2019 and ends on March 31, 2024 (when the underlying lease term ends, unless the underlying lease is terminated early). The sublessee is responsible for all variable lease payments including expenses, costs, taxes, insurance, maintenance, and other charges in connection with the subleased premises. The sublease does not have any renewal options, require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Rent payments increase by 3% each year on the anniversary of the commencement date. The sublease income earned in 2019 was immaterial.

The Company adopted ASC 842 effective January 1, 2019 using the alternative transition approach by recording an operating lease right-of-use asset of $3.7 million and corresponding net operating lease liability of $4.2 million. In addition, effective January 1, 2019, the Company recorded a financial lease right-of-use asset of $0.9 million and corresponding net financial lease liability of $0.5 million at that date. The Company continues to account for leases in the prior period financials statements under ASC Topic 840.

The following table presents the lease related assets and liabilities recorded on the Company's consolidated balance sheets related to its operating and finance leases:

	December 31, 2019
	(in thousands)
Operating lease right-of-use assets	$ 3,124
Finance lease right-of-use assets	779
Total right-of-use assets	$ 3,903
Operating lease liability-short-term	$ 761
Operating lease liability-long-term	2,895
Finance lease liability-short-term	190
Finance lease liability-long-term	1
Total lease liabilities	$ 3,847
Weighted average remaining lease term - operating leases	4.2 years
Weighted average remaining lease term - finance leases	0.6 years
Weighted average discount rate	5%

Lease cost was $0.8 million for the year ended December 31, 2019 and rent expense was $0.8 million, and $0.7 million for the years ended December 31, 2018 and 2017, respectively. Lease cost and rent expense is included in cost of revenue, research and development and selling, general and administrative expenses in the accompanying consolidated statements of operations as follows:

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Cost of revenue	$ 64	$ 42	$ —
Research and development	496	417	326
Selling, general and administrative	241	293	407
Total rent expense	$ 801	$ 752	$ 733

The Company's office space leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. These leases do not have any renewal options or rent escalation clauses. Variable expenses generally represent the Company's share of the landlord's operating expenses. In addition to the Lease, the Company has entered into operating and financial lease agreements for office and lab equipment that commenced prior to January 1, 2019 and expire at various dates through 2024. The Company does not have any arrangements where it acts as a lessor except for the one sublease of a portion of its office space referred to above.

Supplemental cash flow information related to operating leases for the year ended December 31, 2019 were as follows:

	(in thousands)
Cash paid for amounts included in the measurement of lease liabilities	$ 1,175
Lease liabilities arising from obtaining ROU asset	—

Maturities of operating lease liabilities for each of the next five years and thereafter are as follows:

	Payment Amounts	
	Finance Leases	Operating Leases
	(in thousands)	
2020	$ 198	$ 927
2021	1	941
2022	—	967
2023	—	995
2024 and thereafter	—	244
Total future minimum lease payments	$ 199	$ 4,074

As of December 31, 2019, the Company has no additional operating lease commitments that have not yet commenced.

As of December 31, 2018, the total estimated future annual minimum lease payment obligations under the Company's non-cancelable leasing arrangements, including the facilities lease described above, are as follows:

	Payment Amounts		
	Operating Leases	Capital Leases	Total
	(in thousands)		
2019	$ 901	$ 344	$ 1,245
2020	899	197	1,096
2021	909	1	910
2022	934	—	934
2023 and thereafter	1,206	—	1,206
Total future minimum lease payments	$ 4,849	$ 542	$ 5,391

Clinical Study and Development Activity Commitments

The Company has entered into agreements with subcontractors to further develop its product candidates. These contracts can be cancelled at any time, with some having certain cancellation fees associated with the termination of the contract, and others that only obligate the Company through the termination date.

Contingencies

From time to time, the Company may be involved in legal proceedings, claims, and litigation in the ordinary course of business. At December 31, 2019, 2018 and 2017, there were no material legal proceedings.

9. Stock-Based Compensation

Summary Stock-Based Compensation Information

The following table summarizes stock-based compensation expense:

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Cost of revenues	$ 161	$ 157	$ 265
Research and development	1,214	1,418	1,028
Selling, general and administrative	1,522	1,604	1,830
Total	$ 2,897	$ 3,179	$ 3,123

	2019	2018	2017
		(in thousands)	
Stock-based compensation from:			
Stock options	$ 2,809	$ 3,008	$ 2,993
Employee stock purchase plan	88	171	130
Total	$ 2,897	$ 3,179	$ 3,123

Stock Option Plan

The Company's board of directors adopted, and the Company's stockholders approved, the Company's 2009 Equity Incentive Plan (2009 Plan) in 2009. The 2009 Plan terminated in connection with the Company's IPO in 2014 and, accordingly, no awards will be granted under the 2009 Plan following the IPO. However, the 2009 Plan will continue to govern outstanding awards granted thereunder. The 2009 Plan provided for the grant of incentive stock options and for the grant of nonstatutory stock options, restricted stock, restricted stock units, and stock appreciation rights to the Company's employees, directors and consultants. As of December 31, 2019, awards covering 0.1 million shares of common stock were outstanding under the 2009 Plan.

In July 2014, the board of directors adopted a 2014 Equity Incentive Plan (2014 Plan) and the Company's stockholders approved it. In May 2017, the Company's stockholders approved an amendment to the 2014 Equity Incentive Plan (2014 Amended Plan), to, among other things, increase the available shares by 2.5 million. In addition, in May 2019, the Company's stockholders approved an amendment to the 2014 Amended Plan (2014 Second Amended Plan), to, among other things, increase the available shares by 2.0 million. The 2014 Second Amended provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to employees and any parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants and parent and subsidiary corporations' employees and consultants. The shares available for issuance under the 2014 Second Amended Plan include shares returned to the 2009 Plan as the result of expiration or termination of awards (provided that the maximum number of shares that may be added to the 2014 Second Amended Plan pursuant to such previously granted awards under the 2009 Plan is 961,755 shares). The maximum number of shares that may be issued under the 2014 Second Amended Plan is 7.5 million plus shares added from 2009 Plan, if any. As of December 31, 2019, a total of 3.4 million shares of common stock were available for issuance pursuant to the 2014 Second Amended Plan. As of December 31, 2019, awards covering 3.5 million shares of common stock were outstanding under the 2014 Second Amended Plan.

In September 2016, the board of directors adopted the 2016 Inducement Equity Incentive Plan (2016 Plan). The 2016 Plan provides for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to new employees. Stock options granted under the 2016 Plan have a term of ten years from the date of grant, the exercise price for the shares to be issued will be no less than 100% of the fair market value per share on the date of grant and generally vest over a four-year period. The maximum aggregate number of shares that may be issued under the 2016 Plan is 500,000 shares. As of December 31, 2019, a total of 0.1 million shares of common stock were available for issuance pursuant to the 2016 Plan. As of December 31, 2019, awards covering 0.4 million shares of common stock were outstanding under the 2016 Plan.

Stock options granted to date under the 2009 Plan and the 2014 Second Amended Plan have a term of ten years from the date of grant, and generally vest over a four-year period. However, in the event that an incentive stock option (ISO) granted to a participant who, at the time the ISO is granted, owns stock representing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company, the term of the ISO shall be five years from the grant date or such shorter term as may be provided in the award agreement.

In July 2014, the board of directors adopted the 2014 Employee Stock Purchase Plan (ESPP) and the stockholders approved it. As of December 31, 2019, a total of 1,548,890 shares of common stock were available for issuance under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for sale under the ESPP on the first day of each fiscal year beginning in 2015, equal to the least of: (i) 355,618 shares; (ii) 1.5% of the outstanding shares of the common stock on the last day of the immediately preceding fiscal year; or (iii) such other amount as may be determined by the administrator. As of December 31, 2019, 167,215 shares have been purchased under the ESPP.

Stock Options

The per share exercise price of all options granted during the years ended December 31, 2019, 2018 and 2017 was equal to the closing price of a share of common stock on the date of grant. The fair value of each stock option granted during the years ended December 31, 2019, 2018 and 2017 is estimated on the grant date under the fair value method using the Black-Scholes model. The estimated fair values of the stock option, including the effect of estimated forfeitures, are then expensed over the requisite service period which is generally the vesting period. The following assumptions were used to estimate the fair value of stock options:

	Years Ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.4%	2.7%	1.9%
Expected volatility	72.6%	71.2%	66.3%
Expected dividend yield	0.0%	0.0%	0.0%
Expected life of options in years	6.2	6.3	5.5

The fair value of equity instruments that are ultimately expected to vest, net of estimated forfeitures, are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model requires multiple subjective inputs, including a measure of expected future volatility. Prior to the Company's IPO in 2014, the Company's stock did not have a readily available market. Consequently, the expected future volatility was based on the historical volatility for comparable publicly traded companies over the most recent period commensurate with the estimated expected term of the Company's stock options. Beginning in the fourth quarter of 2016, the expected future volatility was based on the historical volatility for the Company's common stock. Following the completion of the Company's IPO, the fair value of options granted is based on the closing price of the Company's common stock on the date of grant as quoted on the NYSE American. The risk-free interest rate assumption is based upon observed interest rates during the period appropriate for the expected term of the options. The expected term of the options has been estimated using the simplified method to determine the expected life of the Company's options due to insufficient activity as a basis from which to estimate future exercise patterns. With the exception of 1,217,784 shares of common stock issued in connection with the payment of all accrued and unpaid dividends on the preferred stock immediately prior to the completion of the Company's IPO, the Company had never declared or paid dividends and has no plans to do so in the foreseeable future. Accordingly, the dividend yield assumption is based on the expectation that the Company will not pay dividends on its common stock in the future. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The weighted-average grant date fair values of options granted during the years ended December 31, 2019, 2018 and 2017 were $3.25, $2.47 and $2.92, respectively. Total fair value of options vested during the years ended December 31, 2019, 2018 and 2017 was $2.9 million, $2.7 million and $3.9 million, respectively.

Stock option transactions under the 2014 and 2016 Plans during the year ended December 31, 2019 were as follows:

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2019	4,155	$ 6.12		
Granted	1,390	4.94		
Exercised	(764)	6.02		
Cancelled (forfeited)	(778)	7.09		
Outstanding at December 31, 2019	4,003	$ 5.55	7.63	$ 22,781
Vested and expected to vest at December 31, 2019	3,512	$ 5.66	7.46	$ 19,699
Vested and exercisable at December 31, 2019	1,858	$ 6.65	6.35	$ 9,078

The Company received $4.6 million, $94 thousand and $26 thousand for the years ended December 31, 2019, 2018 and 2017, respectively, for options exercised.

As of December 31, 2019, there was approximately $4.2 million of unrecognized compensation cost related to unvested stock option awards, and the weighted-average period over which this cost is expected to be recognized is 2.64 years.

The total aggregate intrinsic value, which is the amount, if any, by which the exercise price was exceeded by the estimated fair value of the Company's common stock, of options exercised, was $3.2 million, $0.1 million and $0.3 million for the years ended December 31, 2019, 2018 and 2017, respectively.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (ASC 718)*, which simplifies the accounting for nonemployee share-based payment transactions. The Company adopted this standard as of January 1, 2019. The impact of adoption of this standard did not have a material impact on the Company's consolidated financial statements.

10. Retirement Plan

The Company has a 401(k) Savings Plan (401(k) plan). The 401(k) plan is for the benefit of all qualifying employees and permits voluntary contributions by employees up to a maximum percentage allowable by current IRS regulations. During the years ended December 31, 2019, 2018 and 2017, the Company made matching contributions to the 401(k) of $0.4 million, $0.3 million and $0.2 million, respectively.

11. Income Taxes

The components of the income tax (provision) benefit are as follows:

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Current	$ —	$ —	$ 172
Deferred	(1)	—	—
Total (provision) benefit	$ (1)	$ —	$ 172

For the year ended December 31, 2017 the Company recorded an income tax provision benefit attributable to U.S. Federal refundable alternative minimum tax and state income tax. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on its balance sheets at December 31, 2019 and 2018. The Company is subject to taxation in the United States and various state jurisdictions. The Company's tax years 2014 and forward are subject to examination by the United States and tax years 2010 and forward in California and various state tax authorities.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code, including, but not limited to, reducing the U.S. federal corporate tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017.

Pursuant to the SEC Staff Accounting Bulletin ("SAB") No. 118, "Income Tax Accounting Implications of the Tax Cuts and Jobs Act" ("SAB 118"), a company may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. Those scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the revaluation of deferred taxes by recording a net tax provision of $6.4 million in the period ending December 31, 2017 which is offset by a full valuation allowance. This tax expense is primarily due to the corporate rate reduction. The Company has also recorded a tax benefit of $0.2 million for the AMT credits which are refundable in tax year 2018 through 2022. During the quarter ended December 31, 2018, the Company completed its accounting for the impacts of the Tax Act. There were no significant changes to its estimate.

As of December 31, 2019, the Company had federal and state research and development credits carryforwards of approximately $7.5 million and $4.2 million, respectively, to offset potential tax liabilities. The federal research and development credits have a 20-year carryforward period and begin to expire in 2030 unless utilized. California research and development tax credits have no expiration. The Company has $82.7 million federal net operating loss carryforwards and $32.9 million of state net operating loss carryforwards as of December 31, 2019. Of the total federal net operating loss carryforwards, the Company has $41.2 million with no expiration dates. The remaining federal and state net operating losses will begin to expire in 2036 unless utilized.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. If an ownership change has occurred, the Company's ability to use its NOLs or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

Significant components of the Company's deferred tax assets as of December 31, 2019 and 2018 are shown below. A valuation allowance of $29.9 million and $30.5 million for the years ended December 31, 2019 and 2018, respectively, has been established to offset deferred tax assets, as realization of such assets is uncertain.

	December 31, 2019	2018
	(in thousands)	
Deferred tax assets		
Net operating losses	$ 19,660	$ 19,860
Stock-based compensation	1,388	1,502
Research and development credits	9,444	8,157
Deferred revenue	19	1,907
Accruals and other	805	678
Lease Liability	934	—
Total deferred tax assets	32,250	32,104
Deferred tax liabilities		
Depreciation and amortization	(510)	(464)
Intangible assets	(1,024)	(1,097)
ROU Asset	(798)	—
Total deferred tax liabilities	(2,332)	(1,561)
Valuation allowance	(29,918)	(30,543)
Net deferred tax asset	$ —	$ —

The provision for income taxes differs from the U.S. federal statutory tax rate primarily due to state and local income taxes, valuation allowance established, R&D credits and the impact of tax reform. A reconciliation of the Company's effective tax rate and federal statutory tax rate at December 31, 2019, 2018 and 2017 is as follows:

	December 31,		
	2019	2018	2017
		(in thousands)	
Federal income taxes	$ (222)	$ 8,328	$ 8,791
State income taxes	(48)	1,065	949
State rate changes	(790)	(110)	392
Impact of change in federal income tax rates	—	—	(6,401)
Stock-based compensation	(162)	(401)	(623)
Valuation allowance	(14)	(11,332)	(4,728)
Research and development credits	1,287	2,684	1,897
Permanent items and other	(51)	(234)	(105)
Total income tax (provision) benefit	$ (1)	$ —	$ 172

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company has an uncertain tax position with respect to its research and development credits as of December 31, 2019.

The following is a tabular reconciliation of the Company's Unrecognized Tax Benefits activity (excluding interest and penalties):

	December 31,		
	2019	2018	2017
		(in thousands)	
Beginning balance of unrecognized tax benefits	$ 1,394	$ 1,032	$ 730
Additions based on tax positions related to the current year	232	351	361
Additions based on tax positions of prior years	16	11	—
Reductions for tax positions of prior years	—	—	(59)
Ending balance of unrecognized tax benefits	$ 1,642	$ 1,394	$ 1,032

As of December 31, 2019, if recognized, approximately $1.6 million would affect the effective tax rate if the Company did not have a full valuation allowance.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. No accrued interest or penalties were included in its consolidated balance sheets at December 31, 2019 or 2018, and the Company did not recognize any interest and/or penalties in its consolidated statements of operations during the years ended December 31, 2019, 2018, or 2017.

The Company does not anticipate significant increases or decreases within the next 12 months with respect to its unrecognized tax benefit.

The Company is subject to income tax in the United States, California and Massachusetts. The Company is subject to income tax examination by various state tax authorities for the years beginning in 2009 due to net operating losses and state statutes.

12. Net Income (Loss) Per Share of Common Stock

The following table summarizes the computation of basic and diluted net income (loss) per share attributable to common stockholders of the Company:

	December 31,		
	2019	2018	2017
	(in thousands, except per share data)		
Net income (loss)	$ 1,058	$ (39,593)	$ (25,684)
Weighted average shares used to compute basic net income (loss) per share	31,602	28,340	23,503
Dilutive effect of employee stock option plans	771	—	—
Dilutive weighted-average common shares outstanding	32,373	28,340	23,503
Basic and diluted net income (loss) per common share	0.03	(1.40)	(1.09)

Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period, determined using the treasury-stock method, if inclusion of these is dilutive. Because the Company reported a net loss for the years ended December 31, 2018 and 2017, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following table summarizes the potentially dilutive securities outstanding at the end of the periods presented:

	December 31,		
	2019	2018	2017
	(in thousands)		
Options to purchase common stock	4,004	4,155	3,237
Employee stock purchase plan	53	61	75
Total	4,057	4,216	3,312

13. Quarterly Financial Data (unaudited)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2019, 2018 and 2017:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Year Ended December 31
	(in thousands, except for per share data)				
2019[(a)(b)]					
Revenues	$ 7,862	$ 2,811	$ 15,248	$ 24,405	$ 50,326
Cost of revenues	1,566	1,119	1,145	1,061	4,891
Gross profit	6,296	1,692	14,103	23,344	45,435
Operating expenses	12,423	9,332	11,108	11,748	44,611
Other income, net	69	71	55	40	235
Income tax provision	—	—	—	(1)	(1)
Net income (loss)	(6,058)	(7,569)	3,051	11,634	1,058
Net income (loss) per share, basic	$ (0.19)	$ (0.24)	$ 0.10	$ 0.37	$ 0.03
Net income (loss) per share, diluted	$ (0.19)	$ (0.24)	$ 0.10	$ 0.35	$ 0.03
Weighted-average common shares used in calculating net income (loss) per share:					
Basic	31,487	31,527	31,595	31,805	31,602
Diluted	31,487	31,527	31,595	33,398	32,373
2018					
Revenues	$ 3,746	$ 4,190	$ 3,570	$ 3,351	$ 14,857
Cost of revenues	1,520	924	1,479	1,099	5,022
Gross profit	2,226	3,266	2,091	2,252	9,835
Operating expenses	13,256	14,386	12,868	9,176	49,686
Other income, net	3	39	115	101	258
Net loss	(11,027)	(11,081)	(10,662)	(6,823)	(39,593)
Net loss per common share, basic and diluted	$ (0.47)	$ (0.41)	$ (0.34)	$ (0.22)	$ (1.40)
Weighted-average common shares used in calculating basic and diluted net loss per share	23,569	26,771	31,437	31,461	28,340
2017					
Revenues	$ 2,818	$ 3,029	$ 5,024	$ 17,909	$ 28,780
Cost of revenues	810	905	1,766	1,675	5,156
Gross profit	2,008	2,124	3,258	16,234	23,624
Operating expenses	12,084	14,486	12,111	10,918	49,599
Other income, net	44	38	35	2	119
Income tax benefit	—	—	—	172	172
Net income (loss)	(10,032)	(12,324)	(8,818)	5,490	(25,684)
Net income (loss) per share, basic and diluted	$ (0.43)	$ (0.52)	$ (0.37)	$ 0.23	$ (1.09)
Weighted-average common shares used in calculating net income (loss) per share:					
Basic	23,436	23,486	23,539	23,548	23,503
Diluted	23,436	23,486	23,539	23,697	23,503

(a) - Due to the adoption of ASC 606, Q1-2019 revenue is $2.5 million less than the amount reported in the Q1-2019 10-Q. Refer to Note 7 for more information on this adjustment.

(b) - Due to the adoption of ASC 718, cost of revenues and operating expenses is immaterially different than the amounts reported in the Q1-2019, Q2-2019, and Q3-2019 10-Qs.

14. Subsequent Events As discussed in Note 1, in January and February 2020, the Company sold 1,753,443 shares of common stock for net proceeds of $19.4 million.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's (SEC) rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K, were, in design and operation, effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this assessment, management has concluded that its internal control over financial reporting was effective as of December 31, 2019.

The registered public accounting firm that audited our financial statements as of and for the year ended December 31, 2018, included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting, and such report is included below.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Pfenex Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited Pfenex Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes and financial statement schedule II (collectively, the consolidated financial statements), and our report dated March 11, 2020 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG LLP

San Diego, California
March 11, 2020

Inherent Limitations on Effectiveness of Controls

Management recognizes that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. ***Other Information***

Not applicable.

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2019 fiscal year.

Codes of Ethics and Conduct

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Code of Ethics and Conduct is posted on the investor relations page of our website at http://pfenex.investorroom.com/corporate-governance. We will post amendments to our Code of Ethics and Conduct or waivers of our Code of Ethics and Conduct for directors and executive officers on the same website.

Item 11. *Executive Compensation*

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2019 fiscal year.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2019 fiscal year.

Item 13. *Certain Relationships and Related Transactions and Director Independence*

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2019 fiscal year.

Item 14. *Principal Accounting Fees and Services*

The information required by this item is incorporated herein by reference from our definitive proxy statement relating to our 2020 annual meeting of shareholders. The definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the 2019 fiscal year.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) The following documents are filed as part of this report:

1. Financial Statements

   See Index to Financial Statements at Item 8 herein.

2. Financial Statement Schedules

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

	Years Ended December 31,		
	2019	2018	2017
		(in thousands)	
Allowance for Doubtful Accounts:			
Beginning balance	$ —	$ —	$ 50
Reductions and write-offs	—	—	(50)
Ending balance	$ —	$ —	$ —

All other schedules have been omitted because they are not required, not applicable, or the required information is otherwise included.

3. Exhibits

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. ***Form 10-K Summary***

None.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-36540	3.2	July 29, 2014
3.2	Amended and Restated Bylaws of the Registrant.	S-1	333-196539	3.3	June 5, 2014
4.1	Specimen Stock Certificate.	S-1/A	333-196539	4.1	June 23, 2014
4.2*	Description of Common Stock of the Company.				
10.1+	2009 Equity Incentive Plan and form of award thereunder.	S-1	333-196539	10.1	June 5, 2014
10.2+	Amended and Restated 2014 Equity Incentive Plan and form of award thereunder.	8-K	001-36540	10.1	May 9, 2019
10.3+	2014 Employee Stock Purchase Plan.	S-1/A	333-196539	10.3	July 7, 2014
10.4+	2016 Inducement Equity Incentive Plan and forms of award thereunder.	10-Q	001-36540	10.4	November 9, 2016
10.5	Form of Indemnification Agreement.	S-1	333-196539	10.4	June 5, 2014
10.6	Lease Agreement, dated June 22, 2010, between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	S-1	333-196539	10.5	June 5, 2014
10.7	First Amendment to Multi-Tenant Industrial/Commercial Lease dated September 4, 2014 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	8-K	001-36540	10.1	September 25, 2014
10.8	Second Amendment to Multi-Tenant Industrial/Commercial Lease dated November 19, 2015 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	10-K	001-36540	10.7	March 10, 2016
10.9	Third Amendment to Multi-Tenant Industrial/Commercial Lease dated February 24, 2016 between the Registrant and BRS-Tustin Safeguard Associates II, LLC.	10-Q	001-36540	10.2	May 9, 2016
10.10†	Technology License Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1/A	333-196539	10.8	June 25, 2014
10.11	Grant Back License Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.9	June 5, 2014
10.12	Technology Assignment Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.10	June 5, 2014
10.13	Contribution Assignment and Assumption Agreement, dated November 30, 2009, between the Registrant and The Dow Chemical Company.	S-1	333-196539	10.11	June 5, 2014
10.14+	Executive Employment Agreement, dated June 20, 2014, between the Registrant and Patrick K. Lucy.	S-1/A	333-196539	10.23	June 23, 2014

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.15+	Executive Employment Agreement, dated August 3, 2017, between the Registrant and Evert B. Schimmelpennink.	8-K	001-36540	10.1	August 3, 2017
10.16+	Executive Employment Agreement, effective February 1, 2018, between the Registrant and Susan A. Knudson.	8-K	001-36540	10.1	January 4, 2018
10.17+	Executive Employment Agreement, effective October 1, 2018, between the Registrant and Shawn A. Scranton, PharmD.	8-K	001-36540	10.1	September 11, 2018
10.18+	Executive Employment Agreement, effective March 18, 2019, between the Registrant and Martin B. Brenner, DVM.	10-Q	001-36540	10.5	May 9, 2019
10.19+	Executive Incentive Compensation Plan.	S-1/A	333-196539	10.27	June 23, 2014
10.20†	License and Option Agreement, dated July 27, 2016, by and between the Registrant and Jazz Pharmaceuticals Ireland Limited.	10-Q	001-36540	10.1	November 9, 2016
10.21†	Amended License and Option Agreement, dated December 19, 2017, by and between the Registrant and Jazz Pharmaceuticals Ireland Limited.	10-K/A	001-36540	10.68	June 6, 2018
10.22†	Development and License Agreement, dated April 18, 2018, by and between the Registrant and China NT Pharma Group Company Ltd	10-Q	001-36540	10.1	August 8, 2018
10.23†	Development and License Agreement, dated June 11, 2018, by and between the Registrant and Alvogen Malta Operations Ltd.	10-Q	001-36540	10.3	August 8, 2018
10.24†	Development and License Agreement, dated February 25, 2019, between the Registrant and Alvogen Malta (Out-Licensing) Operations Ltd.	10-Q	001-36540	10.1	May 9, 2019
10.25†	MENA Development and License Agreement, dated February 25, 2019, between the Registrant and Alvogen Malta (Out-Licensing) Operations Ltd.	10-Q	001-36540	10.2	May 9, 2019
10.26†	E.U. Development and License Agreement, dated February 25, 2019, between the Registrant and Alvogen Malta (Out-Licensing) Operations Ltd.	10-Q	001-36540	10.3	May 9, 2019
10.27†	Amendment No. 1 to the Development and License Agreement, dated February 25, 2019, between the Registrant and Alvogen Malta Operations Ltd.	10-Q	001-36540	10.4	May 9, 2019
10.28	Sales Agreement, dated as of March 15, 2018, between Pfenex Inc. and William Blair & Company, L.L.C.	8-K	001-36540	1.1	March 15, 2018
10.29†*	Amendment No.1 to the Alvogen ROW Development and License Agreement				

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.30+*	Transition Agreement and Limited Release, effective November 13, 2019, between the Registrant and Susan A. Knudson				
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (contained on signature page).				
31.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1^*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

^ The information in this exhibit is furnished and deemed not filed with the Securities and Exchange Commission for purposes of section 18 of the Exchange Act of 1934, as amended (Exchange Act), and is not to be incorporated by reference into any filing of Pfenex Inc. under the Securities Act of 1933, as amended (Securities Act), or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

† Portions of the exhibit have been omitted pursuant to an order granted by the Securities and Exchange Commission for confidential treatment.

\+ Indicates a management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 11, 2020

Pfenex Inc.

By: /s/ Evert B. Schimmelpennink
Evert B. Schimmelpennink
Chief Executive Officer, President, Secretary, Chief Financial Officer and Director
(Principal Executive and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Evert B. Schimmelpennink and each of them, as his or her true and lawful attorney-in-fact and agent to act, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, and to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their and his or her substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Evert B. Schimmelpennink Evert B. Schimmelpennink	Chief Executive Officer, President, Secretary, Chief Financial Officer and Director *(Principal Executive and Principal Financial and Accounting Officer)*	March 11, 2020
/s/ Jason Grenfell-Gardner Jason Grenfell-Gardner	Chairman and Director	March 11, 2020
/s/ Robin D. Campbell Robin D. Campbell	Director	March 11, 2020
/s/ Phillip M. Schneider Phillip M. Schneider	Director	March 11, 2020
/s/ John Taylor John Taylor	Director	March 11, 2020
/s/ Magda Marquet Magda Marquet	Director	March 11, 2020
/s/ Lorianne Masuoka Lorianne Masuoka	Director	March 11, 2020

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CORPORATE OFFICERS

Evert B. Schimmelpennink
Chief Executive Officer,
President, Secretary and
acting Principal Financial
and Principal Accounting Officer

Patrick K. Lucy
Senior Vice President and
Chief Business Officer

Shawn A. Scranton, PharmD
Senior Vice President and
Chief Operating Officer

Martin B. Brenner, DVM, Ph.D.
Senior Vice President and
Chief Scientific Officer

BOARD OF DIRECTORS

Jason Grenfell-Gardner
Chairman
Former President,
Chief Executive Officer
and Director of Teligent, Inc.

Evert B. Schimmelpennink
Chief Executive Officer,
President, Secretary and
acting Principal Financial
and Principal Accounting
Officer of Pfenex Inc.

Robin D. Campbell, Ph.D.
Former President and
Chief Executive Officer
of Naryx Pharma, Inc.

Magda Marquet, Ph.D.
Co-Chief Executive Officer of
ALMA Life Sciences LLC

Lorianne Masuoka, M.D.
Former Chief Medical Officer
of Marinus Pharmaceuticals,
InVivo Therapeutics and
Cubist Pharmaceuticals

Phillip M. Schneider
Former Senior Vice President
and Chief Financial Officer of
IDEC Pharmaceuticals
Corporation

John M. Taylor
President and Principal of
Compliance and Regulatory
Affairs of Greenleaf Health LLC

COMMON STOCK LISTING

NYSE American
Ticker Symbol: PFNX

REGISTRAR AND TRANSFER AGENT

For questions regarding
your account, changes
of address or the
consolidation
of accounts, please
contact the Company's
transfer agent:

American Stock Transfer
& Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
Attn:
Shareholder Services
T: (800) 937-5449
www.amstock.com

LEGAL COUNSEL

Wilson Sonsini Goodrich
& Rosati,
Professional Corporation
San Diego, California

INDEPENDENT AUDITORS

KPMG LLP
San Diego, California

INVESTOR RELATIONS

Pfenex Inc.
Investor Relations
10790 Roselle St.
San Diego, CA 92121
T: (858) 352-4400
InvestorRelations@Pfenex.com

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning Pfenex's plans to advance and commercialize its product candidates; expectations with respect to "A" therapeutic equivalence for PF708; and Pfenex's expectations with regard to future milestones, royalties, and reimbursements from collaborations. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. 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 the regulatory approval process and other matters that could affect the availability or commercial potential of product candidates; challenges related to commencement, enrollment, completion, and analysis of clinical trials; Pfenex's dependence on third parties; and litigation and/or regulatory actions. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in this Annual Report on Form 10-K and Pfenex's other filings with the Securities and Exchange Commission. Except as required by law, Pfenex undertakes no obligation to update or revise any forward-looking statements.

PFENEX

BIOPHARMACEUTICALS

10790 ROSELLE STREET

SAN DIEGO, CA 92121

(858) 352-4400

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