2017
Annual Report

DEAR FIVE PRIME STOCKHOLDERS

We at Five Prime Therapeutics are building a community around scientific and translational innovation. Our extraordinary people collaborate to discover and develop unique protein therapeutics for patients around the world who are in serious need of new and better treatment options.

We are proud of our compelling value proposition.

- **First,** our comprehensive proprietary libraries of the extracellular proteome, differentiated screening capabilities and protein therapeutic generation and engineering capabilities constitute a unique and powerful Investigational New Drug (IND) engine. Our success with this IND engine arises from our ability to answer unbiased questions about the fundamental role that thousands of extracellular signaling proteins play in the processes and mechanisms of various diseases. Using our industry-leading engine, we have identified novel pathways and targets in immuno-oncology (I-O) that we believe will continue to fill our pipeline with new product candidates beyond those that we have already disclosed.
- **Second,** we have a rapidly expanding pipeline and are progressing into late-stage development. Recognizing the importance of I-O, in 2013, we shifted the focus of our internal research efforts to the discovery and development of I-O protein therapeutics. We have advanced two of these assets into the clinic, including cabiralizumab (FPA008), an investigational CSF-1 receptor antibody that we are evaluating in clinical trials in oncology indications and in pigmented villonodular synovitis (PVNS), and bemarituzumab (FPA144), an FGFR2b antibody that we are evaluating as a targeted I-O therapy for tumors that overexpress FGFR2b or amplify the *FGFR2* gene, including gastric and gastroesophageal junction cancer. We expect that three additional candidates from our platform will advance into human trials this year, more than doubling our clinical-stage portfolio.
- **Third,** we continue to enter into strategic collaborations to accelerate our path to global commercialization, expand our development programs and secure funding. We believe these strategic alliances, coupled with our strong balance sheet, will allow us to develop our assets in a way that ensures our long-term growth. The potential of our current programs has been validated by a growing number of prominent development partnerships, including leading pharmaceutical companies such as BMS and Zai Lab, with whom we have partnered to advance our lead programs. These agreements have generated over $650 million in non-dilutive funding for our ongoing development.

I have great confidence in the future of Five Prime and believe that few companies of our size have similar capabilities and expertise. Moreover, our collaborative culture, powerful engine for innovation, and vast potential to transform patient outcomes in serious diseases, make Five Prime Therapeutics a leader in I-O.

On behalf of Five Prime Therapeutics, its Board of Directors and employees, thank you for your continued support, and we look forward to updating you on our progress.

Aron Knickerbocker
President & Chief Executive Officer
Five Prime Therapeutics, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2017

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: 001-36070

Five Prime Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-0038620**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

111 Oyster Point Boulevard
South San Francisco, California 94080
(415) 365-5600
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	**Nasdaq Global Select Market**

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 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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. (Check one):

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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 Act). Yes ☐ No ☒

As of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $619 million, based on the closing price of the registrant's common stock on The Nasdaq Global Select Market on June 30, 2017 of $30.11 per share. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

As of February 20, 2018, the registrant had 34,860,499 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2018 Annual Meeting of Stockholders of the registrant are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2017.

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In this report, unless otherwise stated or the context otherwise indicates, references to "Five Prime," "the company," "we," "us," "our" and similar references refer to Five Prime Therapeutics, Inc. The Five Prime logo and RIPPS® are our registered trademarks. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- our receipt of future milestone payments and/or royalties, and the timing of such payments;
- our or our partners' ability to timely advance drug candidates into and through clinical data readouts and successful completion of clinical trials;
- the timing of the initiation, progress and results of preclinical studies and research and development programs;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- the implementation, timing and likelihood of success of our plans to develop companion diagnostics for our product candidates;
- our ability to establish and maintain collaborations and necessary licenses;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we establish and maintain for intellectual property rights covering our product candidates and technology;
- the size of patient populations targeted by products we or our partners develop and market adoption of such products by physicians and patients;
- the timing or likelihood of regulatory filings and approvals;
- the ability to negotiate adequate reimbursement and pricing for our drug candidates with third-parties and government authorities;
- developments relating to our competitors' and our industry; and
- our expectations regarding licensing, acquisitions and strategic operations.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail under the heading "Risk Factors" and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this report.

We obtained the industry, market and competitive position data in this annual report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third-parties. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions we use are appropriate, neither such research nor these definitions have been verified by any independent source.

PART I.

Item 1. Business.

Our Company

We are a clinical-stage biotechnology company focused on discovering and developing innovative protein therapeutics to improve the lives of patients with serious diseases. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are needed. We have an emphasis in immuno-oncology, an area in which we have clinical, preclinical and discovery programs and product and discovery collaborations. In addition, we plan to use companion diagnostics where appropriate to allow us to select patients most likely to benefit from treatment with our product candidates. Our most advanced product candidates are identified below.

- **Cabiralizumab (FPA008)** is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are studying in clinical trials as a monotherapy in tenosynovial giant cell tumor, also known as diffuse pigmented villonodular synovitis, or PVNS, and in multiple cancers in combination with Bristol-Myers Squibb Company's PD-1 immune checkpoint inhibitor, *Opdivo*® (nivolumab). In October 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- **Bemarituzumab (FPA144)** is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are developing to treat patients with gastric (stomach) or gastroesophageal junction, or GEJ, cancer and bladder cancer. In December 2017, we entered into a license and collaboration agreement, or the China collaboration agreement, with Zai Lab (Shanghai) Co., Ltd., or Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan.
- **FPA150** is a CD8 T cell checkpoint inhibitor antibody that targets B7-H4 that we are developing as a monotherapy in multiple cancers. We plan to begin a Phase 1 clinical trial for FPA150 in the first half of 2018.

We have a differentiated target discovery platform and comprehensive libraries of transmembrane and extracellular soluble proteins that we believe encompass substantially all the body's medically important targets for protein therapeutics. We have identified approximately 700 of these proteins, which we refer to as the immunome, that we believe modulate immune cell interactions and may be important in understanding and treating cancer in patients using immuno-oncology therapeutics. Our target discovery platform and capabilities position us well to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and the focus of our research activities. We are applying our biologics discovery platform, including cell-based screening, immunome-by-immunome biophysical interaction screening, *in vivo* screening, receptor-ligand matching technologies and bioinformatics, to our immuno-oncology research programs. We have identified several targets that we believe could be useful in immuno-oncology that we are actively validating. We are also conducting research to discover additional targets. We generate and preclinically test therapeutic proteins, including antibodies and fusion proteins containing or directed to the targets we discover and validate. We plan to continue to advance selected therapeutic candidates into clinical development.

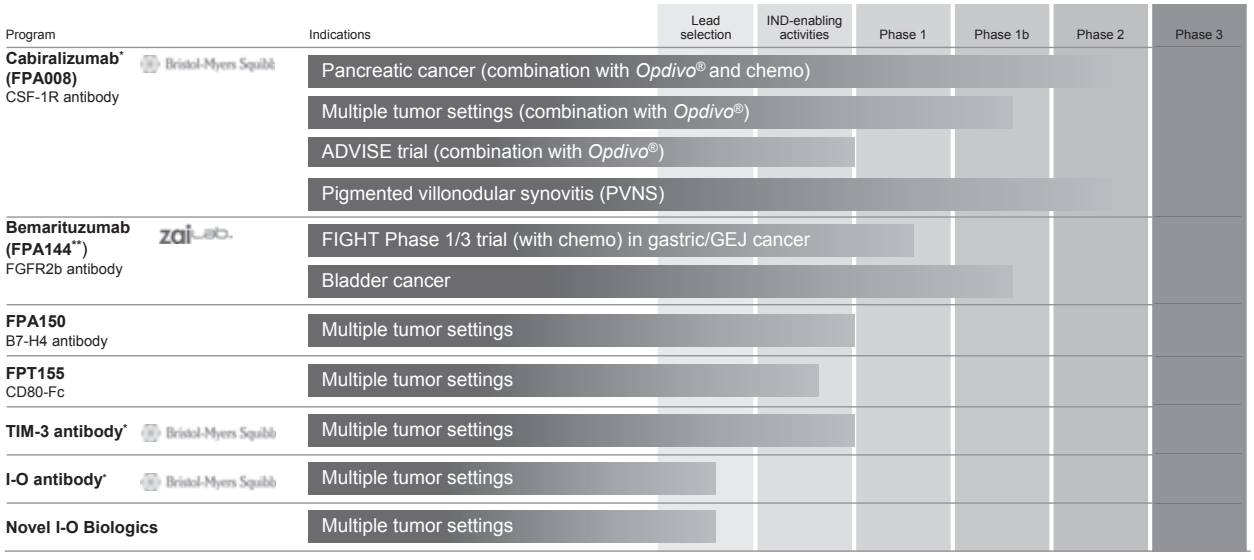
Clinical Strategy

Our goal is to use our differentiated target discovery platform and libraries to maintain our leadership position in the discovery of innovative protein therapeutic targets and to build a leadership position in the development and commercialization of immuno-oncology therapeutics. The key elements of our strategy to achieve this goal are:

- ***Focus on immuno-oncology protein therapeutics.*** Cancer therapeutics accounted for $113 billion in global sales in 2016, and immuno-oncology therapeutics represent a growing portion of these sales. However, there continues to be significant medical need for innovative and effective therapies to treat cancer. With the productivity of our discovery platform and the significant experience and expertise of our research, preclinical and clinical scientists in the field of immuno-oncology, we believe we are well positioned to discover new targets and develop effective, innovative protein therapeutics.
- ***Continue to advance and expand our internal pipeline.*** Three of our product candidates, cabiralizumab, bemarituzumab and FPA150, are currently in clinical development, and others, including FPT155 are in preclinical or earlier development. We plan to focus our resources on the further development of these product candidates, discovering and developing new therapeutic candidates with our platform, and potentially in-licensing additional product rights from third-parties to expand our development pipeline.
- ***Establish additional product and clinical collaborations to supplement our internal development capabilities and generate funding.*** From time to time, we expect to establish additional research and development collaborations. These collaborations will supplement our research, development, manufacturing, regulatory and commercialization capabilities, provide us with significant funding to advance our pipeline and validate our technology.
- ***Build a commercial enterprise by retaining rights for products in targeted specialty markets.*** We plan to build sales and marketing capabilities in selected specialty markets in the United States that we can adequately serve as we work toward becoming a focused commercial organization. We currently have global rights to all our product candidates, except that we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan, and granted BMS exclusive global rights to develop and commercialize cabiralizumab. Our cabiralizumab collaboration agreement with BMS provides us with an option to co-promote cabiralizumab in the United States.

Our Pipeline

The following table shows the stage of development of our most advanced product candidates:

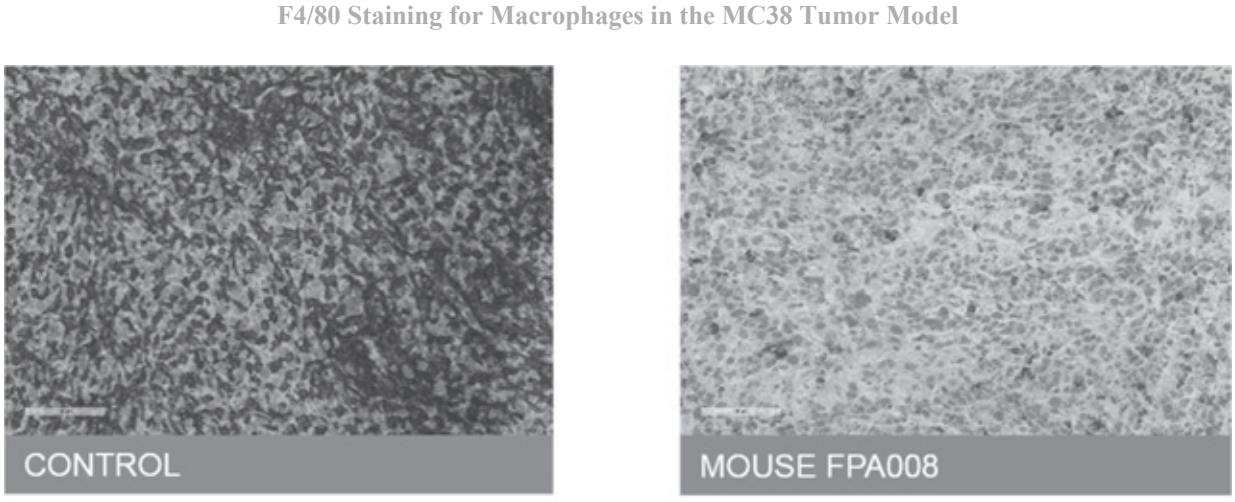


Clinical Programs

Cabiralizumab

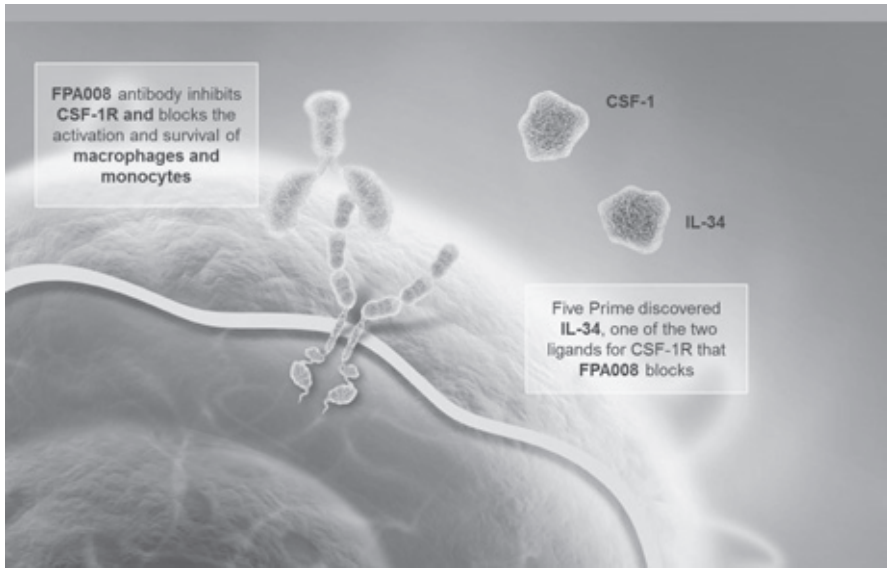
Cabiralizumab is an antibody that inhibits CSF1R. CSF1R is a cell surface protein that controls the survival and function of certain immune response cells called monocytes and macrophages. Monocytes and macrophages are elevated or activated in multiple disease settings. In cancer, macrophages suppress the immune system's ability to kill cancer cells. In joint diseases, macrophages contribute to inflammation and, in diseases such as PVNS, can form tumor masses. Cabiralizumab blocks the activation and survival of these cell types. In many cancers, inhibition of CSF1R reduces the number of immunosuppressive tumor-associated macrophages, or TAMs, thereby facilitating an immune response against tumors. The staining images in Figure 1 below show the inhibitory effect cabiralizumab has on TAMs in a tumor model. We believe the combination of cabiralizumab with T cell checkpoint inhibitors, such as PD-1 inhibitors, or immune agonists may have synergistic therapeutic effects in treating cancer.

Figure 1: Inhibition of Tumor-Associated Macrophages by Cabiralizumab



Using our differentiated target discovery platform and libraries, we discovered a protein called interleukin-34, or IL-34, that is a key regulator of monocyte and macrophage numbers and activity. Once we discovered IL-34, we were able to use our protein libraries and ligand-receptor matching technology to identify its receptor, CSF1R. This receptor is known to be expressed on the surface of monocytes and macrophages. Before our discovery of IL-34, CSF1R was thought to have only one ligand called CSF1. Both CSF1 and IL-34 bind to and activate CSF1R and therefore promote the survival and activity of monocytes and macrophages. Cabiralizumab blocks the binding of both CSF1 and IL-34 to CSF1R and thereby inhibits the activity and survival of these cells (Figure 2).

Figure 2: Cabiralizumab Mechanism of Action



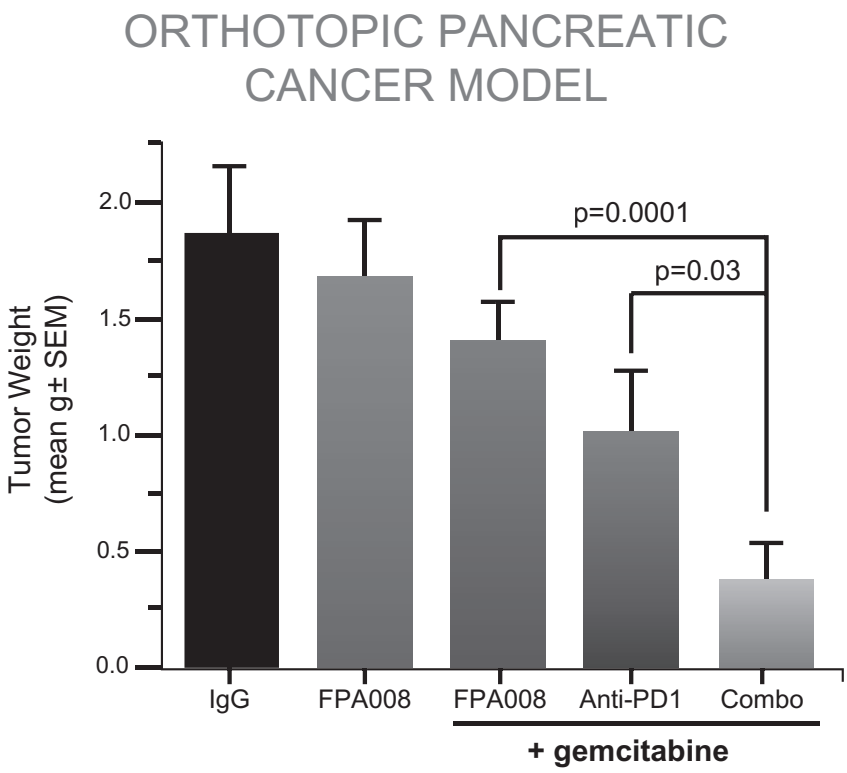
Cabiralizumab in Immuno-Oncology

We believe that there is a strong rationale for combining cabiralizumab with checkpoint inhibitors to treat cancer, including that:

- TAMs are immunosuppressive and act by inhibiting CD8 T cell responses while enhancing recruitment and differentiation of regulatory T cells, or Tregs;
- TAMs often correlate with poor prognosis in cancer patients;
- TAMs appear to be sensitive to CSF1R inhibition; and
- we believe that CSF1R inhibition in combination with checkpoint inhibitors (e.g., anti-PD1 or anti-CTLA-4 antibodies) or immune agonists (e.g., anti-CD40 antibodies) may synergistically induce tumor regressions.

These points suggest that combining an anti-CSF1R antibody, such as cabiralizumab, with an anti-PD1 antibody, such as *Opdivo*, may benefit cancer patients. In preclinical studies, we observed cabiralizumab to be highly effective in blocking the growth of pancreatic tumors when combined with an anti-PD1 antibody and gemcitabine, as shown in Figure 3 below.

Figure 3: Tumor Weight Reduction of Cabiralizumab in Combination with Anti-PD1 Antibody and Gemcitabine



Clinical Development of Cabiralizumab in Immuno-Oncology

We are currently conducting a Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining cabiralizumab with *Opdivo* as a potential treatment for a variety of cancers. We have completed enrollment in this trial and continue to treat patients still on study. In the Phase 1b portion of the trial we are evaluating the safety, tolerability and preliminary efficacy of cabiralizumab in combination with *Opdivo* in the following tumor settings:

- non-small cell lung cancer, or NSCLC;
- anti-PD-1 therapy resistant NSCLC (either de novo or acquired resistance);
- squamous cell carcinoma of the head and neck;
- pancreatic cancer;
- renal cancer;
- ovarian cancer; and
- glioblastoma multiforme.

In parallel with advancing into the Phase 1b portion of the trial, we expanded the Phase 1a portion of the trial to enable us to continue to study cabiralizumab as monotherapy and as combination therapy with *Opdivo* in patients with certain tumor types beyond those addressed in the Phase 1b cohorts, including in patients whose tumors are refractory to PD-1 checkpoint inhibitors.

In November 2017, we presented preliminary safety, tolerability and efficacy data from patients from the Phase 1a/1b clinical trial at the Society for Immunotherapy of Cancer 32nd Annual Meeting, or the SITC presentation. As of the August 1, 2017 data cutoff for the SITC presentation, we had tested cabiralizumab as monotherapy in advanced solid tumors at escalating doses in 24 patients, in combination with *Opdivo* in advanced solid tumors at escalating doses of cabiralizumab in 10 patients, and in combination with *Opdivo* in advanced solid tumors in disease-specific cohorts at a dose of 4 mg/kg of cabiralizumab every two weeks in 195 patients. We observed a tolerable safety profile of cabiralizumab monotherapy and of cabiralizumab in combination with *Opdivo*. The most common treatment-related laboratory abnormalities were elevations in creatine kinase and serum liver enzymes without an associated elevation in bilirubin levels or other clinical sequelae. These treatment-related adverse abnormalities are believed to be secondary to cabiralizumab's depletion of Kupffer cells and have been observed with other CSF1R-targeting agents. The most common treatment-related adverse events were: periorbital edema (20.8%), fatigue (29.2%), nausea (12.5%) and pruritus (8.3%). Grade 5 treatment-related adverse events in the trial occurred in three (1.3%) patients treated with a combination of cabiralizumab and *Opdivo*. The Grade 5 events were pneumonitis in a patient with thyroid cancer and respiratory distress and acute respiratory distress in two patients with lung cancer.

Among the other data, we observed preliminary evidence of a durable clinical benefit of the combination therapy in the cohort of patients with advanced pancreatic cancer. Based on radiographic assessments of anti-tumor activity in the 31 second- or later-line patients who had advanced pancreatic cancer, we observed, as of the August 1, 2017 data cutoff date:

- five patients with durable clinical benefit (16%);
- four confirmed objective responses (13%); and
- disease control for at least five to over nine months.

All four confirmed objective responses were in patients with microsatellite stable tumors who had received an average of three prior therapies. In addition, the responses were accompanied by steep declines in levels of the pancreatic tumor marker CA-19-9 over the baseline.

The data suggest that a combination therapy of cabiralizumab with *Opdivo* may benefit patients with pancreatic cancer, including those with microsatellite stable tumors, and support further study of cabiralizumab in combination with *Opdivo* in pancreatic cancer.

Based on the clinical data we observed in the cohort of patients with pancreatic cancer in the Phase 1b portion of this trial, we enrolled 35 patients with second- or later-line pancreatic cancer in the expansion of the Phase 1a portion of our Phase 1a/1b clinical trial to further evaluate the combination of cabiralizumab and *Opdivo* in this patient population. We are collecting pre- and on-treatment tumor biopsy samples from these patients, and are conducting comprehensive biomarker analyses to evaluate potential biomarker signatures that may predict responsiveness to this therapeutic combination and to assess changes that occur in the tumor microenvironment following treatment.

Also based on the clinical data we presented at the SITC presentation, BMS opened and is currently enrolling patients in a randomized, multi-arm Phase 2 clinical trial to determine the efficacy of cabiralizumab in combination with *Opdivo*, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer (NCT03336216). BMS plans to enroll approximately 160 patients with pancreatic cancer in the study, who will be randomized to one of four study arms based on the patient's prior therapy. In January 2018, the dosing of the first patient in the trial by BMS triggered a $25 million milestone payable to us pursuant to the license and collaboration agreement between the companies established in 2015.

Cabiralizumab in PVNS

PVNS is a rare neoplastic joint disease, characterized by a locally aggressive tumor of the synovium. It is characterized by local overexpression of CSF1, which recruits macrophages into the joints, forming a non-malignant tumor mass. It is associated with high morbidity, and there are no approved therapies for the condition. We believe that administering cabiralizumab to PVNS patients will reduce infiltration of monocytes and macrophages into affected joints of these patients and inhibit the activity and survival of the monocytes and macrophages that form the bulk of the tumor mass, resulting in tumor shrinkage, pain reduction and increased use of affected joints.

There are two primary forms of PVNS: localized and diffuse. In localized PVNS, the tumor involves the tendons that support the affected joint or occurs in just one area of the affected joint. Localized PVNS is often surgically resectable and typically responds well to surgical treatment. Diffuse PVNS is more widespread throughout an entire joint. Accordingly, diffuse PVNS tends to be more destructive, may not be resectable and is more difficult to treat than localized PVNS.

Clinical Development of Cabiralizumab in PVNS

We are conducting a Phase 1/2 clinical trial of cabiralizumab monotherapy as a potential treatment for diffuse PVNS. During the Phase 2 portion of the trial, we are evaluating tumor response rate and duration and measures of pain and joint function in PVNS patients. We completed patient enrollment in the initially-planned 30-patient Phase 2 cohort in April 2017.

In June 2017, we presented a poster at the 2017 American Society of Clinical Oncology, or ASCO, Annual Meeting with updated pharmacokinetics, or PK, pharmacodynamics, or PD, and safety data from 21 patients treated with cabiralizumab and efficacy data from 11 patients treated with cabiralizumab in our ongoing Phase 1/2 clinical trial.

Based on the data, we concluded that the PK and PD of cabiralizumab support dosing of up to 4 mg/kg administered every two weeks. We did not observe any dose-limiting toxicities of cabiralizumab at doses up to 4 mg/kg administered every two weeks. The most common treatment-related adverse events were periorbital and eyelid edema, rash and pruritis, which are all class effects for compounds targeting the CSF1R pathway.

We also observed clinical benefit in patients with diffuse PVNS in doses of cabiralizumab of up to 4mg/kg administered every two weeks. Based on radiographic assessments by RECIST 1.1 of anti-tumor activity of the 11 patients treated with cabiralizumab at the 4mg/kg dose, we observed, as of the March 7, 2017 data cut-off date:

- four confirmed radiographic responses and one unconfirmed radiographic response; and
- improvements in median Ogilvie-Harris composite score of pain and function in both responders and non-responders.

In September 2017, we amended the study to enroll up to 30 additional patients with diffuse PVNS in the Phase 2 portion of the trial to refine the dosing schedule and optimize the therapeutic index of cabiralizumab in PVNS. Data from these additional patients are intended to support the design of our planned pivotal trial of cabiralizumab in PVNS. We plan to decide in the second half of 2018 whether to advance cabiralizumab to a pivotal trial in diffuse PVNS patients based on the data we obtain from the new dosing schedule.

In January 2016, the U.S. Food and Drug Administration, or the FDA, granted cabiralizumab Orphan Drug Designation for the treatment of PVNS. Orphan Drug Designation is granted by the FDA to products that treat rare diseases, defined as those affecting fewer than 200,000 people in the United States.

In December 2016, the European Commission, following an evaluation by the European Medicines Agency's Committee for Orphan Medicinal Products, designated cabiralizumab as an orphan medicinal product for the treatment of PVNS. The European Commission grants orphan medicinal product designation to products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the European Union.

Orphan Drug Designation in the United States and orphan medicinal product designation in the European Union each provide certain benefits and incentives in their respective jurisdictions, including a potential period of marketing exclusivity for the first marketing application if regulatory approval is received for the designated indication, potential tax credits for certain activities and waiver of certain administrative fees.

Bemarituzumab (FPA144)

Bemarituzumab is an antibody that inhibits FGFR2b that we are initially developing to treat a subset of gastric (stomach) and GEJ cancer patients whose tumors overexpress FGFR2b, as determined by an immunohistochemistry, or IHC, diagnostic test, or amplify the *FGFR2* gene, as determined by a circulating tumor DNA, or ctDNA, blood-based diagnostic test. This subset of patients with tumors that overexpress the FGFR2b protein or amplify the *FGFR2* gene is associated with lower overall survival. We are working with third-parties specializing in companion diagnostic development to develop IHC and blood-based companion diagnostics to identify gastric and GEJ cancer patients who have FGFR2b overexpressing tumors or *FGFR2* gene amplification and who would be most likely to benefit from treatment with bemarituzumab.

We believe that bemarituzumab acts on tumor cells in two ways:

- bemarituzumab binds to FGFR2b and blocks certain FGFs from binding to FGFR2b, preventing these FGFs from promoting the growth of the tumor cells; and
- once bemarituzumab binds to FGFR2b on the surface of the tumor cell, bemarituzumab recruits natural killer immune cells into the tumor microenvironment to kill the tumor cell in a process called antibody-dependent cell-mediated cytotoxicity, or ADCC.

Clinical Development of Bemarituzumab

We are conducting a Phase 1 clinical trial of bemarituzumab to evaluate the safety, PK and efficacy of bemarituzumab as monotherapy in patients with metastatic gastric and GEJ cancer and bladder cancer whose tumors overexpress the FGFR2b protein. We have closed enrollment in the four cohorts in the expansion portion of the Phase 1 trial in which we were evaluating bemarituzumab in patients with metastatic gastric and GEJ cancer. We continue to enroll and treat patients in the cohort of patients with bladder cancer.

In June 2017, we presented updated safety and efficacy data from 64 patients from the Phase 1 clinical trial in a clinical poster at the 2017 ASCO Annual Meeting, or the ASCO presentation. As of the March 20, 2017 data cut-off date for the ASCO presentation, we had tested bemarituzumab in advanced solid tumors at doses of up to 15 mg/kg given as monotherapy every two weeks, including in patients with gastric or GEJ cancer. We did not observe any dose-limiting toxicities or a maximum-tolerated dose. In addition, unlike small molecule FGF receptor kinase inhibitors, which block signaling through a broad number of FGF receptors and can lead to hyperphosphatemia, we did not observe any treatment-related hyperphosphatemia in patients treated with bemarituzumab. All treatment-related adverse events were Grades 1, 2 or 3. All treatment-related ocular adverse events were Grades 1 or 2, and no retinal toxicity was reported.

With respect to the patients with gastric or GEJ cancer, we observed preliminary anti-tumor activity with bemarituzumab monotherapy in late-line patients who had a median of three prior therapies and whose tumors overexpress the FGFR2b protein. Based on radiographic assessments by RECIST 1.1 of anti-tumor activity in the 21 patients who had high FGFR2b+ overexpressing gastric or GEJ cancer, we observed, as of the March 20, 2017 data cut-off date:

- four confirmed partial responses and one unconfirmed partial response;
- an objective response rate, or ORR, of 19.0%;
- a median duration of response of 15.4 weeks; and
- a disease control rate, or DCR, at 6 weeks of 57.1%.

We designed our initial Phase 1 clinical trial testing bemarituzumab as monotherapy to evaluate the safety and tolerability of bemarituzumab as well as to gain early evidence of effectiveness, including by evaluating ORR, DCR and duration of response of patients with gastric or GEJ cancer that overexpresses FGFR2b. We believe that the ORR, DCR and duration of response and safety data that we have generated in our initial Phase 1 clinical trial support the evaluation of bemarituzumab in a registrational trial. Because patients with gastric or GEJ cancer that overexpresses FGFR2b have a worse prognosis as compared to those patients that do not overexpress FGFR2b, we believe that patients with FGFR2b-overexpressing disease progress more rapidly and that such patients are less likely to survive and become third- or even second-line patients. As a result, we believe testing bemarituzumab as a front-line treatment would increase the pool of patients that would be eligible to enroll in the trial and would result in faster enrollment and completion of a registrational trial than had we decided to test bemarituzumab as a second- or third-line treatment. In addition, because of the heterogeneity of advanced gastric and GEJ cancer, and because our preclinical data show additive efficacy against FGFR2b-overexpressing gastric cancer when adding bemarituzumab to chemotherapy, we believe that testing bemarituzumab in combination with chemotherapy may increase the extent and duration of response as compared to treatment with bemarituzumab alone. Moreover, we believe that bemarituzumab's safety profile allows for the combination of bemarituzumab with chemotherapy while maintaining an acceptable safety profile. Based on the foregoing, we designed a global Phase 1/3 registrational trial to test bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, or mFOLFOX6, as front-line treatment of patients with gastric or GEJ cancer that overexpresses FGFR2b, or the FIGHT trial.

Because we had not yet clinically tested bemarituzumab in combination with mFOLFOX6, we included a Phase 1 safety lead-in for the FIGHT trial. During this Phase 1 safety lead-in portion, we will evaluate the safety, tolerability, PK and pharmacodynamics of bemarituzumab in combination with mFOLFOX6 in patients with any type of gastrointestinal cancer to identify a recommended dose of bemarituzumab to use in the Phase 3 portion of the trial. In December 2017, we initiated dosing in the Phase 1 safety lead-in portion of our FIGHT trial. We expect to initiate the global randomized, controlled Phase 3 portion of the trial in mid-2018.

We estimate that approximately 10% of patients with gastric or GEJ cancer have tumors that either have *FGFR2* gene amplification or overexpress the FGFR2b protein. Accordingly, in the Phase 3 portion of the FIGHT trial, we will select for enrollment those patients whose tumors have *FGFR2* gene amplification or FGFR2b protein overexpression. We plan to identify *FGFR2* gene amplification using a ctDNA blood-based test, which will allow us to detect DNA shed from tumors that circulates in blood plasma outside of cells. We plan to identify FGFR2b overexpression using an IHC test, which will allow us to determine FGFR2b overexpression in tumor tissue samples. We are developing both tests in parallel with our clinical development of bemarituzumab in collaboration with third-party diagnostic development partners and plan to use both companion diagnostics concurrently to more effectively identify gastric and GEJ cancer patients whose tumors overexpress FGFR2b or have *FGFR2* gene amplification. We plan to pursue regulatory approval of each companion diagnostic contemporaneously with regulatory approval of bemarituzumab.

Because the observed incidence of gastric and GEJ cancer is higher in Asian populations than in other populations, in December 2017, we entered into the China collaboration agreement with Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan, and pursuant to which Zai Lab will conduct the Phase 3 portion of the FIGHT trial in China. We believe that our collaboration with Zai Lab will allow us to expedite the initiation of the Phase 3 portion of the FIGHT trial at clinical sites in China and will enhance our ability to enroll patients at clinical sites in China, which we believe will reduce the overall time to fully enroll the Phase 3 portion of the FIGHT trial.

In addition, in July 2017, we initiated dosing in a Phase 1 clinical trial in Japan evaluating bemarituzumab as a monotherapy to treat patients with gastric or GEJ cancer. We expect to complete this trial in 2018. This trial is intended to enable the inclusion of Japanese patients in our FIGHT trial.

Market Opportunity

Globally, gastric cancer is the fifth most common malignancy with the third highest mortality. In the United States, the prevalence of gastric cancer is approximately 95,700 patients, of which we believe approximately 9,570 have tumors that overexpress FGFR2b or are *FGFR2* gene-amplified and are more likely to respond to bemarituzumab. Globally, the prevalence of gastric cancer is approximately 1.5 million patients, of which we believe approximately 150,000 have tumors that overexpress FGFR2b and or are *FGFR2* gene-amplified are more likely to respond to bemarituzumab.

In June 2016, the FDA granted Orphan Drug Designation to bemarituzumab for the treatment of gastric cancer, including GEJ cancer, in patients whose tumors overexpress FGFR2b. We believe that our clinical development organization is well-suited to conduct a focused clinical development plan for FGFR2b-overexpressing or *FGFR2* gene-amplified gastric and GEJ cancer.

Under our China collaboration agreement, we granted Zai Lab an exclusive license to develop bemarituzumab in China, Hong Kong, Macau and Taiwan. We plan to continue to seek strategic collaborators to develop and commercialize bemarituzumab in other territories. We plan to retain the right to commercialize or co-commercialize bemarituzumab in the United States.

FPA150

FPA150 is a CD8 T cell checkpoint inhibitor antibody that targets B7-H4. B7-H4 is a member of the B7 family of checkpoint inhibitors and shares significant homology with the other B7 family members, including PD-L1 and PD-L2. B7-H4 is expressed in several human tumors, including breast, ovarian, endometrial, lung and pancreatic cancers, and its expression correlates with poor prognosis. We designed FPA150 to target tumor cells through two distinct mechanisms of action: (i) by blocking B7-H4 from sending an inhibitory signal to CD8 T cells, and (ii) by enhancing ADCC against B7-H4-expressing tumor cells.

In December 2017, we filed an investigational new drug application, or IND, to initiate a Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of FPA150 monotherapy as a potential therapy in patients with a variety of cancers. In January 2018, we received clearance from the FDA to proceed with the clinical development of FPA150.

We plan to evaluate FPA150 in escalating doses in advanced solid tumors in the Phase 1a portion of our Phase 1a/1b clinical trial, which we expect to initiate in the first half of 2018. Because FPA150 is expected to have an immunomodulatory effect and our Phase 1 trial is the first-in-human evaluation of FPA150, the starting dose of the dose escalation portion of the trial is lower than we would have selected for a development candidate that does not have an immunomodulatory effect. We expect the Phase 1a dose-escalation portion of our trial will continue into 2019. In the Phase 1b portion of the trial, we plan to evaluate FPA150 in various disease-specific cohorts, including in breast cancer, ovarian cancer, endometrial cancer and urothelial bladder cancer. We plan to develop an IHC-based assay in collaboration with a diagnostic development partner to select patients whose tumors overexpress B7H4 during the Phase 1b portion of the trial.

FPT155

FPT155 is a soluble CD80-Fc fusion protein. CD80 is a member of the B7 family of checkpoint inhibitors that is involved in modulating T cell priming and activation. This program came from our *in vivo* screens, which demonstrated that a soluble form of CD80 had potent *in vivo* anti-tumor activity when compared with 500 other immunome proteins. FPT155 uses the binding interactions of soluble CD80 to (i) block CTLA-4 from competing for endogenous CD80, allowing CD28 signaling to prevail in T cell activation in the tumor microenvironment and (ii) directly engage CD28 to further enhance its co-stimulatory T-cell activation activity without inducing super agonism.

We are currently conducting IND-enabling activities for FPT155, with the goal of filing an IND or its foreign equivalent in the second half of 2018.

Immuno-Oncology Drug Discovery and Research Programs

Overview

We are currently focusing our internal research efforts in the area of immuno-oncology. Cancers grow and spread because tumor cells have developed ways to evade elimination by the immune system. For example, cancer cells make proteins that apply the “brakes” to immune cells and prevent the immune cells from killing the tumor cells. One of the most exciting recent discoveries in cancer therapy has been the identification of ways to release these “brakes” and allow the immune cells to once again kill tumor cells. This approach has the potential to not only reduce tumor growth like traditional therapies, but also to potentially eliminate the cancer entirely in some patients. In addition to releasing the “brakes” on immune cells, other discoveries in immuno-oncology have focused on identifying ways to “press on the gas” to amplify the anti-tumor immune response. This second approach targets stimulatory pathways on immune cells. Agents that agonize stimulatory pathways can help immune cells overcome inhibitory signals in the tumor microenvironment, resulting in tumor cell killing.

While checkpoint inhibitor therapies have been validated in the clinic with agents targeting the PD-1/PD-L1 and CTLA-4 pathways to release the “brakes,” a significant proportion of patients do not respond to these treatments. New targets for immuno-oncology are needed to address those patients who do not respond to or cannot tolerate traditional therapies or agents currently in development. We are applying all aspects of our differentiated discovery platform to identify protein partners for molecules known to be involved in the anti-tumor immune response. We believe we have identified promising new antibody targets and ligand traps and are actively researching and validating additional immuno-regulatory targets.

Our Biologics Discovery Platform

We are focused on discovering and developing innovative protein therapeutics. Targets for protein therapeutics are proteins in the body that when inappropriately produced or altered can result in human diseases. Protein therapeutics can be designed to reverse these disease-causing mechanisms. There are thousands of proteins in the body that represent potential protein therapeutic targets or therapeutics themselves, but only a few are targeted by currently marketed protein drugs in immuno-oncology, such as PD-1, PD-L1, CTLA-4, IL-2, interferon alpha and CD3.

Traditional ways to discover new targets for protein therapeutics have relied on a "trial-and-error" approach studying a single or a small number of proteins at a time. We have developed a platform to improve the traditionally difficult process of discovering new protein therapeutic targets. Our platform is based on two components:

- proprietary libraries that we believe include the most comprehensive collections of fully functional human extracellular proteins that are abundant sources of medically-relevant novel targets for protein therapeutics; and
- proprietary technologies and know-how for producing and testing thousands of proteins at a time to test in *in vitro*, *in vivo* and other assays to identify potential protein drugs and antibody candidates.

We believe our platform improves and accelerates the discovery of new drug targets and protein therapeutics because it can:

- identify novel medically relevant protein targets and protein therapeutics that have little or no previously known biological function or are not in the public domain and cannot easily be discovered by other methods;
- determine the best protein target among many alternatives for a particular disease by screening and comparing nearly all possible medically important targets simultaneously; and
- identify new drug targets more quickly and efficiently than previously possible because it can produce and test thousands of proteins at a time rather than one or just a few at a time.

We have used our platform to identify dozens of targets validated in rodent models in several different disease areas, including in collaboration with our partners, and to build a growing pipeline of product candidates. We believe our platform is particularly well positioned to explore new pathways in immuno-oncology.

Growing Database of Protein Function

We have tested each of the proteins in our libraries in numerous screens on different cell types, providing us with an extensive database of information regarding how each protein performs in different screens and whether it is specific to a given disease process or has a broader range of activities. The cumulative data from all our screens allows us to identify the most appropriate target for our product candidates.

Collaborations

A part of our strategy is to establish collaborations with strategic partners. These collaborations supplement our development, manufacturing, regulatory and commercialization capabilities, provide us with significant funding to advance our pipeline and validate our technology. A summary of our key product, clinical and discovery collaborations is set forth below. For information regarding the financial terms of the following agreements, including amounts we have received through December 31, 2017, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Financial Overview – Collaboration and License Revenue."

Cabiralizumab Collaboration Agreement with BMS

In October 2015, we entered into the cabiralizumab collaboration agreement with BMS, pursuant to which we granted to BMS an exclusive, worldwide license to develop and commercialize certain CSF1R antibodies, including cabiralizumab, and all modifications, derivatives, fragments or variants of such antibodies, each of which we refer to as a licensed antibody. The cabiralizumab collaboration agreement superseded the clinical trial collaboration agreement that we entered into with BMS in November 2014.

Under the terms of the cabiralizumab collaboration agreement, BMS is responsible, at its expense, for developing cabiralizumab under a development plan, subject to our option, at our own expense, to conduct certain future studies, including registration-enabling studies to support approval of cabiralizumab in PVNS and in combination with our proprietary internal or in-licensed compounds, including in oncology, each of which we refer to as a Five Prime independent development path. BMS will have the option, prior to our commencement of a clinical trial with respect to a Five Prime independent development path, to include any such clinical trial in the development plan, and BMS would thereafter bear the associated development costs and milestone payments to us with respect to BMS's development of such Five Prime independent development path. If BMS elects to include in the development plan a clinical trial that would have been a Five Prime independent development path, BMS would reimburse us for our development expenses incurred since November 2015, the effective date of the cabiralizumab collaboration agreement, with respect to such Five Prime independent development path.

If BMS does not add a Five Prime independent development path to the development plan before the review of any efficacy data from the first Phase 3 or registration-enabling clinical trial in such Five Prime independent development path, and such Five Prime independent development path indication achieves regulatory approval in the United States or marketing approval in the European Union or Japan, then BMS will reimburse us an amount equal to 125% of our development expenses with respect to such Five Prime independent development path.

We continue to conduct the current Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining *Opdivo* with cabiralizumab in multiple tumor types. BMS bears all costs and expenses relating to this trial, including manufacturing costs for the supply of cabiralizumab, except that we are responsible for our own internal costs, including internal personnel costs.

BMS is responsible for manufacturing and commercialization of cabiralizumab, and we retain rights to a minority co-promotion option in the United States.

Unless earlier terminated by either party, the cabiralizumab collaboration agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the expiration of BMS's payment obligations with respect to each licensed product under the agreement. BMS may terminate the agreement in its entirety or on a region-by-region basis at any time with advance written notice. BMS may also terminate the agreement in its entirety (or on a licensed product-by-licensed product basis) upon written notice based on certain safety reasons. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. We may terminate the agreement in its entirety with written notice for BMS's material breach of its diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for BMS's breach of its diligence obligations with respect to timely commercialization of a licensed product in a region following marketing approval. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

Zai Lab China License and Collaboration Agreement

In December 2017, we entered into the China collaboration agreement with Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab, and all fragments, conjugates, derivatives and modifications thereof, or the licensed antibody, in China, Hong Kong, Macau, and Taiwan, each a region, and collectively, the territory.

Under the terms of the China collaboration agreement, Zai Lab will be responsible, at its expense, for (i) developing and commercializing products containing the licensed antibody, each, a licensed product, under a territory development plan and (ii) performing certain development activities to support our global development and registration of licensed products, including the Phase 3 portion of the FIGHT trial, in the territory, under a global development plan.

Unless earlier terminated by either party, the China collaboration agreement will expire on a licensed product-by-licensed product and region-by-region basis upon the expiration of Zai Lab's payment obligations with respect to each licensed product under the agreement. Zai Lab may terminate the agreement in its entirety at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. We may terminate the agreement in its entirety with written notice for Zai Lab's material breach of its diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for Zai Lab's breach of its diligence obligations with respect to timely commercialization of a licensed product in a region following marketing approval. We may terminate the agreement in its entirety if Zai Lab or its affiliates or sublicensees commences a legal action challenging the validity, enforceability or scope of any of our patents in the territory. Either party also may terminate the agreement in its entirety upon certain insolvency events involving the other party.

BMS Immuno-oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement, or the immuno-oncology research collaboration, with BMS pursuant to which we and BMS are collaborating to carry out a research program to (i) discover novel interacting proteins in two undisclosed immune checkpoint pathways using our target discovery platform, (ii) further the understanding of target biology with respect to targets in these checkpoint pathways, and (iii) discover and pre-clinically develop compounds suitable for development for human therapeutic uses against targets in these checkpoint pathways. Based on data arising from our initial screens, in January 2016, we amended the immuno-oncology research collaboration to add an additional undisclosed checkpoint pathway to the research program, for a total of three immune checkpoint pathways.

In December 2017, we earned a $5 million milestone payment under the discovery collaboration agreement in connection with BMS's filing of an IND for its fully human monoclonal antibody targeting T-cell immunoglobulin and mucin domain-3, or TIM-3, an immune checkpoint receptor that is known to limit the duration and magnitude of T-cell responses. This antibody is BMS's first clinical candidate arising from the collaboration.

The initial three-year research term of the immuno-oncology research collaboration ended in March 2017 and BMS's first extension of the research term will end in March 2018. BMS exercised its option to extend the research term for an additional year to March 2019. BMS will provide us with funding for the additional research we will conduct during the extended term.

Unless earlier terminated by either party, the immuno-oncology research collaboration will expire on a product-by-product and country-by-country basis upon the expiration of all of BMS's payment obligations under the immuno-oncology research collaboration agreement. BMS may terminate the immuno-oncology research collaboration agreement in its entirety or on a collaboration target-by-collaboration target basis at any time with advance written notice. Either party may terminate the immuno-oncology research collaboration agreement in its entirety or on a collaboration target-by-collaboration target basis with written notice for the other party's material breach if such other party fails to timely cure the breach. Either party also may terminate the immuno-oncology research collaboration agreement in its entirety upon certain insolvency events involving the other party.

GSK Muscle Diseases Collaboration

In July 2010, we entered into a research collaboration and license agreement, or the muscle diseases collaboration, with Glaxo Group Limited, or GSK, to identify potential drug targets and drug candidates to treat skeletal muscle diseases. We conducted three customized cell-based screens and one *in vivo* screen of our protein libraries under the muscle diseases collaboration. The research term under this collaboration ended in May 2014. GSK has exercised its option under the muscle diseases collaboration to obtain an exclusive, worldwide license to one undisclosed muscle disease target we identified using our proprietary discovery platform.

The muscle diseases collaboration agreement will terminate upon the expiration of the royalty terms of any products that incorporate or target the protein exclusively licensed under the collaboration. In addition, GSK may terminate the agreement at any time with advance written notice, and either party may terminate the agreement with written notice for the other party's material breach if such party fails to cure the breach or upon certain insolvency events.

GSK Respiratory Diseases Collaboration

In April 2012, we entered into a research collaboration and license agreement, or the respiratory diseases collaboration, with GSK to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease, or COPD, function, with a particular focus on identifying novel protein therapeutics and antibody targets. We conducted six customized cell-based screens of our protein libraries under the collaboration. The research term for this collaboration ended in July 2016.

GSK has exercised options under the respiratory diseases collaboration to obtain an exclusive, worldwide license to two undisclosed respiratory disease targets we identified using our proprietary discovery platform. GSK continues to have the right for limited periods of time to evaluate a limited number of proteins we identified under the respiratory diseases collaboration and obtain an exclusive worldwide license to develop and commercialize products that incorporate or target such proteins.

The respiratory diseases collaboration agreement will terminate upon the expiration of the royalty terms of any products that incorporate or target a protein exclusively licensed under the collaboration. In addition, GSK may terminate the agreement at any time with advance written notice, and either party may terminate the agreement with written notice for the other party's material breach if such party fails to cure the breach or immediately in the case of failure to comply with certain anti-bribery and anti-corruption policies or upon certain insolvency events.

UCB Fibrosis and CNS Collaboration

In March 2013, we entered into a research collaboration and license agreement with UCB, referred to as the fibrosis and CNS collaboration, to identify innovative biologics targets and therapeutics in the areas of fibrosis-related immunologic diseases and central nervous system, or CNS, disorders. We conducted five customized cell-based and *in vivo* screens of our protein libraries under the fibrosis and CNS collaboration. We completed our initial research activities under the fibrosis and CNS collaboration in March 2016. Following the completion of the research activities, UCB has up to a two-year evaluation period during which we may be obligated to perform additional services at UCB's request.

In the course of screening our protein libraries in the collaboration we discovered proteins that may be potential drug targets or drug candidates for fibrosis-related immunologic diseases. Under the collaboration, UCB has the right for limited periods of time to evaluate proteins identified in the screens we conducted and obtain an exclusive worldwide license to develop and commercialize products that incorporate or target the protein. If UCB elects to obtain an exclusive license to a protein it has evaluated, UCB would have sole responsibility for the further development and commercialization of products that incorporate or target the protein, at UCB's cost and expense.

The collaboration agreement will terminate upon the expiration of the royalty terms of any products that incorporate or target a protein exclusively licensed under the collaboration. In addition, UCB may terminate the agreement at any time with advance written notice, and either party may terminate the agreement with written notice for the other party's material breach if such party fails to cure the breach or upon certain insolvency events.

License Agreements

License Agreement with Galaxy

In December 2011, we entered into a license agreement with Galaxy Biotech LLC, or Galaxy, pursuant to which Galaxy granted us an exclusive worldwide license to develop and commercialize FGFR2b antibodies, including bemarituzumab. Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in at least one tumor indication.

In May 2016, we amended the license agreement to revise certain milestone definitions, reduce certain milestone payments and add certain development-related milestone payments that were triggered by dosing of certain patients in the current Phase 1 clinical trial of bemarituzumab, which milestones were deemed achieved as of December 31, 2016. In May 2017, we further amended the license agreement to align the net sales definition under the agreement to the net sales definition under any sublicense we may grant under the agreement and to amend the termination provisions to allow for a direct license between Galaxy and any sublicensee upon termination of the agreement.

Our license agreement with Galaxy will remain in effect until the expiration of our royalty obligations in all countries. For each licensed product, we are obligated to pay Galaxy royalties on net sales of such product on a country-by-country basis for the longer of the life of the licensed patents covering such licensed product in such country or 10 years after the first commercial sale of such licensed product in such country. We cannot determine the date on which our royalty payment obligations to Galaxy would expire because no commercial sales of bemarituzumab have occurred and the last-to-expire relevant patent covering bemarituzumab in a given country may change in the future. Galaxy currently has issued patents, which we have licensed, covering bemarituzumab in the United States, Europe, China, Japan and other countries that expire in 2029. Further patents may issue from pending patent applications in these and other countries, and these patents would expire in 2029. These patent expiration dates do not reflect any patent term adjustments or extensions that may be available.

We may terminate the license agreement for convenience in its entirety or on a country-by-country basis upon prior written notice to Galaxy. Either party may terminate the license agreement in its entirety or with respect to certain countries after the first commercial sale of a licensed product in certain circumstances in the event of an uncured material breach by the other party. Either party may terminate the license agreement in the event of the other party's filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings or upon an assignment of a substantial portion of its assets for the benefit of creditors. Galaxy may terminate the license agreement if we or any of our affiliates challenge the validity or enforceability of any patent licensed to us by Galaxy under the license agreement or if we aid or assist any affiliate or third-party in such a challenge other than as required by law.

Non-Exclusive License with BioWa-Lonza

In February 2012, we entered into a license agreement with BioWa, Inc. and Lonza Sales AG, or BioWa-Lonza, pursuant to which BioWa-Lonza granted us a non-exclusive license to use their Potelligent® CHOK1SV technology, including the CHOK1SV cell line, and a non-exclusive license to related know-how and patents. This license is necessary to produce our bemarituzumab antibody.

We are obligated to pay BioWa-Lonza aggregate milestone payments of up to $25.4 million for development, regulatory and commercialization milestones achieved in our bemarituzumab antibody program. We are also obligated to pay BioWa-Lonza tiered royalties on net sales of bemarituzumab up to mid-single digit percentages of the proceeds of such sales.

Our license agreement with BioWa-Lonza will remain in effect until the expiration of our royalty obligations. For each licensed product, we are obligated to pay BioWa-Lonza royalties on net sales of such licensed product on a country-by-country basis for the longer of the life of the licensed patents covering such licensed product in such country or 10 years after the first commercial sale of such licensed product in a major market country, which includes the United States. However, because we believe the last-to-expire patents currently licensed to us under the license agreement would expire in less than 10 years, we believe the date on which our royalty payment obligations to BioWa-Lonza would expire in any country would be 10 years after the first commercial sale of such product in a major market country.

We may terminate the license agreement for convenience subject to our continuing obligation to pay royalties. BioWa-Lonza may terminate the license agreement in the event of our uncured material breach, if we oppose or dispute the validity of patents licensed to us under the license agreement or if we are declared insolvent, make an assignment for the benefit of creditors, are the subject of bankruptcy proceedings or have a receiver or trustee appointed for substantially all of our property.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates and other biological discoveries relating to new targets, pathways and relevant inventions and technologies that are important to our business. For our product candidates, we generally initially pursue patent protection covering both compositions of matter and methods of use.

Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, combination therapy, biomarker and companion diagnostic related claims. We also rely on trade secrets relating to our discovery platform and product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will also depend significantly on our ability to obtain rights to intellectual property held by third-parties that may be necessary or useful to our business, including for the discovery, development and commercialization of our product candidates. We generally obtain rights to third-party intellectual property through exclusive or non-exclusive licenses. For example, we entered into a non-exclusive license with BioWa-Lonza to use their Potelligent® CHOK1SV technology, which is necessary to produce our bemarituzumab antibody. If we are not able to obtain rights to intellectual property held by third-parties that are necessary or useful to our business, our business could be harmed, possibly materially.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly limited before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third-parties. For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property."

The patent portfolios for our most advanced programs are summarized below:

Cabiralizumab

Our cabiralizumab patent portfolio includes patents and patent applications wholly owned by us as well as patents jointly owned with BMS. Our patent portfolio includes issued U.S. and foreign patents as well as pending U.S. and foreign patent applications covering compositions of matter, methods of use, biomarkers and combination therapies relating to cabiralizumab. The issued U.S. patents and issued foreign patents covering the composition of matter and methods of use expire in 2031. Patents that may issue from the pending U.S. and foreign applications would expire between 2031 and 2038.

Bemarituzumab

Our patent portfolio for bemarituzumab includes patents and patent applications we exclusively licensed from Galaxy, as well as pending U.S. and foreign patent applications wholly owned by us. The patent portfolio, covering compositions of matter, methods of use, companion diagnostic and combination therapy relating to bemarituzumab, includes issued U.S. and foreign patents as well as pending U.S. and foreign patent applications. The issued U.S. patents expire between 2029 and 2030. The issued foreign patents expire in 2029. Patents that may issue from these pending U.S. and foreign applications would expire between 2029 and 2038.

FPA150

Our patent portfolio for FPA150 includes provisional U.S. patent applications wholly owned by us. Those provisional applications cover various aspects of the FPA150 program. U.S. and foreign patent applications claiming priority to those provisional applications, if filed and issued, would expire in 2038.

Manufacturing

We have process development and small-scale, non-clinical manufacturing capabilities. We generally perform cell line and process development for our product candidates and manufacture quantities of our product candidates necessary to conduct preclinical studies of our investigational product candidates. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. We rely on third-party manufacturers to produce bulk drug substance required for our clinical trials and expect to continue to rely on third-parties to manufacture clinical trial drug supplies for the foreseeable future. BMS has the exclusive right to manufacture cabiralizumab drug substance and filled drug product. BMS will supply us with cabiralizumab, at its cost and expense, for our use in the conduct of the current trial and our Phase 2 clinical trial of cabiralizumab in patients with PVNS and will supply us with cabiralizumab for the conduct of our independent cabiralizumab development activities in exchange for a pre-negotiated service fee. We also contract with additional third-parties for the filling, labeling, packaging, storage and distribution of investigational drug products. We have personnel with significant technical, manufacturing, analytical, quality and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes.

We must manufacture drug product for clinical trial use in compliance with current Good Manufacturing Practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements and FDA satisfaction before any product is approved. Our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Commercialization

We have not yet established sales, marketing or product distribution operations. We generally expect to retain some commercial rights in the United States for our product candidates in specialty markets. Pursuant to our cabiralizumab collaboration agreement, we have a co-promotion right in the United States which, if we exercise, will allow us to field a minority percentage of the total United States sales force promotional effort. If we exercise our option to co-promote cabiralizumab in the United States prior to submission of a biological license application, or BLA, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which cabiralizumab is being developed.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Government Regulation and Product Approval

In the United States, the FDA regulates protein therapeutics like cabiralizumab, bemarituzumab, FPA150 and our other product candidates as biological drug products, or biologics, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and related regulations. Biologics are also subject to other federal, state and local statutes and regulations. Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial actions. These actions could include the suspension or termination of clinical trials by the FDA or an Institutional Review Board, or IRB, the FDA's refusal to approve pending applications or supplements, revocation of a biologics license, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, civil penalties or criminal prosecution. Any administrative or judicial action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of biologics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, purity, potency, labeling, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion and post-market surveillance of our products.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of any future product candidates or approval of product or manufacturing changes, new disease indications, or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Biologics Product Development

The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests;
- submission of an IND application, which must become effective before clinical trials may begin;

- adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of a BLA, which must occur before a biologic can be marketed or sold.

The testing and approval process requires substantial time and financial resources, and we cannot be certain that any new approvals for our product candidates will be granted on a timely basis, if at all.

Before testing any compound in human subjects, a company must develop extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice, or GLP, regulations and the United States Department of Agriculture's Animal Welfare Act and related regulations.

Prior to commencing the first clinical trial in humans, an initial IND application must be submitted to the FDA. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in humans. The IND application automatically becomes effective 30 days after receipt by the FDA unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial and places the trial on clinical hold. In such case, the IND application sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND application or a new IND submission must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site. Informed consent must also be obtained from each study subject. Regulatory authorities, an IRB, a data safety monitoring board or the study sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk.

A clinical trial sponsor is required to submit to the National Institutes of Health, or NIH, for public posting on NIH's clinical trial website details about certain active clinical trials and clinical trial results. For purposes of BLA approval, human clinical trials are typically conducted in the following phases, which may overlap:

- Phase 1 — the biologic is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, reactivity, absorption, metabolism, distribution and excretion. These trials may also provide early evidence of effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2 — clinical trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — when Phase 2 evaluations demonstrate that a dosage range of the product appears effective and has an acceptable safety profile and provide sufficient information for the design of Phase 3 clinical trials, Phase 3 clinical trials are undertaken to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded patient population at multiple clinical trial sites. Phase 3 clinical trials are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for product approval by the FDA.

All of these trials must be conducted in accordance with Good Clinical Practice, or GCP, requirements in order for the data to be considered reliable for regulatory purposes.

The Biologic License Application Approval Process

In order to obtain approval to market a biologic in the United States, a BLA must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational product for the proposed indication. Each BLA submission requires a substantial user fee payment unless a waiver or exemption applies. The application includes all relevant data available from pertinent nonclinical studies 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 trials intended to test the safety and effectiveness of a use of a product and from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review a BLA for completeness before it accepts it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA, or the filing period, to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, which includes determining whether it is effective for its intended use, and whether the product is being manufactured in accordance with cGMP, and to assure and preserve the product's identity, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure that the benefits of the biologic outweigh its risks. A REMS may include various elements depending on what the FDA considers necessary for the safe use of the drug. These elements range from a medication guide or patient package insert to training and certification requirements for prescribers and/or pharmacies to safe use conditions that must be in place before the drug is dispensed. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS or the FDA will not approve the BLA.

The FDA's standard review time for a BLA for a new molecular entity is 10 months from the end of the 60-day filing period. Based on pivotal clinical trial results submitted in a BLA, at the discretion of the FDA or upon the request of an applicant, the FDA may grant a priority review designation to a product, which sets the target date for FDA action on the application at six months from the end of the filing period. Priority review is given for a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness compared to marketed products or offer a therapy where no satisfactory alternative therapy exists. Priority review designation does not change the scientific or medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its review of a BLA, it will either communicate to the sponsor that it will approve the product, or issue a complete response letter to communicate that it will not approve the BLA in its current form and to inform the sponsor of changes that the sponsor must make or additional clinical, nonclinical or manufacturing data that must be received before the FDA can approve the application, with no implication regarding the ultimate approvability of the application. If a complete response letter is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Resubmitting a BLA in response to a complete response letter can add additional time to the approval process for a product.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the BLA. Additionally, 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 testing and approval process for a biologic requires substantial time, effort and financial resources and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 clinical trials may be made a condition to be satisfied for continuing product approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. Conversely, the results of Phase 4 clinical trials can raise new safety or effectiveness issues that were not apparent during the original review of the product, which may result in product restrictions or even withdrawal of product approval. The FDA has express statutory authority to require sponsors to conduct post marketing studies or clinical trials to specifically address safety issues identified by the agency. If any of our products are subject to post-marketing requirements and commitments, there may be resource and financial implications for our business.

Even if a product candidate receives regulatory approval, the approval will be limited to specific disease states, patient populations and/or dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study or clinical trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, requirements to conduct additional studies or trials, or even complete withdrawal of the product from the market. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

FDA Post-Approval Requirements

Any products manufactured or distributed by us or on our behalf pursuant to FDA approvals are subject to continuing regulation by the FDA, including requirements for record-keeping, reporting of adverse experiences with the biologic, and submitting biological product deviation reports to notify the FDA of unanticipated changes in distributed products. Manufacturers are required to register their facilities with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP standards. This requires us and our third-party manufacturers to implement certain quality processes, manufacturing controls and documentation requirements in order to ensure that the product is safe, has the identity and strength, and meets the quality, purity and potency characteristics that it purports to have. Certain states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may halt our clinical trials, refuse to approve any BLA or other application, force us to recall a drug from distribution, shut down manufacturing operations or withdraw approval of the BLA for that biologic. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures, and injunctive action.

The FDA and other federal and state agencies closely regulate the labeling, marketing and promotion of drugs. While doctors may prescribe any product approved by the FDA for any use as long as consistent with any REMS restrictions, if applicable, a company can only make claims relating to safety and efficacy of a product that are consistent with FDA approval, and the company is allowed to market a drug only for the particular use and treatment approved by the FDA. In addition, any claims we make relating to our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions, potential civil and criminal penalties, criminal prosecution, and agreements with governmental agencies that materially restrict the manner in which we may promote or distribute drug products. Government regulators, including the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities, recently have increased their scrutiny of the promotion and marketing of drugs.

Orphan Drug and Orphan Medicinal Product Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions, which are generally diseases or conditions that affect fewer than 200,000 individuals in the United States. If a sponsor demonstrates that a biologic is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product. Orphan designation must be requested before submitting a BLA.

Under the Pediatric Research Equity Act, or the PREA, submission of a pediatric assessment is not typically required for pediatric investigation of a product that has been granted orphan drug designation. However, under the FDA Reauthorization Act of 2017, the scope of the PREA was extended to require pediatric studies for products intended for the treatment of an adult cancer that are directed at a molecular target that the Secretary of Health and Human Services determines to be substantially relevant to the growth or progression of a pediatric cancer. In addition, the FDA issued guidance in 2017 that it no longer intends to grant orphan drug designation to products for pediatric subpopulations of common diseases unless the use of the drug in the pediatric subpopulation meets the criteria for an orphan disease or unless the disease in the pediatric subpopulation is considered a different disease from the disease in the adult population.

The benefits of orphan drug designation include research and development tax credits and exemption from FDA user fees. Orphan designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Generally, if a product that receives orphan designation is approved for the orphan indication, it receives orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same use. Additionally, if a biologic designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity.

Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or provides a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease, which could create a more competitive market for us.

After the FDA grants orphan designation, the identity of the applicant, as well as the name of the therapeutic agent and its designated orphan use, are disclosed publicly by the FDA.

Similarly, the European Commission grants orphan medicinal product designation to products intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating affecting not more than five in 10,000 people. In order to receive orphan designation, there must also be no satisfactory method of diagnosis, prevention or treatment of the condition, or if such a method exists, the medicine must be of significant benefit to those affected by the condition. In addition, sponsors are required to submit to the EMA's Pediatric Committee, or the PDCO, and comply with a pediatric investigation plan, or a PIP, in order to seek marketing authorization in the EU.

Designated orphan medicinal products are entitled to a range of incentives during the development and regulatory review process, including scientific assistance for study protocols, a partial or total reduction in fees and eligibility for conditional marketing authorization. Once authorized, orphan medicinal products are entitled to 10 years of market exclusivity in all EU member states. However, marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10-year period with the consent of the marketing authorization holder for the original orphan medicinal product or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of such product. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is established to be safer, more effective or otherwise clinically superior to the original orphan medicinal product. After five years, a member state can request that the period of market exclusivity be reduced to six years if it can be demonstrated the criteria for orphan designation no longer apply and the medicine is sufficiently profitable. The period of market exclusivity may be extended by two years for medicines that have also complied with an agreed PIP.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created a licensure framework for biosimilars, which could ultimately subject our biological product candidates to competition from biosimilars. Under the BPCIA, a manufacturer may submit an abbreviated application for licensure of a biologic that is "biosimilar to" a referenced branded biologic. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively than if a "full" BLA were submitted, by relying to some extent on the FDA's previous review and approval of the reference biologic to which the proposed product is similar.

Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted to the sponsor of the reference product. No biosimilar application may be submitted until four years after the date of approval of the reference product, and no such application, once submitted, may receive final approval until twelve years after that same date (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results are reported to the FDA). Once approved, biosimilar products likely would compete with (and in some circumstances, may be deemed under the law to be "interchangeable with") the previously approved reference product.

FDA Regulation of Companion Diagnostics

As part of our clinical development plans, we plan to engage third-party collaborators to develop companion diagnostics to identify patients most likely to respond to our product candidates. Companion diagnostics are classified as medical devices under the Federal Food, Drug, and Cosmetic Act in the United States. The FDA regulates medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, reporting, recordkeeping, advertising and promotion, export and import, sales and distribution, and post-market surveillance. Unless an exemption applies, companion diagnostics require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA. According to a 2014 guidance issued by FDA officials, the use of companion diagnostics with therapeutic products raises important concerns about the safety and effectiveness of both the companion diagnostic devices and the corresponding therapeutic products and, therefore, ordinarily will require a PMA before they are marketed. Because the diagnostic tests that we plan to develop are essential for the safety and effective use of our therapeutics in selected patients, these diagnostic tests would be subject to the PMA approval process.

The PMA process is costly, lengthy and uncertain. PMA applications must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. For companion diagnostic tests, a PMA application typically includes data regarding analytical and clinical validation studies. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. FDA review of an initial PMA application is required by statute to take between six to ten months. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application, and where practical, will identify what is necessary to secure approval of the PMA. The FDA may also determine that additional clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and the data then submitted in an amendment to the PMA. Once granted, a PMA may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

We and any third-party collaborator who we engage to develop companion diagnostics will work cooperatively to generate the data required for submission with the PMA application, and will remain in contact with the Center for Devices and Radiological Health, or CDRH, at the FDA to ensure that any changes in requirements are incorporated into the development plans. We anticipate that meetings with the FDA with regard to our drug product candidates, as well as companion diagnostic product candidates, will include representatives from the Center for Drug Evaluation and Research, or the CDER, and CDRH to ensure that the BLA and PMA submissions are coordinated to enable the FDA to conduct a parallel review of both submissions. The 2014 guidance issued by the FDA addresses issues critical to developing companion diagnostics, such as biomarker qualification, establishing clinical validity, the use of retrospective data, the appropriate patient population and when the FDA will require that the device and the drug be approved simultaneously. According to the guidance, if safe and effective use of a therapeutic product depends on a diagnostic, then the FDA generally will require approval or clearance of the diagnostic at the same time that the FDA approves the therapeutic product. We plan to structure our programs for the development of our companion diagnostics to be consistent with this guidance.

In the European Economic Area, or the EEA, *in vitro* medical devices are required to conform with essential requirements by undergoing a conformity assessment procedure. The conformity assessment varies according to the type of medical device and its classification. For low-risk devices, the conformity assessment can be carried out internally, but for higher risk devices it requires the intervention of an accredited EEA Notified Body. If successful, the conformity assessment concludes with the drawing up by the manufacturer of an EC Declaration of Conformity entitling the manufacturer to affix the CE mark to its products and to sell them throughout the EEA. We expect our companion diagnostic will require a conformity assessment through an accredited EEA Notified Body, and that the data generated for the U.S. registration will be sufficient to satisfy the regulatory requirements for the European Union and other countries.

Coverage and Reimbursement

In both domestic and foreign markets, sales of any products for which we may receive regulatory approval will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs, such as Medicare and Medicaid, private health insurers and managed care providers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is granted, the reimbursement rates paid for covered products might not be adequate. Even if favorable coverage status and adequate reimbursement rates are attained, less favorable coverage policies and reimbursement rates may be implemented in the future. The marketability of any products for which we may receive regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide coverage and adequate reimbursement to allow us to sell such products on a competitive and profitable basis. For example, under these circumstances, physicians may limit how much or under what circumstances they will prescribe or administer our products and patients may decline to purchase such products. This, in turn, could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The market for any product candidates for which we may receive regulatory approval will depend significantly on the degree to which these products are listed on third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor may individually establish coverage and reimbursement policies, obtaining coverage and adequate reimbursement can be a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Anti-Kickback, False Claims, Physician Payments Sunshine and Other Healthcare Laws

In addition to FDA restrictions on marketing, several other types of U.S. state and federal laws are relevant to certain marketing practices in the pharmaceutical and medical device industries and their other interactions with health care providers. These laws include the Federal Anti-Kickback Statute, false claims statutes, and the Federal Physician Payments Sunshine Act and other healthcare laws. We are subject to these laws and they may affect our business. The Federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal health care programs such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the Federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. The Federal Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 and subsequent legislation, or collectively, the Affordable Care Act, among other things, amends the intent requirement of the Federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that 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 False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions; however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny.

The Federal False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim. Many pharmaceutical and other healthcare companies have faced investigations and private lawsuits and, in many cases, have agreed to significant and burdensome settlements under these laws for a variety of allegedly improper promotional and marketing activities, including inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates; providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees and other benefits to physicians to induce them to prescribe products; or engaging in promotion for "off-label" uses. Federal False Claims Act violations may result in significant civil monetary penalties, including three times the damages incurred by the government from the violation and exclusion from participation in federal healthcare programs. The majority of U.S. states also have statutes or regulations similar to the Federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, and in some states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters. HIPAA also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, requires certain manufacturers of products for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to track payments and other transfers of value to physicians and teaching hospitals, as well as physician ownership and investment interests, and to publicly report such data. Manufacturers subject to the Open Payments Program must submit a report on or before the 90th day of each calendar year disclosing reportable payments made in the previous calendar year. Failure to comply with the reporting obligations may result in civil monetary penalties.

Several states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products in those states and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. In addition, some states require pharmaceutical companies to implement compliance programs or marketing codes.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal or state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including significant criminal and civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, even if they are approved for sale. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical and medical device industries have been a particular focus of these efforts and have been significantly affected by major legislative initiatives.

In March 2010, the Affordable Care Act was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provision of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress also could consider subsequent additional legislation to replace elements of the Affordable Care Act that are repealed. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the European Union, before we may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Corporate Information and Employees

Our principal corporate offices are located at 111 Oyster Point Boulevard, South San Francisco, California 94080 and our telephone number is (415) 365-5600. We were incorporated in December 2001 in Delaware and completed our initial public offering, or IPO, in September 2013. As of December 31, 2017, we had 216 full-time employees and no part-time employees. Of these employees, 166 were primarily engaged in research and development activities and 62 have an M.D. or a Ph.D. degree.

Available Information

Our website address is www.fiveprime.com. We make available on our website, free of charge, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to Our Financial Position and Capital Needs

We expect to incur net losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2001, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million upfront payment we received from Bristol-Myers Squibb Company, or BMS, from our license and collaboration agreement for cabiralizumab, and the fiscal year ended December 31, 2011, due primarily to the $50.0 million upfront payment we received from Human Genome Sciences, Inc. from our license and collaboration agreement for FP-1039. For the fiscal year ended December 31, 2017, we reported a net loss of $150.2 million.

Although we may from time to time report profitable results, we generally expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We expect our operating expenses to increase as we advance our research and development of, and seek regulatory approvals for, our product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown circumstances that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have no source of product revenue and may never become consistently profitable.

To date, we have not generated any revenue from commercialization of our product candidates. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or with our partners, to successfully commercialize products, including any of our current product candidates or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. Our ability to generate future product revenue from our current or future product candidates also depends on additional factors, including our or our partners' ability to:

- successfully complete research and clinical development of current and future product candidates;
- establish and maintain supply and manufacturing relationships with third-parties to ensure adequate, timely and compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize future product candidates for which we obtain marketing approval, if any, and if launched independently or with certain partners, successfully establish a sales force, marketing and distribution infrastructure;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;

- successfully develop, validate and obtain any necessary regulatory approvals of companion diagnostics to our product candidates on a timely basis;
- achieve market acceptance for our or our partners' products, if any;
- acquire rights to and otherwise establish, maintain and protect intellectual property necessary to develop and commercialize our product candidates; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we decide to or are required by the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our products.

Even if we generate revenue from the sale of any of our products that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Although we have sufficient cash and cash equivalents to fund our projected operating expenses and capital expenditure requirements for at least the next 12 months, we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates further into clinical development, advance additional product candidates into clinical trials and increase the number and size of our clinical trials. In addition, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our product candidates through preclinical studies and into clinical development, we may have adverse results that require us or cause our collaboration partner on the program to terminate the program, conduct additional research or development activities or studies or substantially redesign a product candidate. Any of these events may lengthen the development process or increase our development costs. We may need to raise additional funds or otherwise obtain funding through product collaborations if we choose to initiate additional clinical trials for product candidates beyond the programs we have currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, current and future product candidates.

If we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize current and future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or cease operations altogether;
- seek collaborations for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which could have a material adverse effect on our business, operating results and prospects.

Our forecast of the time through which our financial resources will adequately support our operations could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. Our future funding requirements, both short- and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical and clinical studies for our current product candidates and future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential that such authorities may require us to perform more studies than those that we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, maintaining, defending and enforcing any of our patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any of our approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we choose to commercialize ourselves or with our collaboration partners.

If a lack of available capital means that we cannot expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.

Until we generate sufficient product revenue, if ever, we expect to finance our future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. Raising additional funds through the issuance of additional debt or equity securities could dilute our existing stockholders or increase fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits, including reducing the Orphan Drug Credit from 50% to 25% of clinical costs incurred in the United States. Any federal net operating loss incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

Risks Related to Our Business and Industry

We may not advance additional product candidates into clinical development or identify or validate additional drug targets. If we do not advance additional product candidates into clinical development or identify or validate additional drug targets, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the identification and validation of new targets for protein therapeutics and the identification and preclinical development of product candidates to these targets or in these target pathways. We are clinically developing our product candidates cabiralizumab, bemarituzumab and FPA150, and our preclinical program FPT155 is in IND-enabling studies. Our ability to generate product revenues, which we do not expect to occur for many years, if ever, will depend heavily on our ability to identify and validate new targets and identify and advance preclinical product candidates into and through clinical development. The outcome of preclinical studies of our product candidates may not predict the success of clinical trials. Moreover, preclinical results regarding a product candidate are often susceptible to varying interpretations and analyses and may not translate into similar results when the product candidate is tested clinically in humans. Many companies have believed their product candidates performed satisfactorily in preclinical studies, but such product candidates have nonetheless failed in clinical development. Our inability to successfully complete preclinical development of our product candidates could result in additional costs to us, delay or prevent our ability to advance product candidates into clinical development or commercialization, impair our ability to achieve development, regulatory, commercialization or sales milestone payments from our current or future collaboration partners, or to generate and receive royalties on product sales or product revenues from our current or future collaboration partners.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce meaningfully positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our partners must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Despite the results reported from our clinical trials and preclinical studies for our product candidates, we do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials do not produce favorable results, our or our partners' ability to achieve regulatory approval for any of our product candidates may be adversely impacted.

Delays in clinical testing will delay the commercialization of our product candidates, increase our costs and harm our business.

We do not know whether any of our clinical trials will begin as planned, will need to be amended or restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining authorization from the FDA or other regulatory authorities and institutional review boards, or IRBs;
- imposition of a clinical hold following an inspection of our manufacturing or clinical trial operations or clinical trial sites by the FDA or other regulatory authorities, or a decision by the FDA, other regulatory authorities, IRBs or us, or recommendation by a data safety monitoring board, to suspend or terminate a clinical trial at any time for safety or other reasons;
- delays in reaching agreement on acceptable terms with prospective CROs, clinical trial sites, laboratory service providers, CMOs and other service providers we engage to support the conduct of our clinical trials;
- deviations from the trial protocol by clinical trial sites or investigators or failure to conduct a clinical trial in accordance with regulatory requirements;
- failure of third-parties, such as CROs, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation and manufacturing of product candidates and in the delivery of these product candidates to clinical trial sites;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories or the transfer and validation of assays or tests used to identify selected patients;
- delays in completion of patients' participation in a clinical trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a clinical trial due to side effects, disease progression or other reasons;
- withdrawal of clinical trial sites from our clinical trials as a result of the investigator at the clinical trial site ceasing their affiliation with the clinical trial site, changing standards of care or the ineligibility of a clinical trial site to participate in our clinical trials;
- changes in government policies, laws, regulations or administrative actions; or
- lack of adequate funding to continue the clinical trials.

For example, we are conducting the Phase 3 portion of our global Phase 1/3 registrational trial of bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin as front-line treatment for patients with gastric and gastroesophageal, or GEJ, cancer that overexpresses FGFR2b, or the FIGHT trial, in China in collaboration with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Given the potential patient population in China, we believe that our ability to enroll patients at clinical sites in China will reduce the overall time to fully enroll the Phase 3 portion of our FIGHT trial and will therefore allow us to advance and complete the Phase 3 portion of the FIGHT trial in a shorter timeframe. However, Zai Lab's ability to initiate and conduct the FIGHT trial in China depends on Zai Lab's and our ability to comply with the government policies, laws and regulations applicable to conducting clinical trials, obtaining approval for and commercializing drug products in China. The government policies, laws and regulations in China are evolving rapidly and changes to these policies, laws and regulations are difficult to predict. If any such government policies, laws or regulations in China evolve in a way that make it more difficult or inefficient for us or Zai Lab to conduct our FIGHT trial in China, we may experience delays in initiating or conducting the FIGHT trial at our clinical trial sites in China and in fully enrolling the Phase 3 portion of the FIGHT trial, which will delay our ability to obtain approval for and commercialize bemarituzumab.

If we or our partners are unable to timely complete clinical development, we may incur additional costs and our ability to achieve development, regulatory, commercialization or sales milestones or to generate and receive royalties on product sales and product revenues may be impaired.

If we or our partners are unable to timely enroll patients in clinical trials, we will be unable to complete these trials on a timely basis.

The timely completion of clinical trials largely depends on the rate of patient enrollment. Many factors affect the rate of patient enrollment, including:

- the size and nature of the patient population;
- the number and location of clinical trial sites;
- competition with other companies for clinical trial sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- the availability of supplies of drug product for clinical use;
- risk that enrolled subjects will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

There is significant competition for recruiting patients in the clinical trials we and our partners are conducting and plan to conduct, and we or our partners may be unable to timely enroll the patients necessary to complete clinical trials on a timely basis or at all.

For example, we are conducting a Phase 2 clinical trial of cabiralizumab in patients with diffuse PVNS. Very little data regarding the incidence and prevalence of diffuse PVNS exist, but data we have gathered suggest that the prevalence of diffuse PVNS in the United States may be approximately 28,000 patients. We expect that the limited size of the diffuse PVNS patient population will limit patient enrollment rates. Daiichi Sankyo Co., Ltd./Plexxikon Inc., or Daiichi Sankyo, has conducted a Phase 3 clinical trial (ENLIVEN) of pexidartinib (PLX3397) in PVNS, and we believe plans to pursue approval of pexidartinib for use in PVNS. If pexidartinib is approved in any region where we are conducting clinical trials of cabiralizumab in PVNS, it may impact our ability to enroll and timely complete those trials. In addition, Novartis AG, or Novartis, is conducting a Phase 2 clinical trial of its MCS110 CSF1 monoclonal antibody in PVNS and F. Hoffmann-La Roche AG, or Roche, has clinically tested its emactuzumab (RO5509554, RG7155) antibody in PVNS patients. If either or both of Novartis or Roche continue the clinical development of their respective products in PVNS, we would potentially compete with them for patient enrollment in this rare patient population, which may adversely impact the rate of patient enrollment in and the timely completion of our Phase 2 clinical trial of cabiralizumab in PVNS.

Additionally, although we believe selecting patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the *FGFR2* gene using an IHC- or ctDNA blood-based companion diagnostic should increase the percentage of patients eligible for and the probability of success in our clinical trials of bemarituzumab in gastric and GEJ cancer, these selection criteria limit the number of patients eligible for enrollment.

We may not successfully identify, test, develop or commercialize our current or future product candidates, which may force us to abandon our development efforts for one or more programs.

The success of our business depends primarily upon our ability to identify and validate new protein therapeutic targets, including through the use of our discovery platform, and discover, test, develop and commercialize protein therapeutics, which we may develop ourselves or in-license from third-parties. Our research efforts may initially show promise in discovering potential new protein therapeutic targets or candidates, yet fail to yield product candidates for clinical development and ultimate commercialization for numerous reasons, including:

- our research methodology, including our screening technology, may not successfully identify medically relevant protein therapeutic targets or potential product candidates;
- we tend to identify and select from our discovery platform novel, untested targets that may be challenging to validate because of the novelty of the target or that we may fail to validate at all after further research;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make our product candidates unmarketable;
- third-parties on whom we may rely to generate antibody candidates may fail to produce candidates that we can successfully validate or that have the scientific or clinical characteristics necessary to become marketable product candidates;
- our product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies or early-stage clinical trials, which may make our product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients or subjects; or
- our collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a partnered product.

The occurrence of any of these events may force us to abandon our development efforts for one or more programs, which would have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. Research programs to identify new product targets and candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential discovery efforts, programs or product candidates that ultimately prove to be unsuccessful.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The process of manufacturing our product candidates is complex and subject to a number of risks, including the following:

- The process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error leading to process deviations. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended time to investigate and remediate the contamination.
- The manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors.
- Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products to clinical trial sites. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, or because we must undertake costly remediation efforts or seek more expensive manufacturing alternatives.

Certain raw materials necessary for the manufacture of our products, such as growth media, resins and filters, are sourced from a single supplier. We do not have agreements in place that guarantee our supply or the price of these raw materials. Any significant delay in the acquisition or decrease in the availability of these raw materials could considerably delay the manufacture of our product candidates, which could adversely impact the timing of any planned clinical trials or the regulatory approval of that product candidate.

We have process development and small-scale preclinical manufacturing capabilities. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. In the past we have engaged, and we expect in the future to engage, third-party CMOs for the manufacture of bulk drug substance and drug product for our clinical trials and additional third-parties for our supply chain. Any problems we experience with any of these third-parties could delay the manufacturing of our product candidates and the progress of our clinical trials, which could harm our results of operations.

For example, BMS has the exclusive right to manufacture cabiralizumab. Under our cabiralizumab collaboration agreement with BMS, BMS will supply us with cabiralizumab, at its cost and expense, for our use in the conduct of our clinical trial evaluating cabiralizumab in combination with *Opdivo* in multiple tumor types and our Phase 2 clinical trial of cabiralizumab in patients with PVNS and will supply us with cabiralizumab, in exchange for a service fee, for our conduct of our independent development activities with respect to cabiralizumab.

We have not contracted with alternate suppliers in the event the current organizations we utilize for manufacturing are unable to scale production or if we otherwise experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or are unable to do so on commercially reasonable terms or in a timely manner, we may be delayed in the development of our product candidates.

Our reliance on third-party manufacturers subjects us to risks to which we would not be subject if we manufactured product candidates internally, including potential failure of the third-party to abide by regulatory and quality assurance requirements, the possibility of breach of the manufacturing agreement by the third-party due to factors beyond our control (including the third-party's failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of the agreement by the third-party, based on its own business priorities, at a time when finding and retaining a replacement manufacturer may be costly or damaging to our business.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any of our product candidates and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- the FDA's or such comparable foreign regulatory authority's disagreement with the design or implementation of our clinical trials;
- our failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- the failure of our clinical trial data to meet the level of statistical significance required for approval;
- our failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA's or such comparable foreign regulatory authority's disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of our clinical trial data to support the submission and filing of a Biologic License Application or other submission or to obtain regulatory approval;
- our failure to obtain approval from the FDA or such comparable foreign regulatory authority for the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the standard of care or approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information to support approval of a product candidate, including additional preclinical or clinical data, which may delay or prevent approval and our commercialization plans, or result in our decision to abandon the development program with respect to such product candidate. If we were to obtain approval for any of our product candidates, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, 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.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority or otherwise limit the commercial potential of any such product candidate. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of side effects or unexpected characteristics. In such an event, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our products receives marketing approval, and we or others later identify undesirable side effects caused by any such product, numerous potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label for such product;
- regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- regulatory authorities may require the establishment or modification of a risk evaluation and mitigation strategy, or REMS, or a similar strategy that may, for instance, restrict distribution of such product and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market approval or acceptance for a product candidate or otherwise materially harm the commercial prospects for such product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Certain of our product candidates are expected to be effective only in certain selected patient populations, including bemarituzumab and FPA150. If we are unable to successfully develop companion diagnostics for these product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of bemarituzumab.

We plan to develop a companion diagnostic for certain of our product candidates, including bemarituzumab and FPA150. We have collaborated with third-party diagnostic development partners to develop both an IHC- and a ctDNA blood-based assay to use as companion diagnostics for bemarituzumab to identify patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the *FGFR2* gene. We expect that the FDA and comparable foreign regulatory authorities may require the development and regulatory approval of at least one companion diagnostic as a condition to approving bemarituzumab for use in patients that overexpress the FGFR2b protein or amplify the *FGFR2* gene. We are initially seeking to develop bemarituzumab to treat a subset of patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification. Because the IHC-based companion diagnostic will allow us to determine FGFR2b overexpression in tumor tissue samples from patients with gastric or GEJ cancer and the blood-based companion diagnostic will allow us to detect *FGFR2* gene amplification by ctDNA from patients with gastric or GEJ cancer, we plan to use both companion diagnostics concurrently in our FIGHT trial to more effectively identify patients with gastric or GEJ cancer who may qualify for enrollment in the trial.

In addition, we are seeking to develop FPA150 to treat patients with a variety of cancers whose tumors express the B7-H4 protein, as identified by an IHC diagnostic test. We expect that the FDA and comparable foreign regulatory authorities may require the development and regulatory approval of at least one companion diagnostic as a condition to approving FPA150 for use in patients that express the B7-H4 protein. We have collaborated with a third-party diagnostic development partner to develop an IHC assay to use as a lab-developed test to identify patients whose tumors express B7-H4 and plan to use this IHC assay in the Phase 1b portion of our Phase 1a/1b clinical trial of FPA150.

We do not have experience or capabilities in developing or commercializing diagnostics and will depend on the sustained cooperation and effort of our third-party collaborators to perform these functions.

If we or our third-party collaborators are unable to successfully develop companion diagnostics for bemarituzumab or FPA150 or experience delays in doing so, we may suffer significant negative consequences, including:

- the development of bemarituzumab or FPA150, as applicable, may be adversely affected because we may be unable to appropriately select patients for enrollment in our clinical trials;
- bemarituzumab or FPA150, as applicable, may not receive marketing approval if its safe and effective use depends on use of a companion diagnostic; or
- we may not realize the full commercial potential of bemarituzumab or FPA150 if, among other reasons, we are unable to appropriately identify patients with FGFR2b protein overexpression or B7-H4 expression, respectively.

The occurrence of any of these events would harm our business, possibly materially.

Companion diagnostics are also subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization, which may cause delays in developing the companion diagnostics and harm our business.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties, which may inhibit our ability to commercialize our products and generate revenue.

Even if we obtain regulatory approval for a product candidate, the product would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information for such product candidate. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on the product's indicated uses or marketing, or impose ongoing requirements for post-approval studies or post-market surveillance, which may be costly.

In addition, drug product manufacturers and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, regulations and standards. If we or a regulatory authority discover previously unknown problems with one of our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where such product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of such product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which may include imposition of various monetary fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or bring other court action to impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications that we have filed;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may limit or prevent our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, may be subject to enforcement letters, inquiries, investigations and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of products for off-label uses can also subject a company to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which such company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or that such company caused another entity or individual to present such false or fraudulent claims for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will receive a portion of any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements involving fines exceeding $1.0 billion based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, such actions may material adversely affect our business, financial condition and results of operations.

The policies of the FDA or any comparable foreign regulatory authority may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

In order to market and sell our products in other jurisdictions, we or our collaboration partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedures vary among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval and may include additional risks that we cannot predict. In addition, in many countries outside the United States, we or our collaboration partners must secure product reimbursement approvals before regulatory authorities will approve a product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain foreign regulatory approvals on a timely basis, if at all.

For example, we are conducting the Phase 3 portion of our FIGHT trial for bemarituzumab in China in collaboration with Zai Lab and are relying on Zai Lab's ability to obtain approval for bemarituzumab in China, Taiwan, Hong Kong and Macau, or collectively, Greater China, from the CFDA. However, Zai Lab's ability to obtain approval in Greater China depends on Zai Lab's and our ability to comply with the government policies, laws and regulations applicable to conducting clinical trials, obtaining approval for and commercializing drug products in Greater China. The government policies, laws and regulations in China are evolving rapidly and are difficult to predict. If any such government policies, laws or regulations in China evolve in a way that make it more difficult or inefficient for Zai Lab or us to clinically develop, obtain approval for or commercialize bemarituzumab in China, we may experience delays in initiating or conducting the FIGHT trial at our clinical trial sites in China and in fully enrolling the Phase 3 portion of the FIGHT trial, which will delay our ability to obtain approval for and commercialize bemarituzumab.

Further, results and data from clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country or by one regulatory authority outside the United States does not ensure approval by regulatory authorities in any other country or jurisdiction or by the FDA, while a failure or delay in obtaining regulatory approval for any of our product candidates in one country may have a negative effect on the regulatory approval process in other countries and may significantly diminish the commercial prospects of that product candidate, which may cause our business prospects to decline. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market for our product candidates will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our current product candidates and will face such competition with respect to our future product candidates. Many of our competitors have significantly greater financial, technical and human resources than we do. Smaller and early-stage companies may also prove to be significant competitors, particularly through their collaborative arrangements with large and established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used or less costly or have better safety profiles than our products and may also be more successful than us in manufacturing and marketing their products.

Our competitors also currently and will in the future compete with us in recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our research and development programs.

Although there are no approved therapies that specifically target the signaling pathways that our product candidates are designed to modulate or inhibit, there are numerous currently-approved therapies for treating the same diseases or indications for which our product candidates may be useful and many of these currently-approved therapies act through mechanisms similar to those of our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. This may make it difficult for us to differentiate our products from currently-approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

If cabiralizumab were approved for the treatment of cancer or PVNS, it could face competition from products currently in development as single agents or in combination with anti-PD1/PD-L1 agents or other immuno-oncology agents, including Roche's emactuzumab (RO5509554, RG7155) anti-CSF1R antibody, Eli Lilly and Company's LY3022855 (IMC-CS4) anti-CSF1R antibody, Amgen Inc.'s AMG 820 anti-CSF1R antibody, Syndax Pharmaceuticals Inc.'s SNDX6352 anti-CSF1R monoclonal antibody, Pfizer Inc.'s, or Pfizer's, PD-0360324 CSF1 monoclonal antibody, Novartis Pharmaceuticals Corporation's, or Novartis', BLZ945 CSF1R-directed small molecule and MCS110 CSF1 monoclonal antibody, Daiichi Sankyo's pexidartinib (PLX3397), PLX73086 and PLX7486 small molecule tyrosine kinase inhibitors, or TKIs, Array Biopharma Inc.'s ARRY-382 CSF1R small molecule TKI or Deciphera Pharmaceuticals LLC's DCC-3014 CSF1R small molecule TKI, with respect to cancer, and Daiichi Sankyo's pexidartinib (PLX3397) and PLX73086 small molecule TKIs or Novartis' MCS110 CSF1 monoclonal antibody, with respect to PVNS, each of which act in the same pathway as cabiralizumab.

If bemarituzumab were approved for the treatment of gastric and GEJ cancer, it could face competition from currently-approved and marketed products, including 5-fluorouracil, S-1, capecitabine, doxorubicin, cisplatin, oxaliplatin, carboplatin, paclitaxel, irinotecan, docetaxel and *Cyramza™* (ramucirumab), and from products currently in early development, including AstraZeneca plc's AZD-4547 and erdafitinib (JNJ-42756493) pan-FGFR small molecules and Daiichi Sankyo's DS-1123 FGFR2 non isoform specific antibody, as well as antibodies that bind to PD-1/PD-L1, including BMS's *Opdivo* monotherapy and *Opdivo* in combination with BMS's *Yervoy®* (ipilimumab) anti-CTLA-4 antibody, Merck & Co., Inc.'s *Keytruda®* (pembrolizumab), Merck KGaA, Darmstadt, Germany/Pfizer's *Bavencio®* (avelumab), Roche's *Tecentriq®* (atezolizumab), AstraZeneca UK Limited/MedImmune, LLC's *Imfinzi™* (durvalumab) anti-PD-L1 antibody, Astellas Pharma Inc.'s claudiximab (IMAB362) anti-Claudin 18.2 antibody and AstraZeneca UK Limited/MedImmune, LLC's tremelimumab anti-CTLA4 antibody.

If FPA150 were approved for the treatment of cancer, it could face competition from currently-approved and marketed products, including cisplatin, carboplatin, gemcitabine, doxorubicin, paclitaxel, topotecan, *Avastin®* (bevacizumab), *Abraxane®* (paclitaxel protein-bound), *Xeloda®* (capecitabine), *Navelbine®* (vinorelbine), and *Halaven®* (eribulin mesylate), and from antibodies that bind to PD-1/PD-L1, including BMS's *Opdivo* monotherapy and *Opdivo* in combination with BMS's *Yervoy®* (ipilimumab) anti-CTLA-4 antibody, Merck & Co., Inc.'s *Keytruda®* (pembrolizumab), Merck KGaA, Darmstadt, Germany/Pfizer's *Bavencio®* (avelumab), Roche's *Tecentriq®* (atezolizumab), AstraZeneca UK Limited/MedImmune, LLC's *Imfinzi™* (durvalumab), and AstraZeneca UK Limited/MedImmune, LLC's tremelimumab anti-CTLA4 antibody, as well as small molecule poly ADP-ribose polymerase inhibitors, including AstraZeneca UK Limited's *Lynparza®* (olaparib), Tesaro, Inc.'s *Zejula®* (niraparib), Clovis Oncology, Inc.'s *Rubraca®* (rucaparib), Pfizer's talazoparib and AbbVie Inc.'s veliparib.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety profile of our product candidates, including relative to marketed products and product candidates in development by third-parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- our or our partners' ability to commercialize any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- our ability to establish, maintain and protect intellectual property rights related to our product candidates;
- our and our partners' ability to manufacture commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, generally, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. The degree of market acceptance of any of our approved product candidates will depend on numerous factors, including:

- the efficacy and safety profile of the product candidate, as demonstrated in clinical trials;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-parties and government authorities;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Even if we commercialize any of our product candidates, our product candidates may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if those product candidates obtain marketing approval.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and reimbursement of medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary depending on the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any of our approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may charge for such product candidates.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Act includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress will likely consider other legislation to replace elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

We may become subject to product liability lawsuits, which could cause us to incur substantial liabilities and may limit commercialization of any products we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any products that we may develop;
- termination of clinical trials at particular sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards payable to clinical trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

We currently hold $10 million in clinical trial liability insurance coverage, which may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain product liability insurance on commercially reasonable terms for any of our products that have been approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency, privacy and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products that have received marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the federal false claims laws, including the civil False Claims Act (which can be enforced by private citizens through whistleblower or *qui tam* actions), impose civil and criminal penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, or collectively, HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing any money or other assets of a health care benefit program, willfully obstructing a criminal investigation of a healthcare fraud offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program requires manufacturers of drugs, devices, biologics or 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 U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members; and

- analogous state and foreign laws and regulations impose similar restrictions to those described above, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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; state and foreign 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 and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, including the EU General Data Protection Regulation, or GDPR, which will become enforceable on May 25, 2018, and imposes privacy and security obligations on any entity that collects or processes health data from individuals located in the EU. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

Efforts to ensure that our business arrangements with third-parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any physician or other healthcare provider or entity with whom we expect to do business is found to have violated applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We must attract and retain highly skilled employees to succeed.

We are experiencing significant growth in our operations as we expand the scope of our research and clinical activities, including our conduct of a Phase 2 clinical trial of cabiralizumab in PVNS, a Phase 1a/1b clinical trial of cabiralizumab in combination with *Opdivo* in multiple cancers, clinical trials, including our FIGHT trial, of bemarituzumab in gastric and GEJ cancer, a Phase 1a/1b clinical trial of FPA150 in multiple cancers and our preclinical development and immuno-oncology research activities. Our success will depend in part on our ability to manage our growth, including increases to our headcount, effectively. To succeed, we must continue to recruit, develop, retain, manage and motivate qualified clinical, scientific, technical and management personnel while facing significant competition for experienced personnel. If we do not successfully attract and retain qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other pharmaceutical companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may appeal more to high-quality candidates than what we offer. If we are unable to continue to attract and retain high-quality personnel, the rate at which we can discover and develop product candidates and our business, and our success in doing so, will be limited.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity, political and economic instability in the countries in which we operate and other events beyond our control, which could harm our business.

Our computer and other systems, or those of our partners, CROs or other service providers, may fail or be interrupted, including due to fire, earthquake or other natural disasters, hardware, software, telecommunication or electrical failures or terrorism, or suffer security breaches, including due to computer viruses or unauthorized access, which could significantly disrupt or harm our business or operations. For example, a computing system failure could result in the loss of research or preclinical or clinical data important to our discovery, research or development programs, interrupt the conduct of ongoing experiments or otherwise impair our ability to operate, which could result in delays in the advancement of our programs or cause us to incur costs to recover or reproduce lost data. Our facility is in a seismically-active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disaster and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our protein libraries, most of which we maintain at our headquarters. We maintain one copy of each of our protein libraries offsite in Central California. If both facilities were impacted by the same event, we could lose all our protein libraries, which would have a material adverse effect on our ability to discover new targets.

Risks Related to Our Dependence on Third-Parties

BMS has exclusive global rights for the development and commercialization of cabiralizumab, and Zai Lab has exclusive rights for the development and commercialization of bemarituzumab in Greater China. BMS or Zai Lab's failure to timely develop or commercialize cabiralizumab or bemarituzumab, respectively, would have a material adverse effect on our business and operating results.

We granted BMS an exclusive global license to develop and commercialize cabiralizumab, subject to certain rights that we retained. Additionally, we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in Greater China, subject to certain rights that we retained in the territory. Either or both of our cabiralizumab collaboration with BMS or our bemarituzumab collaboration with Zai Lab may not be successful due to several factors, including the following:

- cabiralizumab or bemarituzumab may fail to demonstrate in clinical trials sufficient efficacy with an acceptable safety profile to support regulatory approval;
- BMS may be unable to manufacture sufficient quantities of cabiralizumab or Zai Lab may not be able to obtain from us or manufacture, as applicable, bemarituzumab, in a timely or cost-effective manner;
- BMS or Zai Lab may be unable to obtain regulatory approval to commercialize cabiralizumab or bemarituzumab, respectively, even if preclinical and clinical testing is successful;
- BMS or Zai Lab may not succeed in obtaining sufficient reimbursement for cabiralizumab or bemarituzumab, respectively, if approved; and
- existing or future products or technologies developed by competitors may be safer, more effective or more conveniently delivered to patients than cabiralizumab or bemarituzumab.

In addition, we could be adversely affected by:

- BMS's or Zai Lab's failure to timely perform their respective obligations under our collaboration agreements;
- BMS's or Zai Lab's failure to timely or fully develop or effectively commercialize cabiralizumab or bemarituzumab, respectively; or
- a material contractual dispute with BMS or Zai Lab.

Any of the foregoing could adversely impact the likelihood and timing of any milestone payments we are eligible to receive under our collaboration agreements with BMS and Zai Lab and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

Each of BMS and Zai Lab has the right to terminate its collaboration agreement with us without cause as well as upon the existence of certain conditions and, in some cases, BMS or Zai Lab may terminate on short notice. BMS or Zai Lab could also separately pursue alternative potentially competitive products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by cabiralizumab or bemarituzumab, respectively.

We may not succeed in establishing and maintaining additional development collaborations, which could adversely affect our ability to develop and commercialize product candidates.

A part of our strategy is to enter into additional product development collaborations, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate development partners and the negotiation process is time-consuming and complex. Moreover, we may not succeed in our efforts to establish a development collaboration or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, development of our product candidates and programs may be deemed to be too early in development for collaborative efforts or third-parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish new development collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such development collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into new development collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to establish and maintain additional development collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all the risk related to the development of any such product candidates.

We rely on third-party CROs to conduct our clinical trials, and the unsatisfactory performance by such CROs may harm our business.

We rely on CROs to perform most of the activities related to the conduct of our clinical trials, including site identification, screening, preparation, training, initiation and monitoring, and document preparation and coordination, program management and data management. However, we do not directly control the conduct, timing, expense or quality of the performance of these activities. The performance of our CROs will impact the quality and validity of our clinical trial results, which we rely on for business planning purposes and include in submissions to regulatory authorities. Although we contract with CROs to conduct most clinical trial-related activities, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal and regulatory requirements. Our reliance on CROs does not relieve us of our legal and regulatory responsibilities with respect to our clinical trials.

We and our CROs are required to comply with current Good Clinical Practices, or GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all our products in clinical development. Regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot ensure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with product produced in accordance with cGMP requirements. Our failure, or the failure of our clinical trial sites or third-party CROs or contract manufacturing organizations, or CMOs, to comply with applicable GCP and cGMP may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. 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 revenues could be delayed.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of our licensors and collaborators to obtain, maintain and defend patents and other intellectual property rights and to operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed patent and other intellectual property rights to and from our partners. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, whereas other licenses do not give us such rights.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the patents covering technology that we license to or from our partners, and we may have to rely on our partners to fulfill these responsibilities. Consequently, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the strategy for prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent prosecution process is expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third-party files a patent application covering or publishes information disclosing a similar, independently-developed invention. Such competitor's patent application may hinder our ability to obtain patent protection for these inventions or may limit the scope of patent protection we may obtain.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively exclude others from commercializing competitive technologies and products. The patent prosecution process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of protection if patents issue from such applications. Our and our licensors', licensees' or collaborators' rights in the technology claimed in patent applications cannot be enforced against third-parties practicing such technology unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology.

Furthermore, because the amount of time required for the development, testing and regulatory review of new product candidates is lengthy, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolios may not provide us with adequate protection against third-parties seeking to commercialize products similar or identical to ours. We expect to request extensions of patent terms to the extent available in countries where we obtain issued patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the expiration of the patent. However, there are no assurances that the FDA or any comparable foreign regulatory authority will grant such extensions, in whole or in part. In such case, our competitors may launch their products earlier than might otherwise be anticipated.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Moreover, the requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. Therefore, it may be more difficult to obtain patent protection in certain countries relative to others.

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. Consequently, we and our licensors or collaborators may not be able to prevent third-parties from practicing our and our licensors' or collaborators' inventions in certain countries outside the United States. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we and our licensors or collaborators have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' 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 rights, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and could provoke third-parties to assert counterclaims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate and, even if we prevail, the damages or other remedies awarded, if any, may not be commercially meaningful.

Biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents in countries outside the United States, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third-parties. In those countries, we and our licensors or collaborators may have limited remedies if compelled to grant a license to a third-party, which could materially diminish the value of the applicable patents and limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from such intellectual property rights.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our rights in our product candidates.

Obtaining and enforcing patents in the biopharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, the Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available under certain circumstances or weakening the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once issued.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes numerous significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, including the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not 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 patent applications and the enforcement or defense of issued patents controlled by us or our licensors or collaborators, all of which could have a material adverse effect on our business and financial condition.

Obtaining and maintaining our patent protection requires 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 if we fail to comply with these requirements.

Periodic maintenance and annuity fees on any issued patent are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third-parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights or to protect our or our licensors' or collaborators' trade secrets. The outcome of such proceedings may determine or alter the validity or scope of intellectual property rights we own or control. Also, third-parties may initiate legal proceedings against us or our licensors or collaborators to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can. Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors or collaborators may not prevent third-parties from infringing or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in a patent infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to impose monetary damages or enjoin the other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Derivation or interference proceedings in the United States or equivalent proceedings in other jurisdictions may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license or offers a license on terms that are not commercially reasonable. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we prevail in such a proceeding, we may incur substantial costs and it may distract our management and other employees from our business and operations.

If we breach the agreements under which third-parties have licensed intellectual property rights to us, we could lose the ability to use certain of our technologies or continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to discover and validate protein therapeutic targets and to identify, test, develop, manufacture, market and sell product candidates without infringing the proprietary rights of third-parties. A third-party may hold intellectual property rights, including patent rights, that are important for or necessary to the development or commercialization of our products. As a result, we are a party to a number of licenses that are important to our business and expect to enter into additional licenses in the future. For example, we have entered into a non-exclusive license with BioWa, Inc. and Lonza Sales AG to use their Potelligent® CHOK1SV technology, which is necessary to produce our bemarituzumab antibody and non-exclusive licenses with each of the National Research Council of Canada and the Board of Trustees of the Leland Stanford Junior University to use materials and technologies that we use in the production of our protein library. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other contractual penalties. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of, or reduction or elimination of our rights under, these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

Third-parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by such third-parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third-parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third-parties to challenge the validity or scope of intellectual property rights controlled by third-parties, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the relevant technology or developing or commercializing our product candidates, or to attempt to license any necessary rights to such technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license, or otherwise offers a license on terms that are not commercially reasonable. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages if we are found to have infringed a patent, including treble damages and attorneys' fees if such infringement was willful. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

Furthermore, because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during the course of this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, the price of shares of our common stock may be materially adversely affected.

We may be subject to claims by third-parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees 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 our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be determined to be owned by a third-party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available or may not be available on commercially reasonable terms. Even if we successfully defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third-parties. We also enter into confidentiality and invention, including patent, assignment agreements with our employees and consultants. Despite these efforts, any of these parties, including their current or former employees or consultants, may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. However, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome of such a claim is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that trade secret to compete with us, which could harm our competitive position.

Risks Related to the Ownership of Our Common Stock

The market price of our stock may be volatile.

The trading price of our common stock has been and is likely to continue to be volatile. Since shares of our common stock were sold in our IPO in September 2013, our closing stock price as reported on The Nasdaq Global Market and The Nasdaq Global Select Market has ranged from $8.49 to $60.98 through February 26, 2018. The following factors, in addition to other risk factors described in this section and elsewhere in this report, may have a significant impact on the market price of our common stock:

- results or status of or plans for clinical trials of our product candidates or those of our competitors, as well as interpretation and perception of such results by third-parties;
- announcements by us, our partners or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our or our partners' growth rates relative to our competitors;
- failure of our partners to effectively execute or changes in our partners' strategies with respect to our products or collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- our dependence on third-parties, including contract manufacturers, CROs and any partners we may engage to develop and provide us with companion diagnostic products;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;

- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry, political and market conditions.

In addition, the stock market in general, and The Nasdaq Global Select Market and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

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

The market price of our common stock may 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.

Our principal stockholders and management own a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2017, we estimate that our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 50% of our common stock. This concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, acting together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

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.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of 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 an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult or costly for a third-party to acquire us, even if doing so would benefit our stockholders, and could make it more difficult to remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive office is currently located in South San Francisco, California, and consists of 115,466 square feet of office and laboratory space, all of which is located in a single building, under a lease that expires on December 31, 2027. We believe that our existing facility is sufficient for our current needs.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market Information

Our common stock is traded on The Nasdaq Global Select Market under the symbol "FPRX." The following table sets forth the high and low intraday sale prices per share of our common stock for the periods indicated as reported by the Nasdaq Global Select Market.

	High	Low
Years Ended December 31, 2017		
First Quarter	$ 52.98	$ 34.71
Second Quarter	37.15	26.65
Third Quarter	41.36	25.97
Fourth Quarter	48.87	19.73

	High	Low
Years Ended December 31, 2016		
First Quarter	$ 41.84	$ 28.01
Second Quarter	50.11	37.03
Third Quarter	55.00	41.13
Fourth Quarter	60.98	45.23

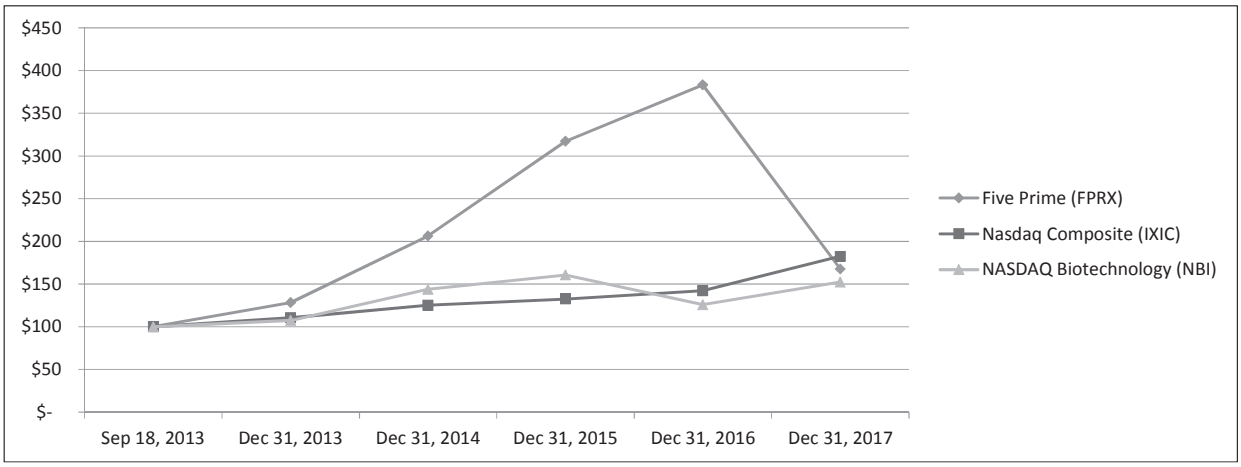
As of February 20, 2018, we had 34,860,499 shares of common stock outstanding held by approximately 30 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name 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.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since our initial public offering on September 18, 2013 with the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The stockholder return shown in the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



$100 investment in stock or index	September 18, 2013	December 31, 2013	December 31, 2014	December 31, 2015	December 31, 2016	December 31, 2017
Five Prime (FPRX)	$ 100.00	$ 128.36	$ 206.42	$ 317.28	$ 383.10	$ 167.58
Nasdaq Composite Index (IXIC)	$ 100.00	$ 110.39	$ 125.17	$ 132.34	$ 142.27	$ 182.45
Nasdaq Biotechnology (NBI)	$ 100.00	$ 107.41	$ 144.04	$ 160.49	$ 125.69	$ 152.16

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data.

You should read the following selected financial data together with the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this report and our financial statements and the accompanying notes included elsewhere in this report. We have derived the statements of operations data for the years ended December 31, 2017, 2016 and 2015 and the balance sheet data as of December 31, 2017 and 2016 from our audited financial statements appearing in this report. We have derived the statements of operations data for the years ended December 31, 2014 and 2013 and the balance sheet data as of December 31, 2015, 2014 and 2013 from our audited financial statements not included in this report. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
(in thousands, except per share amounts)	**2017**	**2016**	**2015**	**2014**	**2013**
Statement of Operations Data:					
Collaboration and license revenue	$ 39,508	$ 30,691	$ 379,801	$ 19,231	$ 13,791
Operating expenses:					
Research and development	150,908	94,072	70,197	43,173	32,785
General and administrative	40,002	35,831	22,631	13,632	10,427
Total operating expenses	190,910	129,903	92,828	56,805	43,212
Income (loss) from operations	(151,402)	(99,212)	286,973	(37,574)	(29,421)
Interest income	2,978	2,467	487	210	62
Other income (expense), net	(94)	—	(3)	(60)	487
Income (loss) before income taxes	(148,518)	(96,745)	287,457	(37,424)	(28,872)
Income tax benefit (provision)	(1,704)	31,048	(37,810)	—	—
Net income (loss)	$ (150,222)	$ (65,697)	$ 249,647	$ (37,424)	$ (28,872)
Basic net income (loss) per share attributable to common stockholders [1]	$ (5.38)	$ (2.44)	$ 9.73	$ (1.79)	$ (5.23)
Diluted net income (loss) per share attributable to common stockholders [1]	$ (5.38)	$ (2.44)	$ 9.23	$ (1.79)	$ (5.23)
Weighted average shares of common stock outstanding used in computing basic net income (loss) per share [1]	27,945	26,955	25,661	20,865	5,523
Weighted average shares of common stock outstanding used in computing diluted net income (loss) per share [1]	27,945	26,955	27,035	20,865	5,523

(1) See Note 7 to our financial statements for an explanation of the method used to calculate basic and diluted net income (loss) per share of common stock and the weighted average number of shares used in computation of the per share amounts.

	As of December 31,				
(in thousands)	**2017**	**2016**	**2015**	**2014**	**2013**
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 292,690	$ 421,748	$ 517,466	$ 149,054	$ 75,722
Working capital	260,209	401,384	448,913	131,443	63,835
Total assets	344,047	448,281	548,285	155,631	81,791
Total stockholders' equity	265,202	391,575	433,206	85,205	58,026

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

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in "Special Note Regarding Forward-Looking Statements and Industry Data" and "Risk Factors."

Overview

We are a clinical-stage biotechnology company focused on discovering and developing innovative protein therapeutics to improve the lives of patients with serious diseases. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are needed. We have an emphasis in immuno-oncology, an area in which we have clinical, preclinical and discovery programs and product and discovery collaborations. In addition, we plan to use companion diagnostics where appropriate to allow us to select patients most likely to benefit from treatment with our product candidates. Our most advanced product candidates are identified below.

- **Cabiralizumab (FPA008)** is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are studying in clinical trials as a monotherapy in tenosynovial giant cell tumor, also known as diffuse pigmented villonodular synovitis, or PVNS, and in multiple cancers in combination with Bristol-Myers Squibb Company's, or BMS, PD-1 immune checkpoint inhibitor, *Opdivo*. In October 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with BMS pursuant to which we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- **Bemarituzumab (FPA144)** is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are initially developing to treat patients with gastric (stomach) or gastroesophageal junction, or GEJ, cancer and bladder cancer. In December 2017, we entered into a license and collaboration agreement, or the China collaboration agreement, with Zai Lab (Shanghai) Co., Ltd., or Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan.
- **FPA150** is a CD8 T cell checkpoint inhibitor antibody that targets B7-H4 that we are developing as a monotherapy in multiple cancers. We plan to begin a Phase 1 clinical trial for FPA150 in the first half of 2018.

We have a differentiated target discovery platform and comprehensive libraries of transmembrane and extracellular soluble proteins that we believe encompass substantially all the body's medically important targets for protein therapeutics. We have identified approximately 700 of these proteins, which we refer to as the immunome, that we believe modulate immune cell interactions and may be important in understanding and treating cancer in patients using immuno-oncology therapeutics. Our target discovery platform and capabilities position us well to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and the focus of our research activities. We are applying our biologics discovery platform, including cell-based screening, immunome-by-immunome biophysical interaction screening, *in vivo* screening, receptor-ligand matching technologies and bioinformatics, to our immuno-oncology research programs. We have identified several targets that we believe could be useful in immuno-oncology that we are actively validating. We are also conducting research to discover additional targets. We generate and preclinically test therapeutic proteins, including antibodies and fusion proteins containing or directed to the targets we discover and validate. We plan to continue to advance selected therapeutic candidates into clinical development.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations and we expect that our expenses will increase as we advance our product candidates into later stages of clinical development and increase the number of product candidates in clinical development. We have incurred losses in each period since our inception in 2002, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million upfront payment we received from BMS from our license and collaboration agreement for cabiralizumab, and the fiscal year ended December 31, 2011, due primarily to the $50.0 million upfront payment we received from GSK from our license and collaboration agreement for FP-1039. For the years ended December 31, 2017 and 2016, we reported net loss of $150.2 million and net loss of $65.7 million, respectively.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the balance sheets and the reported amounts of collaboration revenue and expenses during the reporting periods. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances at the time we make such estimates. Actual results and outcomes may differ materially from our estimates, judgments and assumptions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in the financial statements prospectively from the date of the change in estimate. Our significant accounting policies are more fully described in Note 2 to our financial statements.

We define our critical accounting policies as those accounting principles generally accepted in the United States of America that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations as well as the specific manner in which we apply those principles. We believe the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments are as follows:

Revenue Recognition

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; transfer of technology has been completed or services have been rendered; our price to the customer is fixed or determinable; and collectability is reasonably assured.

The terms of our collaborative research and development agreements include upfront and license fees, research funding, milestone and other contingent payments to us for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

Multiple-Element Revenue Arrangements. Our collaborations primarily represent multiple-element revenue arrangements. To account for these transactions, we determine the elements, or deliverables, included in the arrangement and determine which deliverables are separable for accounting purposes. We consider delivered items to be separable if the delivered items have stand-alone value to the customer. If the delivered items are separable, we allocate arrangement consideration to the various elements based on each element's relative selling price. The identification of individual elements in a multiple-element arrangement and the estimation of the selling price of each element involve significant judgment, including consideration as to whether each delivered element has standalone value to the customer. The revenue recognition standard established the hierarchy of determining the estimated selling price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, or third-party evidence of selling price if VSOE is not available, or our best estimate of selling price, if neither VSOE nor third-party evidence is available. Determining the best estimate of selling price for a deliverable requires significant judgment. We use our best estimate of selling price to estimate the selling price for licenses to our proprietary technology since the VSOE or third-party evidence of selling price for these deliverables is not available.

We recognize consideration allocated to an individual element when all other revenue recognition criteria are met for that element. Our multiple-element revenue arrangements generally include the following:

- **Exclusive Licenses**. The deliverables under our collaboration agreements generally include exclusive licenses to discover, develop, manufacture and commercialize certain compounds. To account for this element of the arrangement, we evaluate whether the exclusive license has standalone value apart from the undelivered elements to the collaboration partner based on the consideration of the relevant facts and circumstances of each arrangement, including the research and development capabilities of the collaboration partner and other market participants. We recognize arrangement consideration allocated to licenses upon delivery of the license if facts and circumstances indicate that the license has standalone value apart from the undelivered elements, which generally include research and development services. If facts and circumstances indicate that the delivered license does not have standalone value from the undelivered elements, we recognize the revenue as a combined unit of accounting.

  We have determined that some of our exclusive licenses lack standalone value apart from the related research and development services. In those circumstances, we recognize collaboration revenue from non-refundable upfront and license fees in the same manner as the undelivered item(s), which is generally the period over which we provide the research and development services. For circumstances in which upfront and license fees are contingently refundable, we defer the recognition of the upfront and license fees until such time that the consideration is considered to be fixed or determinable.

- **Research and Development Services**. The deliverables under our collaboration and license agreements generally include deliverables related to research and development services we perform on behalf of the collaboration partner. As the provision of research and development services is a part of our central operations and we are principally responsible for the performance of these services under the agreements, we recognize revenue on a gross basis for research and development services as we perform those services. Additionally, we recognize research funding related to collaborative research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms as long as we will receive payment for such services upon standard payment terms.

Milestone Revenue. Our collaboration and license agreements generally include contingent and milestone payments related to specified research, development and regulatory milestones and sales-based milestones. Research, development and regulatory contingent and milestones payments are typically receivable under our collaborations when our collaborator claims or selects a target, initiates or advances a covered product candidate in preclinical or clinical development, upon submission for marketing approval of a covered product with regulatory authorities, upon receipt of actual marketing approvals of a covered product or for additional indications, or upon the first commercial sale of a covered product. Sales-based milestones are typically receivable when annual sales of a covered product reach specified levels.

At the inception of each arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. We evaluate factors such as the scientific, regulatory, commercial and other risks that we must overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

We have elected to adopt the Accounting Standards Codification (ASC) 605-28, *Revenue Recognition — Milestone Method,* such that we recognize any payment that is contingent upon the achievement of a substantive milestone entirely in the period in which the milestone is achieved. A milestone is defined as an event that can only be achieved based in whole or in part on either our performance or the occurrence of a specific outcome resulting from our performance for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved. Therefore, a milestone does not include events for which occurrence is contingent solely on the performance of a collaborative partner. To be substantive, a milestone must meet all of the following criteria: the consideration receivable upon the achievement of the milestone is commensurate with either our performance after the agreement to achieve the milestone or the enhancement of value of delivered items as a result of a specific outcome resulting from our performance after the agreement to achieve the milestone, the consideration relates solely to past performance, and the consideration is reasonable relative to all of the deliverables and payment terms in the arrangement.

On January 1, 2018, we adopted Accounting Standards Update (ASU) 2014-09, which differs from the current accounting standard in many respects. See Note 2 to our financial statements for information regarding our adoption of ASU 2014-09.

Research and Development Expenses

Research and development expenses consist of costs we incur for our own and for sponsored and collaborative research and development activities. Expenses we incur related to collaborative research and development agreements approximate the revenue recognized under these agreements. Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, or CROs, and clinical manufacturing organizations, or CMOs, that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient enrollment and activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

We expense payments for the acquisition and development of technology as research and development costs if, at the time of payment, the technology is under development, is not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing, has not reached technical feasibility, or otherwise has no foreseeable alternative future use.

Stock-Based Compensation

We issue stock-based compensation awards in the form of restricted stock awards and stock options. We measure stock-based compensation expense related to these awards based on the fair value of the award on the date of grant and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which generally equals the vesting period.

Restricted stock awards we grant to employees generally vest over three years, though we have granted awards with shorter vesting schedules from time to time. We base stock-based compensation expense related to restricted stock awards on the closing market value of our common stock at the date of grant and recognize expense ratably over the requisite service period.

Stock options we grant to employees generally vest over four years. We have selected the Black-Scholes option pricing model to determine the fair value of stock option awards, which requires the input of various assumptions that require management to apply judgment and make assumptions and estimates, including:

- The expected term of the stock option award, which we calculate using the simplified method in accordance with the Securities and Exchange Commission Staff Accounting Bulletin Nos. 107 and 110, which calculates the expected term as the midpoint of the contractual term of the options and the ordinary vesting period, as we have insufficient historical information regarding our stock options to provide another basis for estimate. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term;
- The expected volatility of the underlying common stock, which in 2013 and prior years was estimated based on the average historical volatility of a peer group of comparable publicly traded life sciences and biotechnology companies over the expected term, as we did not have significant trading history for our common stock during those periods. We estimated volatility for options granted in 2014 and 2015 based on the average of the historical volatility of our common stock price and a peer group of public companies. We selected the peer group on the basis of operational and economic similarity with our business operations. Beginning in 2016, we estimated volatility for options based on the historical volatility of our common stock price since we became publicly traded;
- The assumed dividend yield, which is based on our expectation of not paying dividends for the foreseeable future;
- The fair value of our common stock is determined on the date of grant, as described below.

We estimated the fair value of each stock option using the Black-Scholes option-pricing model based on the date of grant of such stock option with the following assumptions:

	Year Ended December 31,		
	2017	2016	2015
Expected term (years)	5.5-6.3	5.5-6.3	5.5-6.1
Expected volatility	66-70%	69-74%	71-76%
Risk-free interest rate	1.9-2.2%	1.3%-1.8%	1.4-1.9%
Expected dividend yield	0.0%	0.0%	0.0%

We account for restricted stock awards granted to individual service providers who are not employees or directors at fair value by remeasuring the cost based on the closing stock price at the end of that reporting period.

We account for stock options granted to individual service providers who are not employees or directors at estimated fair value using the Black-Scholes option-pricing method. These stock options are subject to periodic remeasurement over the period during which the services are rendered.

For stock options granted subsequent to our September 2013 IPO, the exercise price equals the closing market price of the underlying common stock on the grant date.

Income Taxes

We account for income taxes using the liability method, under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act is generally effective on January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. Because of the impacts of the Tax Act, the SEC issued Staff Accounting Bulletin No. 118 Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) that allows us to record provisional amounts for those impacts, with the requirement that the accounting be completed in a period not to exceed one year from the date of enactment. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting for the deferred tax re-measurement to be provisional. The primary impact of the Tax Act resulted from the re-measurement of deferred tax assets and liabilities due to the change in the corporate tax rate ("Corporate Tax Rate Change"), reducing our deferred tax assets by $27.1 million with a corresponding reduction in our valuation allowance, which had no effect on our effective tax rate. Additional work will be necessary for a more detailed analysis of our deferred tax assets and liabilities as well as potential correlative adjustments. We do not expect any material subsequent adjustments to these amounts. Adjustments, if any, are not expected to have any impact to our results of operations due to our loss position and valuation allowance.

Our income tax provision for 2017 is based on the Internal Revenue Service reducing our tentative net operating loss carryback refund claim filed in March 2017. Our income tax benefit for 2016 relates to our ability to carry back 2016 losses to the 2015 tax year and to obtain a refund of taxes paid related to a prior period. Valuation allowances are provided when the expected realization of the deferred tax assets does not meet the more-likely-than-not criteria. As a result, deferred tax assets at the end of 2017 are subject to a full valuation allowance. We are required to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. It is our practice to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

New Accounting Standards

For a discussion of new accounting standards, please read Note 2 to our financial statements.

Financial Overview

Collaboration and License Revenue

We have not generated any revenue from product sales. We have derived our revenue to date from upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaboration partners and licensees. We currently have an active immuno-oncology research collaboration and cabiralizumab license and collaboration agreement with BMS. We completed the research term of our research collaboration in respiratory diseases with GSK and our fibrosis and CNS research collaboration with UCB Pharma S.A., or UCB, in July 2016 and March 2016, respectively, but are still eligible for certain contingent payments under the agreements governing these collaborations. For additional information on these collaborations, please see the section titled "Business – Collaborations" located elsewhere in this report.

Summary Revenue by Collaboration and License Agreements

The following is a comparison of collaboration and license revenue for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
(in millions)	**2017**	**2016**	**2015**
R&D Funding			
Cabiralizumab Collaboration - BMS	$ 17.8	$ 8.5	$ 3.5
Immuno-oncology Research Collaboration - BMS	2.5	3.3	2.5
Respiratory Diseases Collaboration - GSK	—	2.4	4.0
FP-1039 Product Collaboration - GSK	—	—	0.1
Fibrosis and CNS Collaboration - UCB	—	0.1	0.9
Ratable Revenue Recognition			
Cabiralizumab Collaboration - BMS	5.9	5.9	6.4
Immuno-oncology Research Collaboration - BMS	4.5	4.4	4.5
Respiratory Diseases Collaboration - GSK	—	0.8	2.7
Fibrosis and CNS Collaboration - UCB	3.0	3.0	3.0
Milestone and Contingent Payments			
Immuno-oncology Research Collaboration - BMS	5.0	—	—
Respiratory Diseases Collaboration - GSK	0.5	1.8	0.6
Fibrosis and CNS Collaboration - UCB	0.3	0.4	0.1
Other License Revenue			
Cabiralizumab Collaboration - BMS	—	—	350.0
bluebird bio License Agreement	—	0.1	1.5
Total	$ 39.5	$ 30.7	$ 379.8

We expect that any revenue we generate will fluctuate from period to period as a result of the timing and amount of milestones and other payments from our existing collaborations and licenses or entry into any new collaboration or license agreements.

BMS License and Collaboration Agreement

In October 2015, we entered into the cabiralizumab collaboration agreement with BMS, pursuant to which we granted to BMS an exclusive, worldwide license to develop and commercialize certain CSF1R antibodies, including cabiralizumab, and all modifications, derivatives, fragments or variants of such antibodies, each of which we refer to as a licensed antibody. The cabiralizumab collaboration agreement superseded the clinical trial collaboration agreement that we entered into with BMS in November 2014, or the clinical trial collaboration agreement. We continue to conduct the current Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining *Opdivo*® (nivolumab) with cabiralizumab in multiple tumor types, or the Phase 1a/1b trial, that we commenced under the clinical trial collaboration agreement. BMS bears all costs and expenses relating to the Phase 1a/1b trial, including manufacturing costs for the supply of cabiralizumab, except that we are responsible for our own internal costs, including internal personnel costs.

Pursuant to the cabiralizumab collaboration agreement, BMS obtained license rights and paid us an upfront fee of $350.0 million, which we fully recognized as revenue in the fourth quarter of 2015. We identified the license to BMS and the associated transfer of manufacturing and other know-how as substantive deliverables under this agreement. We fully delivered these deliverables as of December 31, 2015. Additionally, with respect to each licensed product under the collaboration, we will be eligible to receive up to (i) $505.0 million in specified developmental and regulatory milestone payments for all combination therapies of such licensed product with *Opdivo*; (ii) $542.5 million in specified developmental and regulatory milestone payments for combination therapies of such licensed product with one or more of BMS' or our proprietary products, at least one of which is not *Opdivo*, in the field of oncology; and (iii) $340.0 million in specified developmental and regulatory milestone payments for therapeutic uses of such licensed product in PVNS and non-oncology indications.

BMS will also be obligated to pay us, with respect to each licensed product in each country, tiered percentage royalties ranging from the high teens to the low twenties, subject to reduction in certain circumstances, on worldwide net sales of such licensed product until the latest of (i) the expiration of certain patents covering such licensed product in such country, (ii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such country, (iii) the date of the first commercial sale in such country of a biosimilar product with respect to such licensed product or (iv) 12 years after the first commercial sale of such licensed product in such country. Under the cabiralizumab collaboration agreement, BMS will be obligated to pay us an additional low single-digit percentage royalty on net sales in the U.S. in the event we exercise our co-promotion option. We cannot determine the date on which BMS's potential royalty payment obligations to us would expire because BMS has not yet developed any licensed products under the agreement and therefore we cannot identify the date of the first commercial sale or any related patents covering or regulatory exclusivity periods with respect to such licensed product.

Under the original terms of the 2014 clinical trial collaboration agreement, BMS paid us an upfront fee of $30.0 million in December 2014. At that time, the $30.0 million upfront fee was contingently refundable. Since the upfront fee was not considered to be fixed or determinable, we recorded it as deferred revenue. Upon signing the cabiralizumab collaboration agreement, the $30.0 million upfront fee was no longer refundable. Accordingly, we began recognizing revenue ratably, using a cumulative catch up method, over the estimated performance period through 2019. During 2017, we recognized $23.7 million of revenue under the cabiralizumab collaboration agreement, including $17.8 million of revenue for research funding. As of December 31, 2017, we had deferred revenue of $11.8 million related to the cabiralizumab collaboration agreement, which we expect to recognize through March 2019.

Zai Lab China License and Collaboration Agreement

In December 2017, we entered into a license and collaboration agreement with Zai Lab, or the China collaboration agreement, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab, and all fragments, conjugates, derivatives and modifications thereof, or the licensed antibody, in China, Hong Kong, Macau, and Taiwan, each a region, and collectively, the territory.

Under the terms of the China collaboration agreement, Zai Lab will be responsible, at its expense, for (i) developing and commercializing products containing the licensed antibody, each, a licensed product, under a territory development plan and (ii) performing certain development activities to support our global development and registration of licensed products, including the Phase 3 portion of our Phase 1/3 global registrational trial to test bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, or mFOLFOX6, as front-line treatment of patients with gastric or gastroesophageal junction, or GEJ, cancer that overexpresses FGFR2b, or the FIGHT trial, in the territory, under a global development plan.

Pursuant to the China collaboration agreement, with respect to each licensed product, we are eligible to receive up to $39 million of specified development, regulatory, and commercial milestone payments. Zai Lab will also be obligated to pay us a royalty, on a licensed product-by-licensed product and region-by-region basis, in the high teens or low twenties, depending on the number of patients Zai Lab enrolls in the FIGHT trial, subject to reduction in certain circumstances, on net sales of each licensed product in each region until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region. We cannot determine the date on which Zai Lab's potential royalty payment obligations to us would expire because Zai Lab has not yet developed any licensed products under the China collaboration agreement and we therefore cannot at this time identify the date of the first commercial sale or any related patents covering or regulatory exclusivity periods with respect to such licensed product.

Under the China collaboration agreement, provided that Zai Lab enrolls and treats a specified number of patients in the FIGHT trial in China, Zai Lab is eligible to receive a low single-digit percentage royalty, on a licensed product-by-licensed product basis on net sales of a licensed product outside the territory until the 10th anniversary of the first commercial sale of each such licensed product outside the territory.

Under the China collaboration agreement, we recorded a $4.2 million receivable in December 2017 for the non-refundable and non-creditable upfront fee of $5.0 million (net of expected value-added tax withholdings of $0.8 million). We applied ASC 605-25, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for this agreement. In accordance with this guidance, we concluded that the agreement consideration shall be recognized over the period that the development services are provided under a global development plan. As of December 31, 2017, services under the global development plan had not begun. Accordingly, as of December 31, 2017, we had deferred revenue relating to the collaboration of $4.2 million, which we expect to recognize beginning in 2018 over the estimated performance period.

BMS Immuno-Oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement, or the immuno-oncology research collaboration with BMS. The initial three-year research term of the immuno-oncology research collaboration ended in March 2017. In each of December 2016 and December 2017, BMS exercised its option to extend the research term for an additional year to March 2018 and March 2019, respectively.

We received an upfront payment of $20.0 million in April 2014 in connection with our entry into the immuno-oncology research collaboration. Through December 31, 2017, we received $11.6 million of research funding.

We are eligible to receive up to $240.0 million per collaboration target in specified developmental, regulatory and commercialization contingent payments. These payments are comprised of aggregate developmental contingent payments of up to $53.0 million, aggregate regulatory contingent payments of up to $74.0 million and aggregate commercialization contingent payments of up to $113.0 million. We are also eligible to receive up to $60.0 million in sales-based contingent payments per collaboration product. In December 2017, we recognized $5.0 million related to a developmental contingent payment, which we received in February 2018.

In connection with the immuno-oncology research collaboration, BMS purchased 994,352 shares of our common stock at a price per share of $21.16, for an aggregate purchase price of $21.0 million. We determined that the purchase price of $21.16 per share exceeded the fair value of our common stock by $2.4 million and, therefore, recorded the $2.4 million as deferred revenue, which we recognized in the same manner as the $20.0 million upfront payment and allocated to the deliverables under the collaboration.

During 2017, we recognized $12.0 million of revenue under the immuno-oncology research collaboration, including $5.0 million of contingent payments. As of December 31, 2017, we had deferred revenue relating to the immuno-oncology research collaboration of $6.3 million, which we expect to recognize through March 2019.

GSK Respiratory Diseases Collaboration

In April 2012, we entered into research collaboration and license agreement, or the respiratory diseases collaboration, with GSK to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease, or COPD, function with a particular focus on identifying novel protein therapeutics and antibody targets. We conducted six customized cell-based screens of our protein library under this agreement. Under the terms of the agreement, GSK paid us an upfront technology access payment of $7.5 million at the inception of the respiratory diseases collaboration. In addition, GSK agreed to pay us $10.5 million of research funding over the research program term. Pursuant to the respiratory diseases collaboration, GSK exercised its option to expand the research plan to include two additional screening assays. In January 2016, we amended our respiratory diseases collaboration to extend the research term by three months to July 2016 to allow additional validation of the protein targets we discovered and to increase the research funding that GSK was obligated to pay us under the collaboration by $0.7 million. We had fully received all research funding as of December 31, 2016.

We are eligible to receive up to $124.3 million in potential target evaluation and selection fees and contingent payments with respect to each protein target for which GSK will have sole responsibility for the further development and commercialization of products that incorporate or target such protein target, or a track 1 target. GSK is also obligated to pay us tiered low- to mid-single digit royalties on global net sales for each product that incorporates or targets each such track 1 target. We are eligible to receive up to $193.8 million in potential target evaluation and selection fees and contingent payments with respect to each protein target for which we will develop biologics that incorporate or target the protein targets through to clinical proof of mechanism in either a phase 1 clinical trial or a phase 2 clinical trial, or a track 2 target. GSK is also obligated to pay us tiered high-single to low-double digit royalties on global net sales for each product that incorporates or targets each such track 2 target. During 2017, we recognized $0.5 million of revenue under the respiratory diseases collaboration from target and selection fees.

We fully recognized the deferred revenue in 2016 following the completion of our obligation to provide research services.

UCB Fibrosis and CNS Collaboration

In March 2013, we entered into a research collaboration and license agreement, or the fibrosis and CNS collaboration, with UCB to identify innovative biologics targets and therapeutics in the areas of immunologic diseases and central nervous system disorders. The research term of the fibrosis and CNS collaboration ended in March 2016.

We are eligible to receive up to $92.2 million in potential evaluation and selection fees and contingent payments with respect to each protein target for which UCB elects to obtain an exclusive license, comprising aggregate target evaluation and selection fees of up to $0.4 million, preclinical and development-related contingent payments of up to $11.8 million, regulatory-related contingent payments of up to $20.0 million and commercial-related contingent payments of up to $60.0 million. UCB is also obligated to pay us tiered low- to mid-single digit royalties on global net sales for each product that incorporates or targets the protein. During 2017, we received $0.3 million in target evaluation and selection fees.

At the inception of the fibrosis and CNS collaboration, UCB made an upfront payment to us of $6.0 million and agreed to pay us $6.6 million for technology fees and $2.0 million for research funding. As of December 31, 2015, we fully collected on the technology access fees and research funding under the fibrosis and CNS collaboration. During 2017, we recognized $3.3 million of revenue under the fibrosis and CNS collaboration. As of December 31, 2017, we had deferred revenue of $0.6 million related to this agreement.

Our initial research activities under this agreement were completed in March 2016. Upon the completion of those research activities, UCB has up to a two-year evaluation period during which we may be obligated to perform additional services at the request of UCB.

bluebird bio, Inc. License Agreement

In May 2015, we entered into an exclusive license agreement, referred to as the bluebird license agreement, with bluebird bio, Inc., or bluebird, under which we licensed to bluebird human antibodies to an undisclosed cancer target to research, develop and commercialize chimeric antigen receptor, or CAR, T cell therapies using such antibodies. Under the bluebird license agreement, bluebird paid us a $1.5 million upfront fee in 2015.

There are no other deliverables under the agreement other than the license grant. We recognized the $1.5 million upfront fee as revenue upon delivery of the license grant, which was completed in 2015.

In January 2017, bluebird delivered to us written notice of termination of the license agreement. Pursuant to the terms of the license agreement, the termination became effective on May 17, 2017. Following termination, bluebird had no future payment obligations to us in connection with the license agreement.

Research and Development

Research and development expenses consist of costs we incur in performing internal and collaborative research and development activities. Expenses incurred related to collaborative research and development agreements generally approximate the revenue recognized under these agreements. Research and development costs consist of salaries and benefits, including associated stock-based compensation, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities, including manufacturing, on our behalf.

We are conducting research and development activities on several disease targets and product candidates.

We have a research and development team that designs, manages and evaluates the results of all our research and development activities. We conduct most of our core target discovery and early research and preclinical activities internally and rely more heavily on third-parties, such as clinical research organizations, or CROs, and clinical manufacturing organizations, or CMOs, for the execution of our IND-enabling and development activities, such as GLP toxicology studies, drug substance and drug product manufacturing, lab-developed test and companion diagnostic development, and the conduct of our clinical trials. We account for research and development costs on a program-by-program basis. In the early phases of research and discovery, our costs are often related to conducting target screening, evaluation and validation activities and conducting research activities with respect to selected targets and target pathways and are not necessarily allocable to a specific program. We assign costs for such activities to a distinct non-program related project code. We allocate research and development management, overhead, common usage laboratory supplies and facility costs on a full-time equivalent basis.

The following is a comparison of research and development expenses for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
(in millions)	**2017**	**2016**	**2015**
Development programs:			
Cabiralizumab	$ 29.5	$ 19.9	$ 18.8
Bemarituzumab	34.8	21.9	7.8
FPA150	19.0	—	—
FP-1039	1.6	0.3	0.2
Subtotal development programs	84.9	42.1	26.8
Preclinical programs	32.5	18.3	12.9
Discovery collaborations	4.0	8.1	17.9
Early research and discovery	29.5	25.6	12.6
Total research and development expenses	$ 150.9	$ 94.1	$ 70.2

We expect that most of the research and development expenses we incur will continue to relate to activities to support our cabiralizumab, bemarituzumab, and FPA150 development programs and our immuno-oncology preclinical, research and discovery efforts. We expect our research and development expenses to increase as we advance our current product candidates through clinical development and additional product candidates into preclinical and clinical development, in particular as we increase the number and size of our clinical trials and as we expand our internal immuno-oncology preclinical, research and discovery efforts. We expect that our cabiralizumab and bemarituzumab development-related expenses will increase at a faster rate than our other internal program research and development expenses as we advance cabiralizumab through our Phase 2 clinical trial in PVNS and complete our Phase 1a/1b clinical trial in various multiple cancers, and as we advance bemarituzumab in our Phase 1 clinical trial in gastric and bladder cancers, our Phase 1 clinical trial in Japan and our Phase 1/3 FIGHT trial to evaluate bemarituzumab in combination with standard of care chemotherapy. We expect our preclinical program expenses to continue to increase as we initiate additional therapeutic molecule campaigns and advance our preclinical programs into and through IND-enabling studies.

The process of conducting preclinical studies and clinical trials necessary to obtain regulatory approval is costly and time-consuming. We or our partners may never succeed in achieving marketing approval for any of our drug candidates. Numerous factors may affect the probability of success for each drug candidate, including preclinical data, clinical data, competition, manufacturing capability and commercial viability.

The successful development of our drug candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each drug candidate and are difficult to predict for each product. Given the uncertainty associated with clinical trial enrollments and the risks inherent in the development process, we are unable to determine the duration and completion costs of the current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our drug candidates. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the outcome of research, nonclinical and clinical activities of each drug candidate, as well as ongoing assessments as to each drug candidate's commercial potential. We will need to raise additional capital or may seek additional product collaborations in the future in order to complete the development and commercialization of our drug candidates.

General and Administrative

General and administrative expenses consist primarily of salaries and related benefits, including associated stock-based compensation, related to our executive, finance, legal, business development, human resource and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing and tax and legal services, including intellectual property-related legal services.

We expect our general and administrative expenses to increase due to expanded operations to support our increased research and development activities. Also, we expect our intellectual property-related legal expenses, including those related to preparing, filing and prosecuting patent applications and maintaining patents, to increase as our intellectual property portfolio expands.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents and marketable securities.

Other (Expense) Income, Net

Other (expense) income, net consists primarily of the gain or loss on the disposal of property and equipment, if any.

Results of Operations

Comparison for the Years Ended December 31, 2017 and 2016

(in millions)	Year Ended December 31, 2017	2016
Collaboration and license revenue	$ 39.5	$ 30.7
Operating expenses:		
Research and development	150.9	94.1
General and administrative	40.0	35.8
Total operating expenses	190.9	129.9
Interest income	3.0	2.5
Other expense, net	(0.1)	—
Loss before income tax	(148.5)	(96.7)
Income tax benefit (provision)	(1.7)	31.0
Net loss	$ (150.2)	$ (65.7)

Collaboration and License Revenue

Collaboration and license revenue increased by $8.8 million, or 28.7%, to $39.5 million in 2017 from $30.7 million in 2016. This increase was primarily due to the $9.3 million increase in revenue from our cabiralizumab collaboration agreement with BMS and a $4.3 million increase in revenue, primarily from a $5.0 million developmental contingent payment from our immuno-oncology research collaboration with BMS, offset by a $4.5 million decrease in revenue recognized under our respiratory diseases collaboration with GSK as the research term ended in July 2016.

Research and Development

Our research and development expenses increased by $56.8 million, or 60.4%, to $150.9 million in 2017 from $94.1 million in 2016. This increase was primarily due to an increase of $14.2 million to further advance our preclinical programs toward filing INDs. There was also an increase of $9.6 million to advance cabiralizumab in our Phase 2 clinical trial in PVNS and our Phase 1a/1b clinical trial in immuno-oncology, a $12.9 million increase to advance our bemarituzumab development program and a $13.0 million increase to advance our FPA150 development program, which was included in preclinical programs before 2017.

General and Administrative

Our general and administrative expenses increased by $4.2 million, or 11.7%, to $40.0 million in 2017 from $35.8 million in 2016, primarily due to a $1.4 million increase in facilities expense related to our new corporate office and laboratory facility, a $1.0 million increase in stock-based compensation costs and a $0.7 million increase in spending associated with the development of our commercialization strategy.

Income Tax Benefit (Provision)

We recognized a tax expense of $1.7 million in 2017 related to deficiency interest based on the Internal Revenue Service reducing our tentative net operating loss carryback refund claim filed in March 2017. Our income tax benefit for 2016 relates to our ability to carry back 2016 losses to the 2015 tax year and to obtain a refund of taxes paid related to a prior period.

Comparison of the Years Ended December 31, 2016 and 2015

(in millions)	Year Ended December 31, 2016	2015
Collaboration and license revenue	$ 30.7	$ 379.8
Operating expenses:		
Research and development	94.1	70.2
General and administrative	35.8	22.6
Total operating expenses	129.9	92.8
Interest income	2.5	0.5
Income (loss) before income tax	(96.7)	287.5
Income tax benefit (provision)	31.0	(37.8)
Net income (loss)	$ (65.7)	$ 249.6

Collaboration and License Revenue

Collaboration and license revenue decreased by $349.1 million, or 91.9%, to $30.7 million in 2016 from $379.8 million in 2015. This decrease was primarily due to the $350.0 million upfront payment we received in 2015 from BMS under our cabiralizumab collaboration that we entered into in October 2015.

Research and Development

Our research and development expenses increased by $23.9 million, or 34.0%, to $94.1 million in 2016 from $70.2 million in 2015. This increase was primarily due to a $14.1 million increase related to advancing bemarituzumab through our Phase 1 clinical trial, a $13.0 million increase in early research and discovery expenses to discover and validate immuno-oncology targets and generate and select new therapeutic candidates and a $5.4 million increase in preclinical program expenses to advance selected therapeutic candidates into IND-enabling activities, which was offset by a $9.8 million decrease in our discovery collaboration costs.

General and Administrative

Our general and administrative expenses increased by $13.2 million, or 58.4%, to $35.8 million in 2016 from $22.6 million in 2015, primarily due to an $11.9 million increase in payroll and stock-based compensation costs.

Income Tax Benefit (Provision)

We recognized a tax benefit of $31.0 million in 2016. Our provision for income taxes was $37.8 million in 2015 due to taxable income generated in 2015. After the carryback of our 2016 net operating losses to 2015, we have maximized our ability to obtain a refund of prior income taxes paid. The resulting amount of income tax for the 2015 period, after the carryback, relates to minimum taxes.

Liquidity and Capital Resources

As of December 31, 2017, we had $292.7 million in cash and cash equivalents and marketable securities invested in a U.S. Treasury money market fund and U.S. Treasury securities with maturities of 14 months or less.

In January 2018, we closed on a public offering of 5,897,435 shares of our common stock, which included 769,230 shares sold upon the underwriters' full exercise of their option to purchase additional shares, resulting in aggregate gross proceeds of $115 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, and net proceeds of approximately $108 million after deducting these amounts.

In addition to our existing cash and cash equivalents, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain nonclinical, clinical, regulatory and sales-based events and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of these milestones is primarily dependent upon the outcome of our collaborators' and licensees' research and development activities and is uncertain at this time. Our rights to payment under our collaboration and license agreements are our only committed external sources of funds.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical and preclinical research and development services, including clinical trial, manufacturing, laboratory and related supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and CMOs provides us with flexibility in managing our spending and limits our cost commitments at any point in time.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs primarily through equity financings and collaboration and licensing arrangements. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone or royalty payments under our agreements with them, we will not have any committed external sources of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration or licensing arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of December 31, 2017 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months.

Cash Flows

The following is a summary of cash flows for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
(in millions)	**2017**	**2016**	**2015**
Net cash provided by (used in) operating activities	$ (112.2)	$ (79.8)	$ 289.1
Net cash provided by (used in) investing activities.....	174.2	(53.7)	(238.2)
Net cash provided by (used in) financing activities	(9.9)	(8.9)	83.8

Net Cash Provided by (Used in) Operating Activities

Net cash used in operating activities was $112.2 million during the year ended December 31, 2017. The net loss of $150.2 million was offset by non-cash charges of $34.2 million for stock-based compensation expense, $1.6 million for amortization of premium on marketable securities and $2.5 million for depreciation and amortization. The net change in operating assets and liabilities was $0.4 million.

Net cash used in operating activities was $79.8 million during the year ended December 31, 2016. The net loss of $65.7 million was offset by non-cash charges of $32.9 million for stock-based compensation expense, $15.1 million for deferred income taxes, $4.2 million for amortization of premium on marketable securities and $1.7 million for depreciation and amortization. The net change in operating assets and liabilities was $71.1 million, which is primarily due to a $52.8 million decrease in income tax payable and a $16.8 million decrease in deferred revenue from the recognition of revenue in the current period for cash received from collaboration partners in prior periods.

Net cash provided by operating activities was $289.1 million during the year ended December 31, 2015. Primarily due to the $350.0 million upfront payment from BMS for the cabiralizumab collaboration, we had net income of $249.6 million. Non-cash charges were $1.7 million for depreciation and amortization, $11.5 million for stock-based compensation expense, $2.0 million for amortization of premium on marketable securities, $3.1 million from excess tax benefits from employee equity incentive plans and $15.1 million in deferred income taxes. The net change in operating assets and liabilities was $36.2 million, which is primarily due to income taxes payable.

Net Cash Provided by (Used in) Investing Activities

Net cash provided in investing activities in 2017 was primarily due to maturities of marketable securities exceeding purchases of such marketable securities. Purchases of property and equipment was $4.9 million, $3.0 million and $2.4 million during the years ended December 31, 2017, 2016 and 2015, respectively. The property and equipment purchases consisted primarily of purchases of laboratory equipment to support our research and development activities. We expect a significant increase in our capital expenditures in 2018 as we will be paying for our share of tenant improvements to construct our new corporate office and laboratory facility that we relocated to in December 2017.

Net Cash Provided by (Used in) Financing Activities

Net cash used in financing activities was $9.9 million during the year ended December 31, 2017, primarily related to $13.9 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards offset by $4.0 million received from employee stock option exercises and employee stock purchases in 2017.

Net cash used in financing activities was $8.9 million during the year ended December 31, 2016, primarily related to $14.1 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards and $3.1 million from excess tax benefits from employee equity incentive plans, offset by $8.3 million received from employee stock option exercises and employee stock purchases in 2016.

Net cash provided by financing activities was $83.8 million during the year ended December 31, 2015, primarily related to the net proceeds of $78.7 million from our 2015 underwritten public offering. Additionally, we received $5.1 million from employee stock option exercises and employee stock purchases in 2015.

Contractual Obligations and Contingent Liabilities

The following table summarizes our significant contractual obligations as of December 31, 2017:

(in millions) Contractual Obligations	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating leases [1]	$ 77,932	$ 5,092	$ 14,299	$ 15,311	$ 43,230
Total obligations	$ 77,932	$ 5,092	$ 14,299	$ 15,311	$ 43,230

[1] Represents future minimum lease payments under non-cancelable operating leases in effect as of December 31, 2017 for our corporate office and laboratory facility in South San Francisco, California. The minimum lease payments above do not include common area maintenance charges or real estate taxes.

The contractual obligations table above does not include any potential future milestone payments to third-parties as part of certain collaboration and in-licensing agreements, which could total up to $133.3 million, or any potential future royalty payments we may be required to make under our license agreements, including with:

- Galaxy, under which we were granted an exclusive worldwide license for the development, manufacturing and commercialization of anti-FGFR2b antibodies;
- The Regents of the University of California, under which we were granted an exclusive license under certain patent rights related to our FP-1039 program;
- BioWa-Lonza, under which we were granted a non-exclusive license to use their Potelligent® CHOK1SV technology, including the CHOK1SV cell line, and a non-exclusive license to related know-how and patents; and
- Adimab, under which Adimab conducted programs to discover and evaluate antibodies directed against targets of interest to us and under which we licensed certain of these antibodies

Payments under these agreements are not included in the above contractual obligations table due to the uncertainty of the occurrence of the events requiring payment under these agreements, including our share of potential future milestone and royalty payments. These payments generally become due and payable only upon achievement of certain clinical development, regulatory or commercial milestones.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. As of December 31, 2017, we had cash and cash equivalents and marketable securities of $292.7 million consisting of bank deposits, interest-bearing money market accounts and U.S. treasuries. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2017, our cash equivalents and marketable securities have an average maturity of approximately six months and the longest maturity is 14 months. Due to the short-term duration and the lower risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

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

As of December 31, 2017, management, with the participation of our disclosure committee, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2017, the design and operation of our disclosure controls and procedures were 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 such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our 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 U.S. generally accepted accounting principles, or GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our 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.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework), or COSO. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework issued by COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2017.

Our independent registered public accounting firm, Ernst & Young LLP, audited the effectiveness of our internal control over financial reporting. Ernst & Young LLP has issued their attestation report which is included herein.

Changes in Internal Control over Financial Reporting.

There have been no significant changes in our internal control over financial reporting during our most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Five Prime Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Five Prime Therapeutics, Inc. (the "Company") internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Five Prime Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of the Company as of December 31, 2017 and 2016, and the related statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017 and the related notes, and our report dated February 27, 2018 expressed an unqualified opinion thereon.

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 included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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/ Ernst & Young LLP
San Francisco, California
February 27, 2018

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Information About Our Board of Directors" and "Information About Our Executive Officers Who Are Not Directors," "Corporate Governance," "Corporate Governance – Code of Business Conduct and Ethics," "Section 16(a) Beneficial Ownership Reporting Compliance," "Corporate Governance – Committees of the Board of Directors – Nominating and Corporate Governance Committee," "Corporate Governance – Committees of the Board of Directors – Audit Committee" and "Corporate Governance – Committees of the Board of Directors – Compensation Committee" in our Proxy Statement.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Executive Compensation," "Director Compensation" and "Committees of the Board of Directors — Compensation Committee Interlocks and Insider Participation" in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Securities Authorized For Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Corporate Governance – Board of Directors Independence" and "Transactions With Related Persons" in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to the information set forth in the sections titled "Independent Registered Public Accounting Firm Fees and Services" in our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(a)(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(a)(3) Exhibits

The exhibits required to be filed as part of this report are listed in the Exhibit List attached hereto and are incorporated herein by reference.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the company's Current Report on Form 8-K (File No. 001-36070), filed with the SEC on September 23, 2013).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.4 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
4.1	Specimen common stock certificate (incorporated herein by reference to Exhibit 4.1 to the company's Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on September 4, 2013).
10.1+	2002 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.2+	Form of Option Agreement under 2002 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.3+	2010 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.4+	Form of Option Agreement under 2010 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.5+	2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 4.8 to the company's Registration Statement on Form S-8 (File No. 333-191700), filed with the SEC on October 11, 2013).
10.6+	Amendment No. 1 to Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on November 6, 2017)
10.7+	Form of Incentive Stock Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.7 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).

Exhibit No.	Description
10.8+	Form of Non-Qualified Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.8 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.9+	Form of Restricted Stock Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.9 to the company's Registration Statement on Form S-1 (File No. 333-193491), filed with the SEC on January 22, 2014).
10.10+	2013 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.11 to the company's Registration Statement on Form S-8 (File No. 333-191700), filed with the SEC on October 11, 2013).
10.11+	Offer Letter Agreement by and between the company and Aron M. Knickerbocker, dated as of October 18, 2017 (incorporated herein by reference to Exhibit 10.2 to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on November 6, 2017).
10.12+	Offer Letter Agreement by and between the company and Marc L. Belsky, dated as of September 3, 2009 (incorporated herein by reference to Exhibit 10.12 to the company's Registration Statement on Form S-1 (File No. 333-193491), filed with the SEC on January 22, 2014).
10.13+	Offer Letter Agreement by and between the company and Francis Sarena, dated as of December 2, 2010 (incorporated herein by reference to Exhibit 10.10 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.14+	Offer Letter Agreement by and between the company and Robert Sikorski, dated as of August 22, 2014 (incorporated herein by reference to Exhibit 10.14 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.15+	Confidential Resignation Agreement and General Release of Claims by and between the Company and Robert Sikorski, dated as of April 30, 2017 (incorporated herein by reference to Exhibit 10.1 to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on May 5, 2017).
10.16+	Offer Letter Agreement by and between the company and Kevin Baker, dated as of January 7, 2016 (incorporated herein by reference to Exhibit 10.15 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.17+	Offer Letter Agreement by and between the company and Lewis T. Williams, dated as of November 17, 2017.
10.18+	Offer Letter by and between the company and Helen Collins, dated as of May 12, 2016.
10.19+	Executive Severance Benefits Agreement by and between the company and Lewis T. Williams, dated as of April 19, 2007 (incorporated herein by reference to Exhibit 10.11 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.20+	Executive Severance Benefits Agreement by and between the company and Aron M. Knickerbocker, dated as of December 30, 2009 (incorporated herein by reference to Exhibit 10.12 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.21+	Amendment No. 1 to the Executive Severance Benefits Agreement by and between the company and Aron M. Knickerbocker, effective December 5, 2012 (incorporated herein by reference to Exhibit 10.13 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.22+	Amendment No. 2 to the Executive Severance Benefits Agreement by and between the company and Aron M. Knickerbocker, effective October 18, 2017 (incorporated herein by reference to Exhibit 10.3 to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on November 6, 2017).
10.23+	Executive Severance Benefits Agreement by and between the company and Marc L. Belsky, dated as of December 30, 2009 (incorporated herein by reference to Exhibit 10.17 to the company's Registration Statement on Form S-1 (File No. 333-193491), filed with the SEC on January 22, 2014).

Exhibit No.	Description
10.24+	Executive Severance Benefits Agreement by and between the company and Francis Sarena, dated as of February 18, 2011 (incorporated herein by reference to Exhibit 10.14 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.25+	Amendment No. 1 to the Executive Severance Benefits Agreement by and between the company and Francis Sarena, effective May 8, 2013 (incorporated herein by reference to Exhibit 10.15 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.26+	Amendment No. 1 to the Executive Severance Benefits Agreement by and between the company and Marc Belsky, effective January 16, 2014 (incorporated herein by reference to Exhibit 10.18 to the company's Registration Statement on Form S-1 (File No. 333-193491), filed with the SEC on January 22, 2014).
10.27+	Executive Severance Benefits Agreement by and between the company and Robert Sikorski, dated as of September 17, 2014 (incorporated herein by reference to Exhibit 10.23 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.28+	Amendment No. 1 to the Executive Severance Benefits Agreement by and between the company and Robert Sikorski, dated as of January 21, 2016 (incorporated herein by reference to Exhibit 10.24 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.29+	Executive Severance Benefits Agreement by and between the company and Kevin P. Baker, dated as of February 1, 2016 (incorporated herein by reference to Exhibit 10.25 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.30+	Executive Severance Benefits Agreement by and between the company and Helen Collins, dated as of March 20, 2017.
10.31+	Form of Retention Award Agreement (incorporated herein by reference to Exhibit 10.1 to the company's Current Report on Form 8-K (File No. 001-36070), filed with the SEC on May 4, 2015).
10.32+	Form of Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.27 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.33+	Annual Bonus Plan, effective August 21, 2017 (incorporated herein by reference to Exhibit 10.1 to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on November 6, 2017).
10.34+	Annual Bonus Plan, effective January 1, 2018.
10.35+	Form of Indemnification Agreement by and between the company and each of its directors and officers (incorporated herein by reference to Exhibit 10.16 to the company's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on August 16, 2013).
10.36	Lease by and between the company and HCP Oyster Point III LLC, dated as of December 12, 2016 (incorporated herein by reference to Exhibit 10.34 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on February 24, 2017).
10.37†	Exclusive License Agreement by and between the company and Galaxy Biotech, LLC, dated as of December 22, 2011 (incorporated herein by reference to Exhibit 10.23 to the company's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on August 16, 2013).
10.38†	Amendment to the Exclusive License Agreement by and between the company and Galaxy Biotech, LLC, dated as of May 16, 2016 (incorporated herein by reference to Exhibit 10.1 to the company's quarterly report on Form 10-Q (File No. 001-36070), filed with the SEC on August 5, 2016).
10.39††	Amendment No. 2 to the Exclusive License Agreement by and between the company and Galaxy Biotech, LLC, dated as of May 30, 2017.

Exhibit No.	Description
10.40†	Non-Exclusive License Agreement by and among the company, BioWa, Inc. and Lonza Sales AG, dated as of February 6, 2012 (incorporated herein by reference to Exhibit 10.30 to the company's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on August 16, 2013).
10.41†	Research Collaboration and License Agreement, dated as of March 14, 2014, by and between the company and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.1 to Amendment No. 1 the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on August 26, 2014).
10.42†	Amendment No. 1 to the Research Collaboration and License Agreement, dated as of January 21, 2016, by and between the company and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.47 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on March 11, 2016).
10.43†	License and Collaboration Agreement, dated as of October 14, 2015, by and between the company and Bristol-Myers Squibb Company (incorporated herein by reference to Exhibit 10.49 to the company's Annual Report on Form 10-K (File No. 001-36070), filed with the SEC on March 11, 2016).
10.44††	License and Collaboration Agreement, dated as of December 19, 2017, by and between the company and Zai Lab (Shanghai) Co., Ltd.
21.1	Subsidiaries of the company (incorporated herein by reference to Exhibit 21.1 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
23.1*	Consent of Independent Registered Accounting Firm.
24.1	Power of Attorney (included on the signature page to this report).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of 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 Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

\+ Indicates a management contract or compensatory plan.

† Confidential treatment has been granted for certain portions of this exhibit. These portions have been omitted and filed separately with the SEC.

†† Confidential treatment has been requested for certain portions of this exhibit. These portions have been omitted and filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Five Prime Therapeutics, Inc.
(Registrant)

Date: February 27, 2018

/s/ Aron Knickerbocker
Aron Knickerbocker
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 27, 2018

/s/ Marc L. Belsky
Marc L. Belsky
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Aron Knickerbocker and Francis W. Sarena, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this 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, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K 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/ Aron Knickerbocker **Aron Knickerbocker**	Chief Executive Officer, President and Director (Principal Executive Officer)	February 27, 2018
/s/ Marc. L. Belsky **Marc L. Belsky**	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2018
/s/ Lewis T. Williams, M.D., Ph.D. **Lewis T. Williams, M.D., Ph.D.**	Executive Chairman and Director	February 27, 2018
/s/ Franklin M. Berger **Franklin M. Berger**	Director	February 27, 2018
/s/ Fred E. Cohen, M.D., D.Phil. **Fred E. Cohen, M.D., D.Phil.**	Director	February 27, 2018

Signature	Title	Date
/s/ Kapil Dhingra, M.B.B.S. **Kapil Dhingra, M.B.B.S.**	Director	February 27, 2018
/s/ Garry Nicholson **Garry Nicholson**	Director	February 27, 2018
/s/ Sheila Gujrathi, M.D. **Sheila Gujrathi, M.D.**	Director	February 27, 2018
/s/ Peder K. Jensen, M.D. **Peder K. Jensen, M.D.**	Director	February 27, 2018
/s/ Mark McDade **Mark McDade**	Director	February 27, 2018
/s/ William Ringo **William Ringo**	Director	February 27, 2018

FIVE PRIME THERAPEUTICS, INC.
FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2017, 2016 AND 2015

Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Five Prime Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Five Prime Therapeutics, Inc. (the "Company") as of December 31, 2017 and 2016, and the related statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 27, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2003

San Francisco, California

February 27, 2018

FIVE PRIME THERAPEUTICS, INC.

Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2017	**2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 59,790	$ 7,653
Marketable securities	232,900	414,095
Receivable from collaborative partners	13,133	3,959
Income tax receivable	—	4,670
Prepaid and other current assets	5,367	9,748
Total current assets	311,190	440,125
Restricted cash	1,543	1,543
Property and equipment, net	30,762	6,207
Other long-term assets	552	406
Total assets	$ 344,047	$ 448,281
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,237	$ 334
Accrued personnel-related expenses	7,156	7,957
Other accrued liabilities	27,519	15,435
Deferred revenue, current portion	12,713	14,150
Deferred rent, current portion	1,356	865
Total current liabilities	50,981	38,741
Deferred revenue, long-term portion	10,223	17,856
Deferred rent, long-term portion	17,641	—
Other long-term liabilities	—	109
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 28,982,056 issued and 28,178,639 outstanding at December 31, 2017. 28,550,006 issued and 27,509,077 outstanding at December 31, 2016	28	27
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Additional paid-in capital	421,257	396,635
Accumulated other comprehensive loss	(476)	(39)
Accumulated deficit	(155,607)	(5,048)
Total stockholders' equity	265,202	391,575
Total liabilities and stockholders' equity	$ 344,047	$ 448,281

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Operations
(In thousands except per share amounts)

	Year Ended December 31,		
	2017	**2016**	**2015**
Collaboration and license revenue	$ 39,508	$ 30,691	$ 379,801
Operating expenses:			
Research and development	150,908	94,072	70,197
General and administrative	40,002	35,831	22,631
Total operating expenses	190,910	129,903	92,828
Operating income (loss)	(151,402)	(99,212)	286,973
Interest income	2,978	2,467	487
Other expense, net	(94)	—	(3)
Income (loss) before income tax	(148,518)	(96,745)	287,457
Income tax benefit (provision)	(1,704)	31,048	(37,810)
Net income (loss)	$ (150,222)	$ (65,697)	$ 249,647
Net income (loss) per share attributable to common stockholders:			
Basic	$ (5.38)	$ (2.44)	$ 9.73
Diluted	$ (5.38)	$ (2.44)	$ 9.23
Weighted-average shares used to compute net income (loss) per share attributable to common stockholders:			
Basic	27,945	26,955	25,661
Diluted	27,945	26,955	27,035

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Comprehensive Income (Loss)
(In thousands)

	Year Ended December 31,		
	2017	**2016**	**2015**
Net income (loss)	$ (150,222)	$ (65,697)	$ 249,647
Other comprehensive gain (loss):			
Unrealized gain (loss) on marketable securities, net of tax	(437)	35	(75)
Comprehensive income (loss)	$ (150,659)	$ (65,662)	$ 249,572

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Stockholders' Equity
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2014	21,680,494	$ 22	$ 274,180	$ 1	$ (188,998)	$ 85,205
Issuance of common stock upon follow-on offering, net of issuance costs	3,829,994	3	78,690	—	—	78,693
Issuance of common stock under equity incentive plans and related excess tax benefits	606,398	1	8,268	—	—	8,269
Stock-based compensation expense	—	—	11,467	—	—	11,467
Other comprehensive loss	—	—	—	(75)	—	(75)
Net income	—	—	—	—	249,647	249,647
Balances at December 31, 2015	26,116,886	26	372,605	(74)	60,649	433,206
Issuance of common stock under equity incentive plans and related excess tax benefits	1,730,340	1	5,199	—	—	5,200
Repurchase of shares to satisfy tax withholding obligations	(338,149)	—	(14,054)	—	—	(14,054)
Stock-based compensation expense	—	—	32,885	—	—	32,885
Other comprehensive gain	—	—	—	35	—	35
Net loss	—	—	—	—	(65,697)	(65,697)
Balances at December 31, 2016	27,509,077	27	396,635	(39)	(5,048)	391,575
Issuance of common stock under equity incentive plans	992,556	1	4,021			4,022
Repurchase of shares to satisfy tax withholding obligations	(322,994)		(13,909)			(13,909)
Cumulative effect of adoption of ASU 2016-09			337		(337)	—
Stock-based compensation expense			34,173			34,173
Other comprehensive loss				(437)		(437)
Net loss					(150,222)	(150,222)
Balances at December 31, 2017	28,178,639	$ 28	$ 421,257	$ (476)	$ (155,607)	$ 265,202

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2017	2016	2015
Operating activities			
Net income (loss)	$ (150,222)	$ (65,697)	249,647
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,513	1,742	1,678
Loss on disposal of property and equipment	95	9	3
Stock-based compensation expense	34,173	32,885	11,467
Amortization of premium on marketable securities	1,621	4,187	2,025
Excess tax benefits from employee equity incentive plans	—	3,123	3,122
Deferred income taxes	—	15,071	(15,071)
Changes in operating assets and liabilities:			
Receivable from collaborative partners	(9,174)	95	(3,644)
Income tax receivable	4,670	(4,670)	—
Prepaid, other current assets, and other long-term assets	4,235	(2,999)	(4,782)
Restricted cash	—	(1,543)	—
Accounts payable	1,903	(1,560)	798
Accrued personnel-related expenses	(801)	1,079	2,260
Deferred revenue	(9,070)	(16,771)	(11,789)
Deferred rent	3,699	(768)	(513)
Income tax payable	—	(52,843)	49,720
Other accrued liabilities and other long-term liabilities	4,174	8,909	4,177
Net cash provided by (used in) operating activities	(112,184)	(79,751)	289,098
Investing activities			
Purchases of marketable securities	(330,363)	(516,752)	(458,058)
Maturities of marketable securities	509,500	466,000	222,250
Proceeds from disposal of property and equipment	12	—	—
Purchases of property and equipment	(4,941)	(2,961)	(2,426)
Net cash provided by (used in) in investing activities	174,208	(53,713)	(238,234)
Financing activities			
Proceeds from issuances of common stock, net of issuance costs	—	—	78,693
Proceeds from issuances of common stock under equity incentive plans	4,022	8,323	5,147
Repurchase of shares to satisfy tax withholding	(13,909)	(14,054)	—
Excess tax benefits from employee equity incentive plans	—	(3,123)	—
Net cash provided by (used in) financing activities	(9,887)	(8,854)	83,840
Net increase (decrease) in cash and cash equivalents	52,137	(142,318)	134,704
Cash and cash equivalents at beginning of year	7,653	149,971	15,267
Cash and cash equivalents at end of year	$ 59,790	$ 7,653	$ 149,971
Supplemental cash flow information			
Income taxes paid	$ 1,704	$ 11,433	$ —
Supplemental schedule of noncash investing and financing activities			
Unpaid property and equipment purchases included in accrued liabilities	$ 9,033	$ 1,232	$ —
Tenant improvements provided by the landlord	$ 14,324	$ —	$ —

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

1. Business

Five Prime Therapeutics, Inc. (we, us, our, or the Company) is a clinical-stage biotechnology company focused on discovering and developing innovative protein therapeutics. We were incorporated in December 2001 in Delaware. Our operations are based in South San Francisco, California and we operate in one segment.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

We consider all highly liquid investments purchased with original maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents are stated at fair value.

Restricted Cash

Restricted cash consists of a certificate of deposit held by our bank as collateral for a standby letter of credit in the same notional amount by our landlord to secure our obligations under our corporate office and laboratory facility lease entered in December 2016. We are required to maintain this restricted cash balance for the duration of the lease, which amount is subject to reduction starting on January 1, 2023 if certain conditions are met. See Note 11 for further discussion on our lease.

Marketable Securities

All marketable securities have been classified as “available-for-sale” and are carried at fair value, based upon quoted market prices. We consider our available-for-sale portfolio as available for use in current operations. Accordingly, we classify certain investments as short-term marketable securities, even though the stated maturity date may be one year or more beyond the current balance sheet date. Unrealized gains and losses, net of any related tax effects, are excluded from earnings and are included in other comprehensive income or loss and reported as a separate component of stockholders’ equity or deficit until realized. Realized gains and losses and declines in value judged to be other than temporary, if any, on available-for-sale securities are included in other income (expense), net. The cost of securities sold is based on the specific-identification method. We adjust the amortized cost of securities for amortization of premiums and accretion of discounts to maturity. We include interest on short-term investments in interest income. In accordance with our investment policy, management invests to diversify credit risk and only invests in debt securities with high credit quality, including U.S. government securities.

We periodically evaluate whether declines in the fair value of our investments below their cost are other than temporary. The evaluation includes consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities, and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. If we determine that the decline in fair value of an investment is below its accounting basis and this decline is other than temporary, we would reduce the carrying value of the security we hold and record a loss for the amount of such decline. We have not recorded any realized losses or declines in value judged to be other than temporary on our investments in debt securities.

Concentrations of Credit Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. Cash and cash equivalents and marketable securities are invested through banks and other financial institutions in the United States. Such deposits in the United States may be in excess of insured limits.

Fair Value of Financial Instruments

We determine the fair value of financial and nonfinancial assets and liabilities using the fair value hierarchy, which describes three levels of inputs that may be used to measure fair value, as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities;

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. For our marketable securities, we review trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We determine the fair value of Level 1 assets using quoted prices in active markets for identical assets. We review trading activity and pricing for Level 2 investments as of each measurement date. Level 2 inputs, obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data. There were no transfers between Level 1 and Level 2 securities in the periods presented.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy.

The following table summarizes our financial instruments that were measured at fair value on a recurring basis by level of input within the fair value hierarchy defined above (in thousands):

	December 31, 2017			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 31,802	$ 31,802	$ —	$ —
U.S. Treasury securities	232,900	232,900	—	—
Certificate of deposit	1,543	—	1,543	—
Total	$266,245	$264,702	$ 1,543	$ —

	December 31, 2016			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 432	$ 432	$ —	$ —
U.S. Treasury securities	414,095	414,095	—	—
Certificate of deposit	1,543	0	1,543	0
Total	$416,070	$414,527	$ —	$ —

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 three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the related lease term.

Impairment of Long-Lived Assets

Long-lived assets include property and equipment. We review the carrying value of long-lived assets for impairment whenever events or changes in circumstances indicate that the assets may not be recoverable. We recognize an impairment loss when the total estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. Through December 31, 2017, there have been no such impairment losses.

Revenue Recognition

We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; transfer of technology has been completed or services have been rendered; our price to the customer is fixed or determinable, and collectability is reasonably assured.

The terms of our collaborative research and development agreements include upfront and license fees, research funding, milestone and other contingent payments to us for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

Multiple-Element Revenue Arrangements. Our collaborations primarily represent multiple-element revenue arrangements. To account for these transactions, we determine the elements, or deliverables, included in the arrangement and determine which deliverables are separable for accounting purposes. We consider delivered items to be separable if the delivered items have stand-alone value to the customer. If the delivered items are separable, we allocate arrangement consideration to the various elements based on each element's relative selling price. The identification of individual elements in a multiple-element arrangement and the estimation of the selling price of each element involve significant judgment, including consideration as to whether each delivered element has standalone value to the customer. The revenue recognition standard established the hierarchy of determining the estimated selling price for deliverables within each agreement using vendor-specific objective evidence, or VSOE, of selling price, if available, or third-party evidence of selling price if VSOE is not available, or our best estimate of selling price, if neither VSOE nor third-party evidence is available. Determining the best estimate of selling price for a deliverable requires significant judgment. We use our best estimate of selling price to estimate the selling price for licenses to our proprietary technology since the VSOE or third-party evidence of selling price for these deliverables is not available.

We recognize consideration allocated to an individual element when all other revenue recognition criteria are met for that element. Our multiple-element revenue arrangements generally include the following:

- **Exclusive Licenses.** The deliverables under our collaboration agreements generally include exclusive licenses to discover, develop, manufacture and commercialize certain compounds. To account for this element of the arrangement, we evaluate whether the exclusive license has standalone value apart from the undelivered elements to the collaboration partner based on the consideration of the relevant facts and circumstances of each arrangement, including the research and development capabilities of the collaboration partner and other market participants. We recognize arrangement consideration allocated to licenses upon delivery of the license if facts and circumstances indicate that the license has standalone value apart from the undelivered elements, which generally include research and development services. If facts and circumstances indicate that the delivered license does not have standalone value from the undelivered elements, we recognize the revenue as a combined unit of accounting.

  We have determined that some of our exclusive licenses lack standalone value apart from the related research and development services. In those circumstances we recognize collaboration revenue from non-refundable upfront and license fees in the same manner as the undelivered item(s), which is generally the period over which we provide the research and development services. For circumstances in which upfront and license fees are contingently refundable, we defer the recognition of the upfront and license fees until such time that the consideration is considered to be fixed or determinable.

- **Research and Development Services.** The deliverables under our collaboration and license agreements generally include deliverables related to research and development services we perform on behalf of the collaboration partner. As the provision of research and development services is a part of our central operations and we are principally responsible for the performance of these services under the agreements, we recognize revenue on a gross basis for research and development services as we perform those services. Additionally, we recognize research funding related to collaborative research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms as long as we will receive payment for such services upon standard payment terms.

Milestone Revenue. Our collaboration and license agreements generally include contingent payments and milestone payments related to specified research, development and regulatory milestones and sales-based milestones. Research, development and regulatory contingent payments and milestone payments are typically receivable under our collaborations when our collaborator claims or selects a target or initiates or advances a covered product candidate in preclinical or clinical development, upon submission for marketing approval of a covered product with regulatory authorities, upon receipt of actual marketing approvals of a covered product or for additional indications, or upon the first commercial sale of a covered product. Sales-based milestones are typically receivable when annual sales of a covered product reach specified levels.

At the inception of each arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. We evaluate factors such as the scientific, regulatory, commercial and other risks that we must overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

We have adopted the Accounting Standards Codification, or ASC 605-28, *Revenue Recognition—Milestone Method*, such that we recognize any payment that is contingent upon the achievement of a substantive milestone entirely in the period in which the milestone is achieved. A milestone is defined as an event that can only be achieved based in whole or in part on either our performance or the occurrence of a specific outcome resulting from our performance for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved. Therefore, a milestone does not include events for which occurrence is contingent solely on the performance of a collaborative partner. To be substantive, a milestone must meet all the following criteria: the consideration receivable upon the achievement of the milestone is commensurate with either our performance after the agreement to achieve the milestone or the enhancement of value of delivered items as a result of a specific outcome resulting from our performance after the agreement to achieve the milestone, the consideration relates solely to past performance, and the consideration is reasonable relative to all of the deliverables and payment terms in the arrangement.

Research and Development Expenses

Research and development expenses consist of costs we incur for our own and for sponsored and collaborative research and development activities. Expenses we incur related to collaborative research and development agreements approximate the revenue recognized under these agreements. Research and development costs are expensed as incurred. Research and development costs consist of salaries and benefits, including associated stock-based compensation, laboratory supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities on our behalf. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations, or CROs, and clinical manufacturing organizations, or CMOs, that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses incurred by them. Further, we accrue expenses related to clinical trials based on the level of patient activity according to the related agreement. We monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial accruals.

We expense payments for the acquisition and development of technology as research and development costs if, at the time of payment, the technology: is under development; is not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use.

Stock-Based Compensation

We recognize compensation expense using a fair-value-based method for costs related to all share-based payments, including restricted stock and stock options. For restricted stock awards, or RSAs, stock-based compensation cost related to employees and directors is based on the closing market value of our common stock at the date of grant and is recognized as expense ratably over the requisite service period. For stock option awards, stock-based compensation cost related to employees and directors is measured at the grant date, based on the fair-value-based measurement of the award estimated using the Black-Scholes option-pricing model, and is recognized as expense over the requisite service period on a straight-line basis. We account for forfeitures as they occur by reversing any expense recognized for unvested awards.

Restricted stock awards granted to individual service providers who are not employees or directors are accounted for at fair value by remeasuring the cost based on the closing stock price at the end of that reporting period. Options granted to individual service providers who are not employees or directors are accounted for at estimated fair value using the Black-Scholes option-pricing model and are subject to periodic remeasurement over the period during which the services are rendered.

Income Taxes

We account for income taxes using the liability method, under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided when the expected realization of the deferred tax assets does not meet the more-likely-than-not criteria. As a result, deferred tax assets at the end of 2016 and 2017 are subject to a full valuation allowance. We are required to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. It is our practice to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

Accounting Pronouncements Adopted in 2017

In March 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, to simplify certain aspects of the accounting for share-based payment transactions to employees. The new standard requires excess tax benefits and tax deficiencies to be recorded as a component of the provision for income taxes in a company's statements of income when stock awards vest or are settled. In addition, it eliminates the requirement to reclassify cash flows related to excess tax benefits from operating activities to financing activities on the consolidated statements of cash flows. The standard also provides an accounting policy election to account for forfeitures as they occur, allows a company to withhold more of an employee's vesting shares for tax withholding purposes without triggering liability accounting, and clarifies that all cash payments made to tax authorities on an employee's behalf for withheld shares should be presented as a financing activity on a company's cash flows statement. We adopted ASU 2016-09 as of January 1, 2017. Starting in the first quarter of 2017, we reflected excess tax benefits or deficiencies from share-based award activity in the consolidated statements of operations as a component of the provision for income taxes, whereas we previously recognized them in equity. We have not adjusted prior periods. In addition, we adopted the aspects of the standard affecting the cash flow presentation prospectively. We will include the cash flow related to excess tax benefits within the operating activities. The presentation requirements for cash flows related to employee taxes paid for withheld shares has no impact on our consolidated statements of cash flows since such cash flows have historically been presented as a financing activity. Finally, we elected to account for forfeitures as they occur, rather than estimate expected forfeitures, on a modified retrospective basis. Our adoption of ASU 2016-09 resulted in a $337,000 decrease to retained earnings as of January 1, 2017 to record the additional stock compensation expense due to the elimination of the estimated forfeiture rate and a $3.1 million increase to deferred tax assets which is fully offset by a valuation allowance because we determined that it is more likely than not that the deferred tax asset will not be fully realized.

Accounting Pronouncements Not Yet Adopted

In May 2014, FASB issued ASU 2014-09, Revenue from Contracts with Customers: Topic 606, that supersedes nearly all existing revenue recognition guidance under GAAP. The FASB subsequently issued amendments to ASU 2014-09 that have the same effective date and transition date. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

ASU 2014-09 differs from the current accounting standard in many respects, such as in the accounting for variable consideration, including milestone payments. Under our current accounting policy, we recognize milestone revenue using the milestone method specified in ASC 605-28, which generally results in the recognition of the milestone payment as revenue in the period that the milestone is achieved. However, under the new accounting standard, it is possible to start to recognize milestone revenue before the milestone is achieved, subject to management's assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. In addition, the current accounting standards include a presumption that revenue from up-front non-refundable fees would be recognized ratably over the performance period, unless another attribution method was determined to more closely approximate the delivery of the goods or services to the customer. The new accounting standard does not have a presumption that entities would default to a ratable attribution approach and will require entities to determine an appropriate attribution method using either output or input methods. As such, the amount and timing of revenue recognition for our license and collaboration agreements will change under the new revenue standard.

We will adopt ASU 2014-09 on January 1, 2018 using the modified retrospective method. We finalized our analysis and currently expect retained earnings to increase by approximately $1.4 million, which is offset by a $1.4 million decrease in deferred revenue, due to the difference between the input method and ratable attribution approach. We also expect related deferred tax assets to decrease by approximately $0.3 million, which is fully offset by a valuation allowance because we determined that it is more likely than not that the deferred tax asset will not be fully realized.

In February 2016, FASB issued ASU 2016-02, *Leases*, which amends existing guidance to require substantially all leases to be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 will become effective for our interim and annual reporting periods during the year ending December 31, 2019 and will apply to all annual and interim reporting periods thereafter. Early adoption is permitted. Under the new standard, we expect to record a right-to-use lease asset and a lease liability on our balance sheet. Under the new standard, we expect to recognize expense on our statement of operations in a manner similar to the current accounting standard.

In May 2017, FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting*, which amends the scope of modification accounting for share-based payment arrangements. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. We will adopt the standard effective January 1, 2018. We do not expect the adoption to have a material impact on our consolidated financial statements.

In November 2016, FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows (Topic 230) – Restricted Cash*. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 will be effective for us beginning January 1, 2018 and will be applied using a retrospective transition method to each period presented. We do not expect the adoption of ASU 2016-18 to have a material impact on our consolidated financial statements.

3. Cash Equivalents and Marketable Securities

The following is a summary of our cash equivalents and marketable securities at December 31, 2017 and 2016 (in thousands):

	December 31, 2017			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$ 31,802	$ —	$ —	$ 31,802
U.S. Treasury securities	233,376	—	(476)	232,900
Total cash equivalents and marketable securities	265,178	—	(476)	264,702
Less: cash equivalents	(31,802)	—	—	(31,802)
Total marketable securities	$ 233,376	$ —	$ (476)	$ 232,900

	December 31, 2016			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$ 432	$ —	$ —	$ 432
U.S. Treasury securities	414,134	54	(93)	414,095
Total cash equivalents and marketable securities	414,566	54	(93)	414,527
Less: cash equivalents	(432)	—	—	(432)
Total marketable securities	$ 414,134	$ 54	$ (93)	$ 414,095

As of December 31, 2017, the amortized cost and estimated fair value of our available-for-sale securities by contractual maturity are shown below (in thousands):

	Amortized Cost	Estimated Fair Value
Debt securities maturing:		
In one year or less	$ 221,877	$ 221,445
In one to two years	11,499	11,455
Total marketable securities	$ 233,376	$ 232,900

Our cash equivalents and marketable securities have an average maturity of approximately six months and the longest maturity is 14 months. We determined that the gross unrealized losses of $476,000 on our marketable securities as of December 31, 2017 were temporary in nature and related primarily to interest rate shifts rather than significant changes in the underlying credit quality of the securities that we hold. We currently do not intend to sell these securities prior to maturity and do not consider these investments to be other-than-temporarily impaired at December 31, 2017. There were no sales of available-for-sale securities in any of the periods presented.

4. Property and Equipment

Property and equipment consist of the following (in thousands):

	December 31,	
	2017	2016
Computer equipment and software	$ 1,892	$ 1,467
Furniture and fixtures	947	804
Laboratory equipment	17,429	14,853
Leasehold improvements	22,175	2,468
	$ 42,443	$ 19,592
Less: accumulated depreciation and amortization	(11,681)	(13,385)
Property and equipment, net	$ 30,762	$ 6,207

We entered into a lease agreement with respect to our new corporate office and laboratory facility in December 2016. During fiscal 2017, we acquired $22.2 million of leasehold improvements in connection with our move to the new office. We received lease incentives totaling $14.3 million from our landlord for a portion of the costs of these leasehold improvements.

5. Other Accrued Liabilities

Other accrued liabilities consist of the following (in thousands):

	December 31,	
	2017	2016
Clinical development	$ 12,580	$ 6,831
Manufacturing	2,835	4,463
Trade payable	3,995	3,729
Unpaid leasehold improvements	7,742	—
Other	367	412
Total accrued liabilities	$ 27,519	$ 15,435

6. Stockholders' Equity

We have 110,000,000 shares of authorized capital stock issuable in series, all with a par value of $0.001 per share, of which 100,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock. Our Board is authorized to determine the designation, powers, preferences and rights of any such series. As of December 31, 2017 and 2016, we had 28,178,639 and 27,509,077 shares of common stock outstanding, respectively. There were no shares of preferred stock outstanding as of December 31, 2017 and 2016.

Equity Incentive Plans

Our Board of Directors, or Board, and stockholders previously approved the 2002 Equity Incentive Plan, or the 2002 Plan, and the 2010 Equity Incentive Plan, or the 2010 Plan, and collectively with the 2002 Plan, the Prior Plans. The 2002 Plan terminated in March 2012. In September 2013, our stockholders approved the 2013 Omnibus Incentive Plan, or the 2013 Plan. As of September 23, 2013, the effective date of the 2013 Plan, we suspended the 2010 Plan and no additional awards may be granted under the 2010 Plan. Any shares of common stock covered by awards granted under the Prior Plans that terminate after September 23, 2013 by expiration, forfeiture, cancellation or other means without the issuance of such shares were added to the 2013 Plan reserve.

The initial number of shares of common stock available for issuance under the 2013 Plan was 3,500,000, which includes the 1,069,985 shares of common stock that were available for issuance under the Prior Plans as of the effective date of the 2013 Plan. Unless our Board provides otherwise, beginning on January 1, 2014 and continuing until the expiration of the 2013 Plan, the total number of shares of common stock available for issuance under the 2013 Plan will automatically increase annually on January 1 by 4% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. Under the plan, any shares that are forfeited or expired are added back to the shares available for issuance. As of December 31, 2017, 1,364,975 shares of common stock were available for future issuance of options, restricted stock and other stock-based awards under the 2013 Plan.

Incentive stock options may be granted with an exercise price of not less than estimated fair value. Stock options granted to a stockholder owning more than 10% of our voting stock must have an exercise price of not less than 110% of the estimated fair value of the common stock on the date of grant. For all stock options granted prior to our initial public offering, our Board determined the estimated fair value of our common stock. For all stock options granted after the completion of our initial public offering in September 2013, the fair value for our underlying common stock is determined using the closing market price on the date of grant. Stock options are granted with terms of up to ten years and generally vest over a period of four years.

The following table summarizes option activity under our stock plans and related information:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Terms (in years)	Aggregate Intrinsic Value (in thousands)
Balance at January 1, 2017	3,454,339	$ 26.80		
Options granted	977,050	$ 41.49		
Options exercised	(222,261)	$ 12.28		
Options forfeited	(320,965)	$ 37.77		
Options expired	(20,518)	$ 43.16		
Balance at December 31, 2017	3,867,645	$ 30.35	7.12	$ 14,234
Options exercisable at December 31, 2017	2,022,807	$ 22.94	5.68	$ 12,954

The weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2017, 2016 and 2015 was $25.78, $27.95 and $14.18 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2017, 2016 and 2015 was $5.4 million, $30.8 million and $10.0 million, respectively.

We recorded stock-based compensation expense related to options granted to employees and directors of approximately $19.3 million, $11.1 million and $4.5 million for the years ended December 31, 2017, 2016 and 2015, respectively. Stock-based compensation expense related to options granted to individual service providers who are not employees or directors was approximately $433,000, $309,000 and $266,000 for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, there was $42.3 million of total unrecognized compensation expense related to unvested employee and director stock options that we expect to recognize over a weighted-average period of 2.6 years.

RSAs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting and are unforfeitable once fully vested. The fair value of RSAs was based upon the closing sales price of our common stock on the grant date.

The following table summarizes the RSAs activity under our stock plans and related information:

	RSAs Outstanding	
	Number of Shares	Weighted-Average Grant-Date Fair Value
Unvested balance at January 1, 2017	1,040,929	$ 28.84
RSAs granted	617,355	$ 40.54
RSAs vested	(719,636)	$ 23.52
RSAs forfeited	(135,231)	$ 42.81
Unvested balance at December 31, 2017	803,417	$ 40.24

The total fair value on the date of vesting of RSAs vested in 2017, 2016 and 2015 was $30.8 million, $33.2 million, and $42,000, respectively.

We recorded stock-based compensation expense related to RSAs granted to employees and directors of approximately $13.7 million, $20.2 million and $6.2 million for the years ended December 31, 2017, 2016 and 2015, respectively. Stock-based compensation expense related to RSAs granted to individual service providers who are not employees or directors was approximately $258,000, $673,000 and $85,000 for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, there was $23.0 million of unrecognized compensation cost related to unvested employee and director RSAs, that we expect to recognize over a weighted-average period of 1.9 years.

Employee Stock Purchase Plan

In September 2013, our stockholders approved the 2013 Employee Stock Purchase Plan, or the ESPP, which became effective as of September 23, 2013. We initially reserved a total of 250,000 shares of common stock for issuance under the ESPP. Unless our Board provides otherwise, beginning on January 1, 2014 and continuing until the expiration of the ESPP, the total number of shares of common stock available for issuance under the ESPP will automatically increase annually on January 1 by the lesser of (i) 1% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year, or (ii) 300,000 shares of common stock. As of December 31, 2017, 949,792 shares of common stock were available for issuance under the ESPP.

Under our ESPP, employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of our common stock on the offering date or the purchase date with a six-month look-back feature. ESPP purchases are settled with common stock from the ESPP's previously authorized and available pool of shares. We issued a total of 50,659 shares under the ESPP in 2017.

The compensation expense related to the ESPP was $506,000, $602,000 and $455,000 for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, there was $355,000 of unrecognized compensation cost related to the ESPP, which we expect to recognize over 4.5 months.

Stock-Based Compensation

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Research and development	$ 18,285	$ 17,960	$ 6,362
General and administrative	15,888	14,925	5,105
Total	$ 34,173	$ 32,885	$ 11,467

We estimated the fair value of each award using the Black-Scholes option-pricing model based on the date of grant of such award with the following assumptions:

	Options			ESPP		
	Year Ended December 31,			Year Ended December 31,		
	2017	2016	2015	2017	2016	2015
Expected term (years)	5.5-6.3	5.5-6.3	5.5-6.1	0.5	0.5	0.5
Expected volatility	66-70%	69-74%	71-76%	42-94%	47-57%	75-96%
Risk-free interest rate	1.9-2.2%	1.3-1.8%	1.4-1.9%	1.0-1.4%	0.4-0.6%	0.1-0.3%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

The expected term of options granted represents the period of time that we expect options granted to remain outstanding, which we determined using the simplified method as we have insufficient historical information to provide a basis for estimate. The expected term of the ESPP rights is equal to the six-month look-back period. Volatility for options granted in 2015 is based on the average of the historical volatility of our stock price and a peer group of public companies. We selected the peer group on the basis of operational and economic similarity with our principal business operations. Volatility for options granted subsequent to 2015 is based on the historical volatility of our stock price since we became publicly traded. Volatility for ESPP rights is equal to our historical volatility over the six-month look-back period. The risk-free interest rate for the expected term of the options is based on the U.S. Treasury yield curve with a maturity equal to the expected term in effect at the time of grant. We have not paid, and do not anticipate paying, cash dividends on our shares of common stock; therefore, the expected dividend yield is zero.

7. Earnings per Share

The computation of basic income (loss) per share is based on the weighted-average number of our common shares outstanding. The computation of diluted income (loss) per share is based on the weighted-average number of our common shares outstanding and dilutive potential common shares, which include shares that may be issued under our equity incentive plans, determined using the treasury stock method.

The following table sets forth the computation of basic and diluted net income (loss) (in thousands, except per share data):

	Year Ended December 31,		
	2017	2016	2015
Numerator:			
Net income (loss)	$ (150,222)	$ (65,697)	$ 249,647
Denominator:			
Denominator for basic income (loss) per share - weighted-average shares	27,945	26,955	25,661
Effect of dilutive securities:			
Equity incentive plans	—	—	1,374
Denominator for diluted income (loss) per share	27,945	26,955	27,035
Income (loss) per share - Basic	$ (5.38)	$ (2.44)	$ 9.73
Income (loss) per share - Diluted	$ (5.38)	$ (2.44)	$ 9.23

We did not include potentially dilutive securities that would have an antidilutive effect. In 2017 and 2016, this consisted of all options to purchase common stock and RSAs. In 2015, this consisted of certain options to purchase common stock and RSAs.

We excluded the following securities from the calculation of diluted net income (loss) per share as the effect would have been antidilutive (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Options to purchase common stock	3,843	2,981	187
RSAs	886	1,278	8
Total	4,729	4,259	195

8. Collaborative Research and Development Agreements

Bristol-Myers Squibb Company

License and Collaboration Agreement

On October 14, 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which we granted BMS exclusive global rights to develop and commercialize certain colony stimulating factor-1 receptor, or CSF1R, antibodies, including our monoclonal CSF1R inhibiting antibody that we refer to as cabiralizumab, and all modifications, derivatives, fragments, or variants of such antibodies, each of which we refer to as a licensed antibody. Under the terms of the cabiralizumab collaboration agreement, BMS is responsible, at its expense, for developing products containing licensed antibodies, each of which we refer to as a licensed product, under a development plan, subject to our option, at our own expense, to conduct certain studies, including registration-enabling studies to support approval of cabiralizumab in PVNS and in combination with our proprietary internal or in-licensed compounds, including in oncology. BMS is responsible for manufacturing and commercializing each licensed product and we will retain rights to a U.S. co-promotion option. This supersedes the clinical trial collaboration agreement we entered into with BMS in November 2014, or the original collaboration agreement.

We continue to conduct our Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining *Opdivo*® (nivolumab), BMS's programmed-death 1 (PD-1) immune checkpoint inhibitor, with cabiralizumab in multiple tumor types, which we commenced under the original collaboration agreement. BMS bears all costs and expenses relating to this trial, including manufacturing costs for the supply of cabiralizumab, except that we are responsible for our own internal costs, including internal personnel costs. We received $17.9 million and $8.0 million of research funding in 2017 and 2016, respectively, related to the research we performed under the cabiralizumab collaboration agreement.

Pursuant to the cabiralizumab collaboration agreement, BMS made an upfront payment of $350.0 million to us in December 2015. We applied ASC 605-25, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for the cabiralizumab collaboration agreement. We identified the license to BMS and the associated transfer of manufacturing and other know-how as substantive deliverables under this agreement. Since all of the deliverables were fully delivered by December 31, 2015, we recognized the $350.0 million upfront license fee associated with the deliverables entirely as revenue in 2015.

Additionally, we are eligible to receive up to $1.05 billion in development and regulatory milestone payments per anti-CSF1R product for oncology indications and up to $340 million in development and regulatory milestone payments per anti-CSF1R product for non-oncology indications, as well as royalties ranging from the high teens to the low twenties, such royalties to be enhanced in the U.S. in the event that we exercise our co-promotion option. We determined that these contingent payments will not be accounted for under the milestone method of revenue recognition as the events that trigger these payments under the agreement with BMS do not meet the definition of a milestone under ASC 605-28, *Milestone Method of Revenue Recognition*, because the achievement of these milestones is solely dependent on BMS's performance. Revenue from these contingent payments will be recognized if and when such payments become due, subject to satisfaction of all the criteria necessary to recognize revenue at that time, because we do not have any outstanding performance obligations under this arrangement. For the year ended December 31, 2017, we did not recognize any revenue for development and regulatory milestone payments.

Under the original collaboration agreement, BMS paid us an upfront fee of $30.0 million in December 2014. Initially, the $30.0 million upfront fee was contingently refundable if certain change of control events occurred prior to a specified date. As such, the upfront fee was not considered to be fixed or determinable at that time and was recorded as deferred revenue as of December 31, 2014. Pursuant to the cabiralizumab collaboration agreement, the $30.0 million upfront fee under the original collaboration is no longer contingently refundable. Therefore, upon the effectiveness of the cabiralizumab collaboration agreement, the upfront fee became fixed or determinable and we started recognizing revenue ratably, using a cumulative catch-up method, over the estimated performance period ending in 2019. During 2017, 2016 and 2015, we recognized $5.9 million, $5.9 million, and $6.4 million, respectively, of revenue relating to the upfront fee.

For the years ended December 31, 2017, 2016 and 2015, we recognized $23.7 million, $14.4 million, and $359.9 million, respectively, of revenue under the cabiralizumab collaboration agreement. As of December 31, 2017 and 2016, we had deferred revenue relating to the collaboration of $11.8 million and $17.7 million, respectively.

Immuno-Oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement, or the immuno-oncology research collaboration, with BMS, to carry out a research program to (i) discover novel interacting proteins in two undisclosed immune checkpoint pathways, which we refer to as the checkpoint pathways, using our target discovery platform; (ii) further the understanding of target biology with respect to targets in these checkpoint pathways; and (iii) discover and pre-clinically develop compounds suitable for development for human therapeutic uses against targets in these checkpoint pathways. Under the immuno-oncology collaboration, we granted BMS an exclusive, worldwide license to research, develop and commercialize products directed towards certain targets in the checkpoint pathways. BMS has an option to take exclusive licenses to additional targets we may identify in these checkpoint pathways pursuant to the research plan under the immuno-oncology research collaboration. Based on data arising from our activities under the research plan, in January 2016, we amended the immuno-oncology research collaboration to add an additional checkpoint pathway to the research program, for a total of three immune checkpoint pathways.

We received an upfront payment of $20.0 million from BMS in April 2014 in connection with our entry into the immuno-oncology research collaboration. BMS was obligated to pay us $9.5 million in research funding over the course of the three-year research term based on the research activities currently planned under the research plan. BMS had the option to extend the research term for two additional one-year periods on a year-by-year basis, during which extensions we would be obligated to perform additional services as agreed to with BMS and BMS would be obligated to pay us research funding with respect to such services. The initial research term under the immuno-oncology research collaboration expired in March 2017. In each of December 2016 and December 2017, BMS exercised its option to extend the research term for an additional year to March 2018 and March 2019, respectively.

We applied ASC 605-25, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for the immuno-oncology collaboration. In accordance with this guidance, we concluded that we should account for the immuno-oncology research collaboration as a single unit of accounting because the intellectual property delivered to BMS was not considered to have stand-alone value and recognize the immuno-oncology research collaboration consideration in the same manner as the final deliverable, which is research service. We recorded the $20.0 million upfront payment as deferred revenue and are recognizing it over the five-year research period under the immuno-oncology research collaboration. In addition, BMS agreed to pay us $9.5 million of research funding over the initial three-year research program term and an additional $2.1 million for each extension. We received $2.6 million, $1.6 million and $4.1 million of research funding in 2017, 2016 and 2015, respectively, related to research we performed under the immuno-oncology research collaboration.

We are eligible to receive certain contingent payments with respect to each target subject to the immuno-oncology research collaboration and royalties on sales of products related to such targets, if any. In December 2017, we recognized $5.0 million related to a developmental contingent payment.

In accordance with ASC 605-28, we determined that the remaining contingent payments under the immuno-oncology research collaboration do not constitute milestone payments and will not be accounted for under the milestone method of revenue recognition. The events leading to these payments under the collaboration do not meet the definition of a milestone under ASC 605-28 because the achievement of these events solely depends on BMS's performance. Any revenue from these contingent payments would be subject to an allocation of arrangement consideration and would be recognized over any remaining period of performance obligations, if any, relating to the collaboration. If we have no remaining performance obligations under the immuno-oncology research collaboration at the time the contingent payment is triggered, we would recognize the contingent payment as revenue in full upon the triggering event.

In connection with the immuno-oncology research collaboration, BMS purchased 994,352 shares of our common stock at a price per share of $21.16, for an aggregate purchase price of $21.0 million. We determined that the purchase price of $21.16 per share exceeded the fair value of our common stock by $2.4 million and, therefore, recorded the $2.4 million as deferred revenue that we are recognizing in the same manner as the $20.0 million upfront payment.

For the years ended December 31, 2017, 2016, and 2015, we recognized $12.0 million, $7.7 million and $7.0 million, respectively, of revenue under the immuno-oncology research collaboration. As of December 31, 2017 and 2016, we had deferred revenue relating to the immuno-oncology research collaboration of $6.3 million and $10.6 million, respectively.

The immuno-oncology research collaboration will terminate upon the expiration of all payment obligations under the collaboration. In addition, BMS may terminate the immuno-oncology research collaboration in its entirety or on a collaboration target-by-collaboration target basis at any time with advance written notice and either party may terminate the collaboration in its entirety or on a collaboration target-by-collaboration target basis with written notice for the other party's material breach if such other party fails to timely cure the breach or immediately upon certain insolvency events.

Zai Lab China License and Collaboration Agreement

In December 2017, we entered into a license and collaboration agreement with Zai Lab, or the China collaboration agreement, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab, and all fragments, conjugates, derivatives and modifications thereof, or the licensed antibody, in China, Hong Kong, Macau, and Taiwan, each a region, and collectively, the territory.

Under the terms of the China collaboration agreement, Zai Lab will be responsible, at its expense, for (i) developing and commercializing products containing the licensed antibody, each, a licensed product, under a territory development plan and (ii) performing certain development activities to support our global development and registration of licensed products, including the Phase 3 portion of our Phase 1/3 global registrational trial to test bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, or mFOLFOX6, as front-line treatment of patients with gastric or gastroesophageal junction, or GEJ, cancer that overexpresses FGFR2b, or the FIGHT trial, in the territory, under a global development plan.

Pursuant to the China collaboration agreement, with respect to each licensed product, we are eligible to receive up to $39.0 million of specified development and regulatory milestone payments. Zai Lab will also be obligated to pay us a royalty, on a licensed product-by-licensed product and region-by-region basis, in the high teens or low twenties, depending on the number of patients Zai Lab enrolls in the FIGHT trial, subject to reduction in certain circumstances, on net sales of each licensed product in each region until the latest of (i) the 11th anniversary of the first commercial sale of such licensed product in such region, (ii) the expiration of certain patents covering such licensed product in such region, and (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such licensed product expires in such region. We cannot determine the date on which Zai Lab's potential royalty payment obligations to us would expire because Zai Lab has not yet developed any licensed products under the China collaboration agreement and we therefore cannot at this time identify the date of the first commercial sale or any related patents covering or regulatory exclusivity periods with respect to such licensed product.

Under the China collaboration agreement, we recorded a $4.2 million receivable in December 2017 for the non-refundable and non-creditable upfront fee of $5.0 million (net of expected value-added tax withholdings of $0.8 million). We applied ASC 605-25, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for this agreement. In accordance with this guidance, we concluded that the agreement consideration shall be recognized over the period that the development services are provided under a global development plan. As of December 31, 2017, services under the global development plan had not begun. Accordingly, as of December 31, 2017, we had deferred revenue relating to the collaboration of $4.2 million, which we expect to recognize beginning in 2018 over the estimated performance period.

GlaxoSmithKline LLC

Respiratory Diseases Collaboration

In April 2012, we entered into research collaboration and license agreement, or the respiratory diseases collaboration, with GlaxoSmithKline LLC, or GSK, to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease, or COPD, function with a particular focus on identifying novel protein therapeutics and antibody targets. We conducted six customized cell-based screens of our protein library under this agreement. Under the terms of the agreement, GSK paid us an upfront technology access payment of $7.5 million at the inception of the respiratory diseases collaboration. In addition, GSK agreed to pay us $10.5 million of research funding over the research program term.

We applied ASC 605-25, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for this agreement. In accordance with this guidance, we concluded that the arrangement should be accounted for as a single unit of accounting and that the agreement consideration should be recognized in the same manner as the final deliverable, which is the research service. We recorded the $7.5 million upfront technology access payment as deferred revenue and we recognized such payment over the initial four-year research period under the agreement.

Pursuant to the respiratory diseases collaboration, GSK exercised its option to expand the research plan to include two additional screening assays. We received $2.0 million in additional research funding for the two additional screening assays as of December 31, 2015.

In January 2016, we amended our respiratory diseases collaboration to extend the research term by three months to July 2016 to allow additional validation of the protein targets we discovered and to increase the research funding by $0.7 million that GSK is obligated to pay us under our collaboration. Such funding was fully received as of December 31, 2016.

We are eligible to receive certain option and selection payments, payments for the achievement of certain development activities, and royalties on the sales of products related to targets GSK selects for exclusive development, if any.

We are eligible to receive up to $124.3 million in potential target evaluation and selection fees and contingent payments with respect to each protein target for which GSK will have sole responsibility for the further development and commercialization of products that incorporate or target such protein target, or a track 1 target. GSK is also obligated to pay us tiered low- to mid-single digit royalties on global net sales for each product that incorporates or targets each such track 1 target. We are eligible to receive up to $193.8 million in potential target evaluation and selection fees and contingent payments with respect to each protein target for which we will develop biologics that incorporate or target the protein targets through to clinical proof of mechanism in either a phase 1 clinical trial or a phase 2 clinical trial, or a track 2 target. GSK is also obligated to pay us tiered high-single to low-double digit royalties on global net sales for each product that incorporates or targets each such track 2 target.

In accordance with ASC 605-28, we determined that the remaining contingent payments under the respiratory diseases collaboration do not constitute milestone payments and we will not account for such payments under the milestone method of revenue recognition.

In connection with our entry into the respiratory diseases collaboration, GSK purchased 381,693 shares of our Series A-3 convertible preferred stock at a price of $26.20 per share, resulting in net cash proceeds to us of $10.0 million. We determined that the purchase price of $26.20 per share exceeded the estimated fair value of the Series A-3 convertible preferred stock by $3.1 million and, therefore, recorded the $3.1 million as deferred revenue to be recognized in the same manner as the upfront technology access payment. In connection with our initial public offering in September 2013, all outstanding shares of convertible preferred stock converted into shares of common stock.

In the years ended December 31, 2017, 2016 and 2015, we received $0.5 million, $3.6 million and $3.9 million, respectively, of research funding and milestones related to all research being performed under the respiratory diseases collaboration. Total revenue recognized under the respiratory diseases collaboration was $0.5 million, $5.0 million and $7.3 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, we fully recognized the deferred revenue related to the respiratory diseases collaboration as we completed our obligation to provide research service.

The respiratory diseases collaboration will terminate upon the expiration of the royalty terms of any products that incorporate or target a protein exclusively licensed under the collaboration. In addition, GSK may terminate this agreement at any time with advance written notice, and either party may terminate this agreement with written notice for the other party's material breach if such party fails to cure the breach or immediately in the case of failure to comply with certain anti-bribery and anti-corruption policies or upon certain insolvency events.

FP-1039 License and Collaboration

In March 2011, we entered into a license and collaboration agreement, or the FP-1039 license, with Human Genome Sciences, Inc., or HGS, which was acquired by GSK in 2012. Pursuant to the FP-1039 license, we granted GSK an exclusive license to develop and commercialize our FP-1039 product and other FGFR1 fusion proteins in the United States, the European Union and Canada.

In March 2016, GSK delivered to us a written notice of termination of the FP-1039 license. Pursuant to the terms of the FP-1039 license, termination of the FP-1039 license became effective on September 5, 2016, 180 days after GSK's notice of termination. Prior to GSK's termination of the FP-1039 license, GSK had initiated a Phase 1b clinical trial of FP-1039. In October 2017, GSK completed treatment of patients in this trial. GSK has no future payment obligation to us in connection with this collaboration.

We received an upfront license fee of $50.0 million from GSK in March 2011 in connection with our entry into the FP-1039 license. We identified the initial license, associated technology transfer and services for the conduct of the then-concluding FP-1039 Phase 1 clinical trial as substantive deliverables under the FP-1039 license. As of December 31, 2011, all deliverables under the FP-1039 license were fully delivered and we recognized the related $50.0 million of upfront license fee fully as revenue.

In addition, GSK was obligated to pay us for the costs of all FP-1039 related research and development activities we elected to undertake on behalf of GSK. For the years ended December 31, 2017, 2016 and 2015, we recognized $0, $21,000, and $0.1 million, respectively, in revenue from GSK related to development costs associated with FP-1039.

Muscle Diseases Collaboration

In July 2010, we entered into a research collaboration and license agreement, or the muscle diseases collaboration, with Glaxo Group Limited, or GSK, to identify potential drug targets and drug candidates to treat skeletal muscle diseases. We conducted three customized cell-based screens and one *in vivo* screen of our protein libraries under the muscle diseases collaboration. The research term under this collaboration ended in May 2014. We fully recognized the revenue related to this agreement in 2014 following the completion of our obligation to provide research services in May 2014.

The muscle diseases collaboration will terminate upon the expiration of the royalty terms of any products that incorporate or target a protein exclusively licensed under the collaboration. In addition, GSK may terminate this agreement at any time with advance written notice, and either party may terminate this agreement with written notice for the other party's material breach if such party fails to cure the breach or upon certain insolvency events.

UCB Fibrosis and CNS Collaboration

In March 2013, we entered into a research collaboration and license agreement, or the fibrosis and CNS collaboration, with UCB Pharma, S.A., or UCB, to identify potential biologics targets and therapeutics in the areas of fibrosis-related immunologic diseases and central nervous system disorders.

We applied ASC 605-25, Multiple-Deliverable Revenue Arrangements, to evaluate the appropriate accounting for this agreement. In accordance with this guidance, we concluded that we should account for the arrangement as a single unit of accounting and recognize the agreement consideration in the same manner as the final deliverable of the research services.

Under the terms of the fibrosis and CNS collaboration, UCB paid us an upfront payment of $6.0 million in March 2013. In addition, UCB agreed to pay us $6.6 million for a technology fee and $2.0 million for research funding. All of which was recorded as deferred revenue and being amortized over the initial five-year research period under the agreement. As of December 31, 2015, we fully collected on the technology fees and research funding under the fibrosis and CNS collaboration.

We are eligible to receive certain evaluation and selection fees and contingent payments with respect to each protein target that UCB elects to obtain an exclusive license, and royalties on the sales of products related to such targets, if any.

We are eligible to receive up to $0.4 million of target evaluation and selection fees with respect to each target we have offered to UCB in the collaboration. In accordance with ASC 605-28, we concluded that these fees under the agreement with UCB are substantive and should be accounted for under the milestone method of revenue recognition. During 2017, 2016 and 2015, we received $0.3 million, $0.4 million and $0.1 million in target evaluation and selection fees, respectively.

In accordance with ASC 605-28, we determined that the remaining contingent payments under the agreement do not constitute milestone payments and will not be accounted for under the milestone method of revenue recognition. The events leading to these payments under the agreement with UCB do not meet the definition of a milestone under ASC 605-28 because the achievement of these events solely depends on UCB's performance.

For the years ended December 31, 2017, 2016 and 2015, we recognized $3.3 million, $3.5 million and $4.0 million of revenue, respectively, under the fibrosis and CNS collaboration. As of December 31, 2017 and 2016, we have deferred revenue relating to this agreement of $0.6 million and $3.7 million, respectively. Additionally, UCB is obligated to reimburse us for certain specialized research and development costs associated with the screens under the agreement.

Our initial research activities under this agreement were completed in March 2016. Upon the completion of those research activities, UCB has up to a two-year evaluation period during which we may be obligated to perform additional services at the request of UCB.

The agreement will terminate upon the expiration of the royalty terms of any products that incorporate or target a protein exclusively licensed under the collaboration. In addition, UCB may terminate this agreement at any time with advance written notice, and either party may terminate the agreement with written notice for the other party's material breach if such other party fails to timely cure the breach or upon certain insolvency events.

bluebird bio, Inc. License Agreement

In May 2015, we entered into an exclusive license agreement, or the bluebird license agreement, with bluebird bio, Inc., or bluebird, under which we licensed to bluebird human antibodies to an undisclosed cancer target to research, develop and commercialize chimeric antigen receptor, or CAR, T cell therapies using these antibodies.

Under the bluebird license agreement, bluebird paid us a $1.5 million upfront fee in 2015. There are no other deliverables under the agreement other than the license grant. We recognized the $1.5 million upfront fee as revenue upon delivery of the license grant, which was completed in 2015.

In January 2017, bluebird delivered to us written notice of termination of the license agreement. Pursuant to the terms of the license agreement, the termination became effective on May 17, 2017, which was 120 days after bluebird's notice of termination. Following termination, bluebird had no future payment obligations to us in connection with the license agreement.

9. Acquired Technologies

Galaxy Biotech, LLC

In December 2011, we entered into an exclusive license agreement with Galaxy Biotech, LLC, or Galaxy, for the development, manufacturing, and commercialization of certain anti-FGFR2b monoclonal antibodies. Under the terms of the agreement, we agreed to pay Galaxy an upfront license payment of $3.0 million. We paid the upfront payment in two equal installments in January 2012 and July 2012. As we had full access to the technology and materials upon execution of the agreement, the lead compound was in an early stage of development, and the underlying technology has no alternative future uses, we recorded the entire upfront payment to research and development expenses in our statement of operations for the year ended December 31, 2011. We are also required to make additional payments based upon the achievement of certain intellectual property, development, regulatory, and commercial milestones, as well as royalties on future net sales of products resulting from development of this purchased technology, if any. In May 2016, we amended the license agreement to revise certain milestone definitions, reduce certain milestone payments and add certain development-related milestone payments that were triggered by dosing of certain patients in the current Phase 1 clinical trial of bemarituzumab. We made milestone payments to Galaxy totaling $0, $2.5 million and $0 in 2017, 2016 and 2015, respectively. In May 2017, we further amended the license agreement to align the net sales definition under the agreement to the net sales definition under any sublicense we may grant under the agreement and to amend the termination provisions to allow for a direct license between Galaxy and any sublicensee upon termination of the agreement.

BioWa, Inc. and Lonza Sales AG

In February 2012, we entered into a license agreement with BioWa, Inc. and Lonza Sales AG, or BioWa-Lonza, pursuant to which BioWa-Lonza granted us a non-exclusive license to use their Potelligent® CHOK1SV technology, including the CHOK1SV cell line, and a non-exclusive license to related know-how and patents. This license is necessary to produce our bemarituzumab antibody.

We are obligated to pay BioWa-Lonza aggregate milestone payments of up to $25.4 million for development, regulatory and commercialization milestones achieved in our bemarituzumab antibody program. We are also obligated to pay BioWa-Lonza tiered royalties on net sales of bemarituzumab up to mid-single digit percentages of the proceeds of such sales.

Our license agreement with BioWa-Lonza will remain in effect until the expiration of our royalty obligations. For each licensed product, we are obligated to pay BioWa-Lonza royalties on net sales of such licensed product on a country-by-country basis for the longer of the life of the licensed patents covering such licensed product in such country or 10 years after the first commercial sale of such licensed product in a major market country, which includes the United States. However, because we believe the last-to-expire patents currently licensed to us under the license agreement would expire in less than 10 years, we believe the date on which our royalty payment obligations to BioWa-Lonza would expire in any country would be 10 years after the first commercial sale of such product in a major market country.

We may terminate the license agreement for convenience subject to our continuing obligation to pay royalties. BioWa-Lonza may terminate the license agreement in the event of our uncured material breach, if we oppose or dispute the validity of patents licensed to us under the license agreement or if we are declared insolvent, make an assignment for the benefit of creditors, are the subject of bankruptcy proceedings or have a receiver or trustee appointed for substantially all of our property.

INBRX 110 LP

In July 2015, we entered into a research collaboration and license agreement with INBRX 110 LP, or Inhibrx, to obtain (a) an exclusive, worldwide license to antibodies to GITR for therapeutic and diagnostic uses, and (b) an exclusive option to obtain exclusive, worldwide licenses to multi-specific antibodies developed by Inhibrx that bind to both GITR and other targets.

Pursuant to the agreement, we paid Inhibrx an upfront fee of $10.0 million for the license and for services provided by Inhibrx related to a research cell bank in July 2015. We recorded an expense of $5.0 million for a milestone payment to Inhibrx when the milestone was achieved in May 2017.

We expense payments for the acquisition and development of technology as research and development cost if, at the time of payment, the technology is under development, is not approved by the FDA or other regulatory agencies for marketing, has not reached technical feasibility, or otherwise has no foreseeable alternative future use. In accordance with this policy, we expensed the $8.0 million that we determined to be related to the license upon our entry into the agreement in July 2015 as research and development expense.

In accordance with the ASC 730, *Research and Development Costs*, we concluded that we should defer and capitalize the $2.0 million that we determined to be related to the prepayment for the research cell bank services over the performance period. During both 2016 and 2015, we recognized $1.0 million of expense related to the research cell bank services. As of December 31, 2016, we fully recognized the deferred expense related to this agreement.

On August 28, 2017, we delivered to Inhibrx written notice of termination of the agreement for convenience. Pursuant to the terms of the agreement, the termination became effective on December 27, 2017.

10. Income Taxes

For the year ended December 31, 2017, we recorded an income tax expense of $1.7 million as compared to an income tax benefit of $31.0 million for the year ended December 31, 2016 and an income tax expense of $37.8 million for the year ended December 31, 2015.

For the year ended December 31, 2017, the income tax expense related to deficiency interest was based on the Internal Revenue Service reducing our tentative net operating loss carryback refund claim filed in March 2017. For the year ended December 31, 2016, the federal tax benefit represents the reversal of the federal tax provided in 2015 due to our ability to carryback federal tax attributes generated this year but not in an amount that is lower than any minimum taxes as provided under federal law. The state tax benefit in the current year represents the reversal of prior state income tax also to an amount that is not lower than any minimum tax as provided under state law. For the year ended December 31, 2015, the income tax expense was based on the taxable income generated in 2015 after utilization of our available federal and state net operating loss carryovers as well as any research credits including consideration of any applicable limitations on the use of these attributes as provided by the Internal Revenue Code and similar state statutes.

The components of our income tax (benefit) expense were as follows:

	Year Ended December 31,		
	2017	2016	2015
Current tax (benefit) expense			
Federal	$ 1,703	$ (40,740)	$ 47,369
State	1	(5,340)	5,473
Total current (benefit) expense	1,704	(46,080)	52,842
Deferred tax (benefit) expense			
Federal	—	15,032	(15,032)
State	—	—	—
Total deferred tax (benefit) expense	—	15,032	(15,032)
Total tax (benefit) expense	$ 1,704	$ (31,048)	$ 37,810

The income tax (benefit) expense differs from the amount computed by applying the statutory federal income tax rate as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Federal statutory income tax	$ (51,981)	$ (33,862)	$ 100,610
State statutory income tax	1	(3,471)	3,558
Stock compensation	(4,847)	715	437
Nontaxable equity premiums	(168)	(248)	(443)
Change in valuation allowance	41,633	12,152	(62,705)
Remeasurement of deferred taxes	27,122	—	—
Research and orphan drug credits	(11,029)	(8,029)	(3,846)
Interest charge, net of federal benefit	1,107	—	—
Other permanent items	(134)	1,695	199
Income tax (benefit) expense	$ 1,704	$ (31,048)	$ 37,810

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%. Although the Tax Act is generally effective January 1, 2018, GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date, which was December 22, 2017. Since the Tax Act was passed late in the fourth quarter of 2017, and ongoing guidance and accounting interpretation are expected over the next 12 months, we consider the accounting for the deferred tax re-measurement to be provisional. The primary impact of the Tax Act resulted from the re-measurement of deferred tax assets and liabilities due to the change in the corporate tax rate, reducing our deferred tax assets by $27.1 million with a corresponding reduction in our valuation allowance, which had no effect on our effective tax rate. Additional work will be necessary for a more detailed analysis of our deferred tax assets and liabilities as well as potential correlative adjustments. We do not expect any material subsequent adjustments to these amounts. Adjustments, if any, are not expected to have any impact to our results of operations due to our loss position and valuation allowance.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets consist of the following (in thousands):

	As of December 31,	
	2017	2016
Net operating loss carryforwards	$ 39,405	$ 5,615
Research and orphan drug credits	42,070	18,182
Deferred revenue	3,701	10,939
Stock-based compensation	7,017	6,908
Capitalized license and depreciation basis differences	—	3,574
Reserves, accruals and tenant improvement allowances	5,299	1,736
Total deferred tax assets	97,492	46,954
Less: valuation allowance	(94,315)	(46,954)
Net deferred tax assets	$ 3,177	$ —
Capitalized license and depreciation basis differences	(3,177)	—
Total deferred tax liabilities	$ (3,177)	$ —
Total net deferred tax assets	$ —	$ —

Based on all available objective evidence, we determined it is more likely than not that we will not fully realize all our net deferred tax assets. The available objective evidence considered was our inability to further recover any taxes previously paid and expectation of future taxable income. Accordingly, we recorded a valuation allowance against all our net deferred tax assets for the years ended December 31, 2017 and 2016. We will continue to maintain a full valuation allowance on our net deferred tax assets until there is sufficient positive evidence to support the reversal of all or some portion of this allowance. Our valuation allowance increased by $47.4 million and $31.4 million during 2017 and 2016, respectively.

At December 31, 2017, we had approximately $156.5 million of federal net operating losses available for future use that expire beginning in 2024 and federal research and Orphan Drug credits of approximately $36.7 million available for future use that expire beginning in 2026.

At December 31, 2017, we also had approximately $154.3 million of state net operating losses available for future use that expire beginning in 2018 and state research credits of approximately $16.4 million that have no expiration date.

Utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation due to ownership change limitations provided by the Internal Revenue Code and similar state provisions. Annual limitations may result in expiration of net operating loss and tax credit carryforwards before some or all of such amounts have been utilized.

We had $13.6 million, $9.4 million and $3.4 million of unrecognized tax benefits as of December 31, 2017, 2016 and 2015, respectively. The unrecognized tax benefits are primarily tax credits for all years and state net operating loss carryover related for certain prior years. As of December 31, 2017, we recorded $1.7 million of interest related to income taxes and no interest or penalties as of December 31, 2016. A reconciliation of our unrecognized tax benefits for the years ended December 31, 2016, 2015 and 2014 is as follows (in thousands):

	Unrecognized Income Tax Benefits
Balance as of December 31, 2014	$ 2,237
Additions for prior year tax positions	615
Additions for current year tax positions	580
Balance as of December 31, 2015	3,432
Additions for prior year tax positions	4,394
Additions for current year tax positions	1,577
Balance as of December 31, 2016	9,403
Additions for prior year tax positions	691
Additions for current year tax positions	3,490
Balance as of December 31, 2017	$ 13,584

In the event we are able to recognize these uncertain positions, most of the $13.6 million of the unrecognized tax benefits would reduce our effective tax rate. We currently have a full valuation allowance against our deferred tax assets, which would impact the timing of the effective tax rate benefit, should any of these uncertain positions be favorably settled in the future. We do not believe it is reasonably possible that our unrecognized tax benefits will significantly change within the next twelve months.

We file U.S. and state income tax returns with varying statutes of limitations. The tax years from 2002 forward remain open to examination due to the carryover of unused net operating losses and tax credits. We have no ongoing tax examinations by tax authorities at this time.

11. Commitments and Contingencies

Operating Leases

We entered into a lease agreement for our new corporate office and laboratory facility in December 2016, which we refer to as the lease. We moved into our new corporate office and laboratory facility in December 2017. The lease has an initial term of 10 years, beginning on the rent commencement date, with an option to extend the lease for an additional period of five years. We did not have to pay rent until the rent commencement date of January 1, 2018 and rent is reduced by 50% for the first six months. The lease contains scheduled rent increases over the lease term. We recognize the related rent expense for the lease on a straight-line basis over the term of the lease with the difference between the rent paid and the straight-line rent expense recorded as deferred rent. As of December 31, 2017 and 2016, deferred rent totaled $5.4 million and $0.9 million, respectively.

We received lease incentives totaling $14.4 million recorded as deferred rent from our landlord for a portion of the costs of leasehold improvements we made to the premises. We amortize the incentives on a straight-line basis over the term of the lease as a reduction of rent expense. As of December 31, 2017 and 2016, the unamortized leasehold improvement incentive totaled $13.6 million and $0.3 million, respectively. In addition, the lease required us to deliver an irrevocable standby letter of credit in an amount of $1.5 million to the landlord for the period commencing on the effective date of the agreement until at least 60 days after the expiration of the lease, subject to 50% reduction on January 1, 2023 if certain conditions are met.

Rent expense for the years ended December 31, 2017, 2016 and 2015 was $6.9 million, $2.3 million, and $2.3million, respectively. The estimated future minimum commitments under our non-cancelable operating leases are as follows (in thousands):

Year ending December 31:	
2018	5,092
2019	7,025
2020	7,274
2021	7,524
2022	7,787
2023 and on	43,230
Total estimated minimum payments	$ 77,932

Indemnifications

As permitted under Delaware law and in accordance with our bylaws, we have agreed to indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is equal to the officer's or director's lifetime.

The maximum amount of potential future indemnification is unlimited; however, we currently hold director and officer liability insurance. This insurance limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

We have certain agreements with service providers and other parties with which we do business that contain indemnification provisions pursuant to which we have agreed to indemnify the party against certain types of third-party claims. We accrue for known indemnification issues when a loss is probable and can be reasonably estimated. We would also accrue for estimated incurred but unidentified indemnification issues based on historical activity. As we have not incurred any indemnification losses to date, there were no accruals for or expenses related to indemnification issues for any period presented.

12. Subsequent Events

In January 2018, under the license and collaboration agreement with BMS, BMS triggered a $25 million milestone payment to us upon the dosing of the first patient in BMS's randomized Phase 2 clinical trial of cabiralizumab in combination with *Opdivo*, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer.

In January 2018, we closed on a public offering of 5,897,435 shares of our common stock for net proceeds of approximately $108 million, which includes 769,230 shares sold upon the underwriters' full exercise of their option to purchase additional shares.

13. Selected Quarterly Financial Information (Unaudited)

The following amounts are in thousands, except per share amounts:

	Quarter Ended			
Quarterly Results of Operations	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
	(Unaudited)			
Revenue	$ 10,135	$ 7,822	$ 8,333	$ 13,218
Net loss	(33,443)	(44,286)	(43,282)	(29,211)
Basic and diluted net loss per share	(1.21)	(1.58)	(1.54)	(1.04)

	Quarter Ended			
Quarterly Results of Operations	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(Unaudited)			
Revenue	$ 6,520	$ 9,229	$ 6,680	$ 8,262
Net loss	(13,040)	(13,137)	(19,414)	(20,106)
Basic and diluted net loss per share	(0.49)	(0.49)	(0.72)	(0.73)

Basic and diluted net income (loss) per share is computed independently for each of the quarters presented. Therefore, the sum of quarterly basic and diluted per share amounts may not equal annual basic and diluted net income (loss) per share amounts.

CORPORATE INFORMATION

MANAGEMENT

Aron Knickerbocker
President and Chief Executive Officer

Nallakkan Arvindan
Senior Vice President, Strategic Technology Operations

Kevin Baker, Ph.D.
Senior Vice President, Development Sciences

Helen Collins, M.D.
Senior Vice President and Chief Medical Officer

Jeff Coon
Senior Vice President, Human Resources

Bryan Irving, Ph.D.
Senior Vice President, Research

Francis Sarena
Chief Strategy Officer and Secretary

BOARD OF DIRECTORS

Lewis T. Williams, M.D., Ph.D.
Executive Chairman of the Board

Aron Knickerbocker
President, Chief Executive Officer and Director

Mark D. McDade
Lead Independent Director

Franklin M. Berger, CFA
Director

Fred E. Cohen, M.D., D. Phil.
Director

Kapil Dhingra, M.B.B.S.
Director

Sheila Gujrathi, M.D.
Director

Peder K. Jensen, M.D.
Director

Garry Nicholson
Director

William R. Ringo
Director

CORPORATE HEADQUARTERS

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP

STOCKHOLDER INFORMATION

Our common stock is listed on The Nasdaq Global Select Market under the ticker symbol **FPRX**.

Copies of our Form 10-K and proxy statement filed with the Securities and Exchange Commission and other information pertinent to our investors, including contact information for investor relations inquiries, are available free of charge on our website at investor.fiveprime.com.

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