FIVE PRIME THERAPEUTICS INC
Form 10-K
March 18, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2014

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.)

Two Corporate Drive

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 x

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 x

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 x 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 x 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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of June 30, 2014, 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 $310.0 million, based on the closing price of the registrant's common stock on the NASDAQ Global Select Market on June 30, 2014 of $15.55 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 March 11, 2015, the registrant had 25,532,719 shares of common stock, par value $0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement, or the Proxy Statement, for the 2015 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, 2014.

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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 RIPAS® 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.

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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,” “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 or our partners’ ability to advance drug candidates into, and successfully complete, clinical trials alone or in combination with other drugs;
- 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 maintain and establish collaborations;
- the implementation of our business model and strategic plans for our business, drug candidates and technology;
- the scope of protection we establish and maintain for intellectual property rights covering our drug candidates and technology;
- the size of patient populations targeted by products we or our partners develop and market adoption of our potential products by physicians and patients;
- the timing or likelihood of regulatory filings and approvals;
- 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.

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PART I.

Item 1. Business.

Our Company

We are a clinical-stage biotechnology company focused on discovering and developing novel protein therapeutics to improve the lives of patients with serious diseases. We currently have three product candidates in clinical development covering multiple potential indications. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are still needed. We have an emphasis in immuno-oncology, an area in which we have clinical and discovery programs and pharmaceutical collaborations. We are pursuing companion diagnostics for two of our clinical programs to allow us to select patients most likely to benefit from treatment and potentially accelerate clinical development and improve patient care. Our most advanced product candidates are identified below.

- FPA008 is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are developing in rheumatoid arthritis and plan to clinically develop in pigmented villonodular synovitis, or PVNS, and in combination with nivolumab in multiple cancers.

- FPA144 is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are developing to treat patients with gastric (stomach) cancer.

- FP-1039/GSK3052230 is a fusion protein that “traps” and neutralizes cancer-promoting fibroblast growth factors, or FGFs, involved in cancer cell proliferation and new blood vessel formation that our partner, GlaxoSmithKline, or GSK, is developing to treat patients with squamous non-small cell lung cancer, or NSCLC, and malignant pleural mesothelioma.

We have a differentiated target discovery platform and library, which we believe encompasses substantially all of the body’s medically important targets for protein therapeutics, which positions us to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and a growing focus of our research and development activities. We are applying all aspects of our biologics discovery platform, including cell-based screening, in vivo screening, receptor-ligand matching technologies and bioinformatics, in our immuno-oncology research program. We have identified novel targets that we believe could be useful in immuno-oncology and are actively validating these and looking for additional targets. We plan to generate therapeutic proteins, including antibodies or ligand traps, directed to the targets we identify and advance select candidates into pre-clinical development and eventually clinical development.

Our Strategy

Our goal is to use our proprietary platform to maintain our leadership position in the discovery of innovative protein therapeutic targets and to develop and commercialize protein therapeutics to treat cancer and inflammatory diseases. The key elements of our strategy to achieve this goal are:

- Focus on protein therapeutics to treat cancer and inflammatory diseases. Protein therapeutics accounted for over $75 billion in global sales in 2013 for the treatment of cancer and inflammatory diseases. However, there continue to be significant medical needs for novel and effective therapies. We believe that our library includes substantially all medically important extracellular proteins involved in cancer and inflammatory diseases, and, combined with the significant experience and expertise of our scientists in these fields, we believe we are well positioned to identify new targets and to develop effective, novel protein therapeutics.
- Continue to advance and expand our internal pipeline. We are currently developing three product candidates, FPA008, FPA144 and FP-1039. We plan to focus our resources on the development of these product candidates and on discovering and developing new product candidates with our platform.
- Employ smarter drug development techniques. We will pursue indications and specific patient populations in which activity of our product candidates can be assessed early in clinical development, potentially in Phase 1 clinical trials. We also plan to use companion diagnostics, where appropriate and feasible, to identify patients most likely to respond to our product candidates, an approach we are currently pursuing in two of our clinical programs. We believe selecting patients using companion diagnostics should increase the probability of success in our clinical trials.

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- Build a commercial enterprise by retaining rights for products in targeted specialty markets. We plan eventually to build sales and marketing capabilities in selected specialty markets in the United States that we can adequately serve with a focused commercial organization. We have retained global rights to FPA008 and FPA144. In our collaboration with GSK for FP-1039, we have an option to co-promote the product in the United States.
- Establish additional product, clinical and discovery collaborations to supplement our internal development capabilities and generate funding. From time to time, we expect to establish additional product and clinical collaborations. These collaborations supplement our development, manufacturing, regulatory and commercialization capabilities, provide us with significant funding to advance our pipeline and validate our technology. In addition, because our discovery platform is broadly applicable, we plan to opportunistically establish discovery collaborations in cancer, immuno-oncology, inflammation or other disease areas if we believe that such collaborations are financially and strategically warranted.

Our Clinical Pipeline

FPA008

FPA008 is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or 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, such as PVNS and RA, macrophages contribute to inflammation. FPA008 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. We believe the combination of FPA008 with T cell checkpoint inhibitors, such as PD-1 inhibitors, or immune agonists may have synergistic therapeutic effects in treating cancer. In PVNS, a rare CSF1-driven tumor with considerable morbidity for which there are no currently approved therapies, inhibition of CSF1R reduces infiltration into the joint of monocytes and macrophages, which form the bulk of the tumor mass, resulting in tumor shrinkage. Inhibition of CSF1R in inflamed joints in rheumatoid arthritis, or RA, patients should block the production of inflammatory cytokines by macrophages and inhibit osteoclasts, monocyte-lineage cells that can cause bone erosions and joint destruction.

Until now, it has been difficult to block monocytes and macrophages because the protein targets that control these cells were only partially known. Using our library and proprietary platform, we discovered a novel protein target called interleukin-34, or IL-34, that is a key regulator of monocyte and macrophage numbers and activity and that is found in inflamed joints of RA patients. Once we discovered IL-34, we were able to use our protein library and our 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. FPA008 blocks the binding of both CSF1 and IL-34 to CSF1R and thereby inhibits the activity and survival of these cells (Figure 1).

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Figure 1: FPA008 Mechanism of Action

FPA008 in Immuno-Oncology

We believe that there is a strong rationale for combining FPA008 with checkpoint inhibitors in cancer, including that:

- TAMs are immunosuppressive and act by inhibiting CD8 T cell responses while enhancing recruitment and differentiation 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 blockade of CSF1R in combination with checkpoint inhibitors (e.g., anti-PD1 or anti-CTLA4 antibodies) or immune agonists (e.g., anti-CD40 antibodies) synergistically induces tumor regressions.

These points suggest that combining an anti-CSF1R antibody, such as FPA008, with an anti-PD1 antibody, such as nivolumab, may benefit cancer patients.

In November 2014, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb Company, or BMS, under which we and BMS are collaborating under a development plan to evaluate the safety, tolerability and preliminary efficacy of combining nivolumab, BMS's investigational PD-1 immune checkpoint inhibitor, with FPA008. We and BMS plan to initially study the FPA008- nivolumab combination as a potential treatment for patients with non-small cell lung cancer, or NSCLC, melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma in a Phase 1a/1b trial, which we expect to commence in mid-2015. We plan to explore tumor- and blood-based biomarkers to better understand which patients are more likely to respond to this novel combination. We are responsible for conducting the trial of the FPA008- nivolumab combination under the development plan with BMS.

We believe that FPA008 may have additive or synergistic therapeutic effects when combined with other T cell checkpoint inhibitors, in addition to PD-1 inhibitors such as nivolumab, or immune agonists. We plan to continue to evaluate the potential clinical development of FPA008 in combination with these other checkpoint inhibitors and immune agonists.

FPA008 in PVNS

PVNS is a rare, locally aggressive tumor of the synovium. It is characterized by local over-expression of CSF1, which recruits macrophages into the joints, forming the non-malignant tumor mass. It is associated with high morbidity, and there are no approved therapies for the condition.

We are preparing to initiate a Phase 1/2 clinical trial of FPA008 in patients with PVNS in mid-2015. In the Phase 1 component of this trial, we plan to select the optimal dose in PVNS patients for the Phase 2 portion. After identifying the optimal dose, the primary objectives of the Phase 2 portion of this trial will be to assess tumor shrinkage, and key secondary objectives include duration of response and joint function in patients with PVNS. PVNS is an orphan indication, and we believe patients with this disease will benefit from CSF1R inhibition achieved with the administration of FPA008. We expect to have preliminary efficacy data from the Phase 1 portion of this trial in patients with PVNS by the end of 2015 or early 2016.

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FPA008 in Rheumatoid Arthritis (RA)

We believe FPA008 has the potential to be more efficacious than current therapies in inflammatory conditions like rheumatoid arthritis because it targets a group of important inflammatory monocytes and macrophages that are key drivers of the inflammation and joint destruction process and are not targeted by currently approved drugs. These cells depend on CSF1R for their activity and survival. These cells secrete a variety of proteins, including tumor necrosis factor alpha, or TNFa, interleukin-6, or IL-6, and interleukin-1 beta, or IL-1ß, that attract and activate inflammatory cells. Derivatives of these inflammatory cells directly destroy bone tissue in joints.

Until now, it has been difficult to block monocytes and macrophages because the protein targets that control these cells were only partially known. Protein therapeutics that are approved to treat RA, such as Humira, Remicade, Enbrel and Actemra, only block single factors released from monocytes and macrophages, and other protein therapeutics such as Orencia® (abatacept) and Rituxan® (rituximab) do not directly inhibit monocytes and macrophages or their factors.

FPA008 reduces the numbers and activity of monocytes and macrophages, and prevents the production and release of inflammatory factors. The advantage of this approach in comparison to, for example, Humira and Actemra, is that the production of multiple deleterious factors is inhibited simultaneously, potentially resulting in better control of inflammation. Another advantage of blocking CSF1R is that a special macrophage that breaks down bone, called an osteoclast, is inhibited. Therefore, not only could FPA008 potentially be superior in reducing inflammation, but it may also directly suppress bone destruction in the joints of patients with inflammatory diseases.

Preclinical Results in RA. We and others have demonstrated that both IL-34 and CSF1 are present at increased levels in the inflamed joints of patients with RA. Biopsy samples of inflamed joints from patients with RA incubated with FPA008 ex vivo showed reduced levels of the inflammatory proteins TNFa, IL-6 and IL-1ß compared with samples incubated with a control antibody (Figure 2). These studies provide evidence that FPA008 can simultaneously inhibit the production of multiple cytokines that cause inflammation in RA.

Figure 2: Incubation of joint tissue from patients with RA with FPA008 results in decreased TNFa, IL-6 and IL-1ß[(1)]

(1) Each pair of linked dots corresponds to samples from the same patient and treated with either a control that does not bind to CSF1R, or with FPA008.

Clinical Development of FPA008 in RA. We are currently conducting a Phase I trial in which we initially tested single- and multiple-ascending doses of FPA008 in healthy volunteers, and are now testing FPA008 in RA patients. In the healthy volunteer portion of this Phase 1 trial, which concluded in 2014, we administered FPA008 in either a single dose or two doses administered 14 days apart to 36 healthy volunteers. We also administered placebo to an additional 10 healthy volunteers during this portion of the trial. In November 2014, we presented results from the healthy volunteer cohorts of this Phase 1 trial in a poster presentation at the 2014 American College of Rheumatology and the Association of Rheumatology Health Professionals Annual Scientific Meeting. The preliminary results from the healthy volunteer portion of the trial demonstrated that FPA008 was well tolerated at doses up to 3 mg/kg. Additionally, at all dose levels tested, we observed pharmacodynamics, or PD, effects of suppression of non-classical CD16+ monocytes (Figure 3) and a decrease of bone turnover biomarkers (CTx, Trap5), all of which we believe indicate the potential for clinical benefit in RA patients. We observed no dose-limiting toxicities during the healthy volunteer portion of this trial. The most common FPA008 treatment-related toxicities were pruritus, eyelid edema with or without facial swelling, fatigue and headache. These events were mild (grade 1 or 2) and reversible. Some

dose-dependent elevations of CK, LDH and AST enzymes were observed, but were not associated with clinical signs or symptoms, were reversible and were expected based on FPA008's inhibition of Kupffer cells in the liver, which clear these enzymes from the blood.

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This trial has since advanced into an open-label evaluation of FPA008 at multiple dose levels in RA patients whose disease is not responsive to methotrexate therapy. The primary endpoint of this Phase 1 trial in RA is safety, with secondary endpoints including pharmacokinetics, PD, and disease activity, as measured by American College of Rheumatology (ACR) scores and magnetic resonance imaging of affected joints. We plan to present preliminary data from part 3 of this Phase 1 trial in RA patients by the end of 2015.

Figure 3: Non-classical CD16+ Monocytes After a Single Dose

FPA144

FPA144 is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are developing to treat a subset of gastric (stomach) cancer patients whose tumors have evidence of high levels of FGFR2b, as determined by a molecular diagnostic test. This subset of tumors with aberrant FGFR2 protein expression is associated with lower overall survival. We believe that approximately 5% of gastric cancer patients have FGFR2 gene-amplified tumors that overexpress FGFR2b, and that additional gastric cancer patients have tumors that overexpress FGFR2b protein without gene amplification. Because FPA144 is a targeted agent for a selected patient population with a high unmet need, we believe there is the potential for an accelerated development path for FPA144.

We believe that FPA144 acts on tumor cells in two ways:

- FPA144 binds to FGFR2b and blocks certain FGFs from binding to FGFR2b stopping these FGFs from promoting the growth of the tumor cells; and
- Once FPA144 binds to FGFR2b on the surface of the tumor cell, FPA144 engages cells of the immune system to kill the tumor cell in a process called antibody-dependent cell-mediated cytotoxicity, or ADCC.

In preclinical studies, FPA144 was highly effective in blocking the growth of gastric tumors that produce abnormally high levels of FGFR2b. This is demonstrated in Figure 4, where human gastric tumors with fibroblast growth factor receptor 2, or FGFR2, gene amplification were treated with increasing doses of FPA144, resulting in significant inhibition of tumor growth and tumor shrinkage when compared to a control antibody.

Figure 4: Increasing doses of FPA144 inhibit growth of human gastric tumors that contain an amplification of the FGFR2 gene in a mouse model

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Clinical Development of FPA144. In December 2014, we began a Phase 1 clinical trial of FPA144. We are currently enrolling patients with any solid tumor to assess safety and tolerability and to identify the optimal dose for gastric cancer patients. For the Phase 1b part, we will enroll gastric cancer patients whose tumors show evidence of FGFR2b protein overexpression or FGFR2 gene amplification, as identified through molecular diagnostic assays. Endpoints of the trial include safety and overall response rate. We expect to complete the dose escalation portion of this trial and begin the expansion portion in molecular diagnostically selected gastric cancer patients by the end of 2015. We also plan to present preliminary safety data from this trial by the end of 2015.

If FPA144 demonstrates activity in gastric cancer patients in the Phase 1 trial, we plan to conduct a pivotal trial of FPA144 as a monotherapy in gastric cancer patients and, in a separate Phase 1b trial, test FPA144 in combination with standard of care chemotherapy in newly diagnosed gastric cancer patients. We may also consider initiating a Phase 1 clinical trial in Japan for further development in that country.

If we see early evidence of a therapeutic effect in patients, we intend to meet with regulatory authorities to discuss the possibility of an expedited clinical development and regulatory pathway for FPA144. We intend to seek orphan drug designation with the FDA before the end of the Phase 1 clinical trial, and if eligible, expedited review and approval programs, including breakthrough therapy and fast track designations for FPA144.

Market Opportunity. Globally, gastric cancer is the sixth most common malignancy with the third highest mortality. In the US, the prevalence of gastric cancer is approximately 74,000 patients, of which we believe approximately 3,700 have FGFR2 gene-amplified tumors that overexpress FGFR2b and are more likely to respond to FPA144. We believe there are additional gastric cancer patients whose tumors overexpress FGFR2b protein without gene amplification who also are more likely to respond to FPA144. Globally, the prevalence of gastric cancer is approximately 1.5 million patients, of which we estimate that approximately 75,000 have FGFR2 gene-amplified tumors that overexpress FGFR2b and that there are additional gastric cancer patients whose tumors overexpress FGFR2b protein without gene amplification who are likely to respond to FPA144.

Given the relatively small population of gastric cancer patients that overexpress the FGFR2b protein in the US and the poor survival of these patients, we believe that this indication will be an orphan indication in the United States. By developing FPA144 for an orphan indication with a significant unmet medical need, we may be able to accelerate the development and approval of FPA144 in the United States. We believe that our clinical development organization is well suited to conduct such a focused, capital-efficient clinical development plan for FGFR2 gene-amplified or FGFR2b over-expressing gastric cancer. We plan to develop and commercialize FPA144 ourselves in the United States. We plan to seek a collaborator to commercialize FPA144 outside of the United States.

FP-1039

FP-1039 is a protein therapeutic we designed to “trap” and neutralize cancer-promoting FGFs. These FGFs act by binding to and activating FGFRs. FGFs and FGFRs regulate tumor cell proliferation and the growth of new blood

vessels, a process called angiogenesis. The FGF family consists of 22 known proteins called ligands that exert their physiological effect on cells by binding to four FGFRs (FGFR1, FGFR2, FGFR3 and FGFR4). Dysregulation of the FGF pathway has been linked to the growth of human tumors and poor patient prognosis.

There are two mechanisms by which FP-1039 may provide clinical benefit in certain tumor settings. The first, by trapping the FGF ligands that help drive tumor growth or survival in which the FGFR1 gene is amplified, and the second, by trapping the ligands, such as FGF-2, that are over-expressed or over-produced by tumor cells. Certain tumors produce an excessive number of FGFR1 genes, a process known as gene amplification. This gene amplification results in excess production, or the over-expression, of FGFR1 protein on the surface of the tumor cell. This over-expression of FGFR1 leads to increased binding of FGFs, which stimulates uncontrolled proliferation of some types of tumor cells. These tumors include squamous non-small cell lung cancer, or squamous NSCLC. Patients who have squamous NSCLC with FGFR1 gene amplification have significantly reduced survival relative to comparable patients whose tumors do not have this amplification. In other settings, certain tumors have uncontrolled cancer cell proliferation due to over-expression of some FGFs, such as FGF-2, that promote tumor growth through angiogenesis. By triggering angiogenesis, cancerous cells can fuel their metabolic needs and direct their own uncontrolled cell division. Mesothelioma is a tumor that has some of the highest over-expression levels of FGF-2 and is a tumor setting of high unmet need.

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Unlike other therapies directed to FGFR1 that indiscriminately block all FGFs, FP-1039 is designed to only block cancer-promoting FGFs that bind to FGF receptor 1, or FGFR1, and therefore may be associated with better tolerability than other known drug candidates targeting the FGF pathway less selectively. For example, FP-1039 does not bind to an FGF called FGF-23, which regulates phosphate levels in the blood, and therefore FP-1039 does not change phosphate levels in the blood. This is in contrast to small molecule inhibitors of FGF receptors being developed by Novartis AG, AstraZeneca plc and others, which block the activity of both cancer-associated FGFs and FGF-23, and are reported to cause abnormally high phosphate levels in the blood, a condition known as hyperphosphatemia. High phosphate levels can lead to calcification in tissues, including blood vessels. In our Phase 1 clinical trial, treatment with FP-1039 in patients with solid tumors was not associated with the side effects seen in the clinical trials with small molecule FGFR inhibitors, which included hyperphosphatemia and retinal detachment. We expect FP-1039 to be better tolerated by patients. We also expect that it could be used in dosages high enough to fully block cancer-promoting FGFs, and that it has the potential to be safely combined with standard of care chemotherapy.

FP-1039 Preclinical Data. In preclinical testing, we observed inhibition of tumor growth with single-agent FP-1039, particularly in tumors with FGFR1 gene amplification, including squamous NSCLC (Figure 5).

Figure 5: Treatment with FP-1039 inhibits growth of squamous NSCLC tumors with FGFR1 gene amplification in mouse models

Furthermore, when combined with standard chemotherapy, FP-1039 treatment improved anti-tumor activity in preclinical models. Figure 6 shows results in a preclinical model of squamous NSCLC with FGFR1 gene amplification in which the addition of FP-1039 to chemotherapy resulted in greater tumor growth inhibition than either FP-1039 or chemotherapy alone.

Figure 6: Addition of FP-1039 to standard chemotherapy results in greater inhibition of growth of squamous NSCLC tumors with FGFR1 gene amplification in mouse models

FGF-2 ligand overexpression is highest in mesothelioma among all tumor models studied and is thought to contribute to tumor growth and angiogenesis. In preclinical testing, we observed inhibition of mesothelioma tumor growth with single-agent FP-1039 (Figure 7).

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Figure 7: Treatment with FP-1039 inhibits growth of mesothelioma in mouse models

Clinical Development of FP-1039. We completed a Phase 1 clinical trial of FP-1039 designed to assess the safety, tolerability and pharmacokinetics of single-agent FP-1039 administered weekly to patients with metastatic tumors. The 39 patients enrolled in the study had a variety of tumors, including advanced or metastatic breast cancer, lung cancer, colon/rectal cancer, prostate cancer, head and neck cancers or uterine cancer. Overall, FP-1039 was well tolerated over the dose range studied and no maximum tolerated dose was observed in this study. As a result, we believe that FP-1039 will be well tolerated in combination with standard of care chemotherapy. In the Phase 1 clinical trial, FP-1039 treatment was not associated with hyperphosphatemia or retinal detachment, both of which have been observed in patients enrolled in trials with the small molecule FGFR inhibitors. We also studied blood levels of FGF-2, one of the most important cancer-promoting FGFs, and observed a significant decrease of FGF-2 in all patients tested.

Our partner, GSK, is conducting a Phase 1b clinical trial of FP-1039 in combination with several chemotherapies in patients with FGFR1 gene-amplified or FGF-2 over-expressing tumors. The trial is designed as a three-arm, multicenter, non-randomized, parallel-group, uncontrolled, open-label Phase 1b clinical trial with up to 120 patients at approximately 40 clinical sites. This Phase 1b clinical trial is designed to evaluate the safety, tolerability, dosage and overall response rate of FP-1039:

- in combination with paclitaxel and carboplatin in previously untreated metastatic squamous NSCLC (Arm A);
- in combination with docetaxel in metastatic squamous NSCLC that has progressed after previous therapy (Arm B); or
- in combination with pemetrexed and cisplatin in mesothelioma (Arm C).

GSK has completed the planned dose escalation portion in one of the three arms and has begun the expansion portion of that arm. All arms continue to enroll patients. We expect GSK to present data from this trial at a scientific meeting by the end of 2015. GSK is responsible for the development and commercialization of FP-1039 in the United States, the European Union and Canada. We have an option to co-promote FP-1039 in the United States.

Clinical development of FP-1039 in patients with FGFR1 gene-amplified tumors will be accompanied by a diagnostic test designed to identify the selected patient population we believe to be the most likely to benefit from FP-1039 and to enable streamlined clinical development. Patients with FGFR1 gene-amplified tumors are identified by staining tests performed on tumor samples. In the current Phase 1b trial of FP-1039, GSK is using a third party central lab to test tumor samples from prospective subjects to identify those with FGFR1 gene-amplified tumors. Neither we nor GSK have yet engaged a third party to develop any companion diagnostic that would be used in any future clinical trials of FP-1039 or required for the registration and approval of FP-1039. In Arm C, enrolled patients with mesothelioma will have their tumors analyzed retrospectively for over-expression of FGF-2.

Market Opportunity. We believe there are currently no approved therapies that specifically block FGFs or FGFRs. We and our partner GSK are currently focusing development of FP-1039 in cancers with FGF pathway dysregulation, which has been linked to the growth of human tumors and poor patient prognosis. We believe the selected patients with FGF pathway dysregulation would be most likely to benefit from treatment with FP-1039. Based on literature

reports and our own data, we estimate that between 10 to 20% of squamous NSCLCs have FGFR1 gene amplification, which would translate to a prevalence of 5,000 to 10,000 squamous NSCLC patients in the US and approximately 23,000 to 46,000 squamous NSCLC patients outside the US with FGFR1 gene amplification. Mesothelioma has the highest FGF-2 levels among various cancers that we have evaluated and a majority of mesothelioma patients have tumors with abnormally high levels of FGF-2. Mesothelioma is an orphan indication in the United States with a prevalence of about 4,000 patients and incidence of about 3,000 patients. Worldwide, there are a total of approximately 14,000 cases of mesothelioma diagnosed each year.

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In March 2011, we entered into a license and collaboration agreement with GSK, or the FP-1039 license, pursuant to which we granted to GSK an exclusive license to develop and commercialize FP-1039 and other FGFR1 fusion proteins in the United States, the European Union and Canada. GSK controls the development of FP-1039, which GSK refers to as GSK3052230, in these territories. We retain rights to develop and commercialize FP-1039 in territories outside the United States, the European Union and Canada and we have a co-promotion option in the United States.

Immuno-Oncology Drug Discovery Program

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 which 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 new approach has the potential of not only reducing tumor growth like traditional therapies, but potentially eliminating the cancer entirely in some patients.

New targets for immuno-oncology are needed to address those patients that do respond to or cannot tolerate agents currently in development. We believe we are well positioned to identify new targets and protein drugs in immuno-oncology because:

- Protein drugs will be the best therapeutic strategy in immuno-oncology. Anti-tumor immunity often involves interactions between extracellular proteins that are not easily modulated with small molecule drugs. We are focused on discovering and developing novel protein therapeutics.
- There are likely many new targets yet to be discovered. For example, the protein partners are not known for several of the proteins thought to have a role in modulating anti-tumor immunity, such as TIM-3, VISTA, B7-H3 and B7-H4. There are likely many additional proteins that regulate the immune response to tumors that have not yet been described or characterized.
- Our biologics discovery platform is designed to identify targets such as those involved in immuno-oncology. Our proprietary library of more than 5,700 human extracellular proteins contains many proteins that are candidate immunomodulators. We are using our discovery platform to discover novel pathways and to identify protein partners for molecules known to be involved in the anti-tumor immune response.

We are applying all aspects of our biologics discovery platform, described below, including cell-based screening, in vivo screening, receptor-ligand matching technologies and bioinformatics in our immuno-oncology research program. We have identified promising new antibody targets and ligand traps and are actively screening for and validating additional targets. We plan to advance select antibody and ligand trap candidates into pre-clinical development and eventually clinical development.

Our Biologics Discovery Platform. 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. Traditional ways to discover new targets for protein therapeutics have relied on a slow “trial-and-error” approach studying a single or a small number of proteins at a time. There are more than 5,700 proteins in the body that

represent potential protein therapeutic targets, but only about 30 are targeted by currently marketed protein drugs in cancer and inflammatory diseases.

We spent seven years successfully developing a platform to improve the traditionally difficult and slow process of discovering new protein therapeutics. The platform is based on two components:

- a proprietary library of more than 5,700 human extracellular proteins that we believe is the most comprehensive collection of fully functional extracellular proteins and is an abundant source of medically relevant novel targets for protein therapeutics; and
- proprietary and new technologies for producing and testing thousands of proteins at a time.

We believe our platform improves and accelerates the discovery of new protein 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 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.

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We have used our platform to identify dozens of targets validated in rodent models, including in collaboration with our partners, and to build a growing pipeline of drug candidates. We believe our platform is particularly well positioned to explore new pathways in cancer, inflammation and their intersection in immuno-oncology, a growing focus of our discovery and clinical activities.

Novel Technologies to Produce and Screen Our Library in High Throughput. We have developed a suite of technologies for producing and screening the proteins in our library that addresses the limitations of traditional drug screening methods when applied to proteins. These technologies are composed of a combination of our own proprietary technology along with other publicly available technologies, including technologies we have in-licensed on a non-exclusive basis from third parties. Generally, we protect these proprietary biologics discovery platform technologies as trade secrets or know-how and do not seek to obtain patents to cover the biologics discovery platform technologies we develop.

High-Throughput Protein Production. The difficulty of producing large numbers of new proteins in a functional form often presents a limitation in the discovery of new protein drugs. Our high-throughput protein production system includes proprietary technologies developed over several years that allow us to produce more than 5,700 proteins per week at therapeutically relevant amounts and with a high level of consistency. We produce the proteins for our cell-based screening system using human cells to best ensure proteins are made in the same correct, functional form in which they are made in the human body. Our technologies enable us to reliably produce our entire protein library in less than three weeks. In contrast, typical methods producing one or a few proteins at a time would take years to produce a library of this size and would have to be repeated for each target discovery screen.

Cell-Based Screens to Identify Protein Therapeutic Targets. We design complex cell-based screens that better model the fundamental biological processes underlying the disease of interest and adapt them to be compatible with our protein library. We have undertaken what we believe to be some of the most complex cell-based screens in high throughput with protein libraries, including screens with rare stem cells and combinations of diseased primary human cell types. We execute these screens on automated, state-of-the-art screening systems designed and built in-house and analyzed using software developed by us. To date, we have screened each of the proteins in our protein library in screens using approximately 50 different cell types.

Rapid In Vivo Protein Production System. Our rapid in vivo protein production system, or RIPPS®, enables us to produce and test the proteins in our library directly in vivo in virtually any rodent model of disease and in high throughput. RIPPS technology identifies new targets that cannot be easily identified in other ways. Further, RIPPS not only identifies novel targets for protein therapeutics—for example, targets for therapeutic antibodies—it can also identify proteins that are new therapeutics themselves because each protein in the library is tested for its ability to affect a disease in a rodent model. RIPPS avoids the costly and time-consuming process required for conventional in vivo testing of efficacy and safety that includes expression, scale up, purification, characterization and formulation of each protein one at a time.

Receptor-Ligand Matching. Some proteins are referred to as ligands and exert their actions by binding to a receptor on a cell surface. In order to optimally treat some diseases, one must know the identity of both the receptor and the ligand. Our comprehensive collection of protein ligands and extracellular domains of cell surface receptors provides us with the ability to identify ligand and receptor pairs. Historically, this information has led to new therapeutic targets by identifying the best target in a disease pathway and has increased the probability of success of drug development by enhancing understanding of the mechanism of action of a therapeutic candidate.

Growing Database of Protein Function. We have tested each of the proteins in our library in numerous screens on different cell types. This provides us with an extensive database of how each protein performs in different screens and whether it is specific to a given disease process or has a broader set of activities. The cumulative data from all the screens allows us to identify the most appropriate target.

Collaborations

A part of our strategy is to establish product, clinical and discovery collaborations. These collaborations supplement our development, manufacturing, regulatory and commercialization capabilities, provide us with significant funding to advance our pipeline and validate our technology. Our discovery collaborations also have demonstrated the breadth of our discovery platform and validated our discovery capabilities. Because our discovery platform is broadly applicable, we plan to opportunistically establish additional discovery collaborations in cancer, immuno-oncology, inflammation or other disease areas if we believe that such collaborations are financially and strategically warranted. A summary of our key product, clinical and discovery collaborations is set forth below.

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Clinical Trial Collaboration with BMS

In November 2014, we entered into a clinical trial collaboration agreement, referred to as the clinical trial collaboration, with BMS, pursuant to which we are collaborating with BMS under a development plan to evaluate the safety, tolerability and preliminary efficacy of combining our FPA008 antibody with nivolumab, BMS's investigational PD-1 immune checkpoint inhibitor, which we refer to together as the combined therapy. Under the development plan, BMS and we plan to initially study the combined therapy as a potential treatment for patients with non-small cell lung cancer, or NSCLC, melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma in a Phase 1a/1b study, which we expect to commence by the second half of 2015. BMS and we may, by mutual agreement, expand the scope of the development plan to study the combined therapy in clinical studies in additional tumor types under the clinical trial collaboration. We are responsible for conducting the clinical study of the combined therapy under the development plan.

The clinical trial collaboration provides for exclusivity with respect to the development, with a collaborative partner, of combination regimens of an anti-PD-1 or PD-L1 antagonist together with an anti-CSF1R antagonist, any of which we refer to as a restricted combination. If either party would like to conduct a clinical trial to study a restricted combination in a particular tumor type that the parties are not then developing or preparing to develop under the development plan, or a proposed new tumor type, then that party may propose that the parties conduct the clinical trial to study the combined therapy under the development plan under the clinical trial collaboration. The non-proposing party will have the right to review such proposed clinical trial and a limited period of time to elect to conduct the clinical trial under the clinical trial collaboration, which election period will not begin in any event until after (i) certain dose escalation and pharmacodynamic conditions are met in the planned Phase 1a portion of the first clinical study of the combined therapy; or (ii) the first subject is dosed in the Phase 1b portion of the first clinical study of the combined therapy, whichever is earlier, and which date we refer to as the initial results date. If the non-proposing party does not elect to conduct the clinical trial under the clinical trial collaboration within the limited review and election period, the original proposing party may thereafter conduct such clinical trial to study a restricted combination in the proposed tumor type and such proposed tumor type would thereafter no longer be exclusive under the clinical trial collaboration.

Under the terms of the agreement, BMS paid us a one-time fee of $30.0 million in December 2014.

If a change of control of FivePrime closes prior to the Initial Results Date, defined as the earlier date of (i) certain dose escalation and pharmacodynamics conditions are met in the planned Phase 1a portion of the first clinical study of the combined therapy; or (ii) the first subject is dosed in the Phase 1b portion of the first clinical study of the combined therapy, then if:

- immediately prior to such change of control, the acquirer in such change of control (or any of its affiliates) owns or controls an anti-PD-1 or anti-PD-L1 antagonist that is then in clinical development for use in treating cancer or is then being commercialized for use in treating cancer;
- BMS is using commercially reasonable efforts in the performance and fulfillment of its activities under the clinical trial collaboration;
- the parties are developing or pursuing the development of the combined therapy under the clinical trial collaboration; and
- a change of control of BMS has not occurred,

we would be obligated to pay to BMS the lesser of (x) $30.0 million or (y) 10% of the aggregate purchase price paid to us or our stockholders at the closing of such change of control (with any contingent consideration being risk-adjusted and discounted).

BMS is responsible for all third party expenses that are directly attributable to the conduct of activities under the development plan, other than manufacturing activities. For manufacturing costs related to FPA008, we are responsible for the full expense of the manufacture and supply of FPA008 for any Phase 1a clinical study under the development plan and each party will be responsible for one half of the full expense of the manufacture and supply of FPA008 for any other clinical study under the development plan. BMS is responsible for the full expense of the manufacture and supply of nivolumab for any clinical study under the clinical trial collaboration. Each party will be responsible for its own internal costs, including internal personnel costs, incurred in the conduct of activities under the development plan.

If we wish to out-license the right to commercialize FPA008 in any territory at any time on or before the date that is 90 days after the initial results date, which we refer to as the ROFR offer period, then for a period of three months BMS will have the exclusive right to negotiate an exclusive license to develop and commercialize FPA008 in such territory, which we refer to as BMS's right of first refusal. If BMS does not exercise its right of first refusal or if we do not reach an agreement with BMS for such exclusive license within the three-month negotiation period, then we would be free to negotiate the out-license of such rights to FPA008 in such territory; provided that we must provide BMS 10 business days to match any offer from a third party for such rights received prior to the date that is 90 days after the end of BMS's ROFR offer period.

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After BMS's ROFR offer period, if we wish to out-license the right in any territory to commercialize FPA008 for use in cancer, then BMS will have a three-month right of first negotiation to obtain exclusive rights to FPA008 for such territory. If BMS does not exercise its right of first negotiation or if we do not reach an agreement with BMS for such rights within such three-month period, then we would be free to out-license any and all rights to FPA008 for such territory.

Unless earlier terminated by either party, the clinical trial collaboration agreement will continue until the date that is 90 days after the completion of all clinical trials under the clinical trial collaboration, the delivery of all study data by both parties and the completion of all obligations under the development plan. Either party may terminate the clinical trial collaboration with written notice (i) if the other party is in material breach and such breach has not been cured within the applicable cure period, (ii) if either party deems it necessary to protect the safety, health or welfare of the subjects enrolled in a clinical trial or (iii) 90 days following the commencement of a clinical hold. Upon any termination of the clinical trial collaboration, depending upon the circumstances, the parties have varying rights and obligations regarding the completion of any ongoing clinical trials.

FP-1039 License and Collaboration with GSK

In March 2011, we entered into a license and collaboration agreement, or the FP-1039 license, with Human Genome Sciences, which was acquired by GSK in August 2012, pursuant to which we granted to GSK an exclusive license to develop and commercialize FP-1039 and other FGFR1 fusion proteins in the United States, the European Union and Canada. GSK controls the development of FP-1039, which GSK refers to as GSK3052230, in these territories. We retain rights to develop and commercialize FP-1039 in territories outside the United States, the European Union and Canada.

GSK paid us an upfront license fee of $50 million in connection with its entry into the FP-1039 license. GSK is obligated to pay us contingent payments, which could total up to $435 million based upon the achievement of pre-specified development, regulatory and commercial criteria. These contingent payments are composed of up to $70 million for the pre-specified development criteria, up to $195 million for the pre-specified regulatory criteria, and up to $170 million for the pre-specified commercial criteria. If certain manufacturing criteria are not met, these aggregate potential contingent payments could total up to $310 million instead of $435 million. We are also eligible to receive tiered royalty payments on a country-by-country basis from the low-double digits to the high-teens based on net sales of FP-1039 for the longer of the life of certain patents covering FP-1039 in such country or 12 years after the first commercial sale of FP-1039 in such country. We cannot determine the date on which GSK's royalty payment obligations to us would expire because no commercial sales of FP-1039 have occurred and the last-to-expire relevant patent covering FP-1039 in a given country may change in the future. Currently, the last-to-expire issued patents covering FP-1039 will expire in 2031 in the United States and in 2026 in certain European countries. Additional patents that may issue in the United States, Europe and Canada from pending patent applications would expire between 2026 and 2034. These patent expiration dates do not reflect any patent term extensions that may be available, which are not determinable at this time.

We have a minority co-promote option for FP-1039 in the United States. To exercise our right to co-promote FP-1039, we must notify GSK prior to the later of (i) five days after the filing of the first Biologic License Application, or BLA, with the FDA, for FP-1039 or (ii) six months after GSK notifies us of the anticipated filing of the first BLA for FP-1039. If we exercise our right to co-promote FP-1039, we would receive a low single-digit increase in the royalty rate that GSK would otherwise pay us relating to net sales in the United States.

GSK is responsible for conducting FP-1039 related research, development and commercialization activities in the United States, the European Union and Canada, at GSK's cost and expense. We do not have any obligation to fund any of these activities.

GSK is obligated to pay us for the costs of all FP-1039-related research and development activities we undertake on behalf of GSK. At the time we entered into the FP-1039 license, we agreed to perform services for the conduct of the then-concluding FP-1039 Phase 1 clinical trial. We also elected to conduct a Phase 2 clinical trial of FP-1039 in endometrial cancer for which we were reimbursed by GSK. Additionally, GSK is obligated to pay us for the costs of other FP-1039-related research and development activities we elect to undertake on behalf of GSK. GSK has paid us $3.4 million for our conduct of these activities through December 31, 2014. The Phase 2 clinical trial of FP-1039 in endometrial cancer was terminated in January 2012. We are no longer conducting any activities with respect to this trial and are not currently undertaking any other FP-1039-related research or development activities on behalf of GSK. GSK is currently conducting a Phase 1b clinical trial of FP-1039 in combination with several chemotherapies in patients with FGFR1 gene-amplified or FGF-2 over-expressing tumors. The trial is designed as a three-arm, multicenter, non-randomized, parallel-group, uncontrolled, open-label Phase 1b clinical trial with up to 120 patients at approximately 20 clinical sites.

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We and GSK agreed to disclose to each other FP-1039 preclinical and clinical data in the form of final study reports from future trials or studies conducted by either of us. We and GSK also agreed that either party may use, at no cost, any such exchanged preclinical or clinical data in regulatory filings we or GSK make with respect to FP-1039 in our respective territories. For example, after GSK completes its Phase 1b clinical trial of FP-1039, we would be able to use the clinical data from that filing in regulatory filings we may file in Japan regarding FP-1039, which is outside of GSK's territory.

The FP-1039 license will terminate upon the expiration of the royalty terms of any products that result from the collaboration. In addition, GSK may terminate this agreement at any time with advance written notice, and either party may terminate this agreement for the other party's material breach if such party fails to cure the breach or upon certain insolvency events. Either party may also terminate the agreement upon certain patent challenges made against one another. In the event that GSK terminates the agreement for convenience or if we terminate for certain material breaches or due to a patent challenge, we will have to pay GSK royalties on any net sales in the United States, the European Union or Canada for 12 years after the first commercial sale.

GSK Muscle Diseases Collaboration

In July 2010, we entered into a research collaboration and license agreement, referred to as the muscle diseases collaboration, with GlaxoSmithKline LLC, or GSK, to identify potential drug targets and drug candidates to treat skeletal muscle diseases. In May 2011, we amended the muscle diseases collaboration to expand the research plan in scope and duration to include an additional cell-based screen and an in vivo screen using our RIPPS technology. We conducted three customized cell-based screens and one in vivo screen of our protein library under the muscle diseases collaboration. The research term under this collaboration ended in May 2014.

In September 2014, GSK exercised its option under the muscle diseases collaboration to obtain an exclusive, worldwide license to an undisclosed muscle disease target we identified using our proprietary target discovery platform and paid us a $1.5 million fee. In addition, we are entitled to receive up to $122.5 million in milestone payments as well as royalties on net sales of products related to the target. The milestone payments consist of preclinical and development-related contingent payments of up to $28.5 million, regulatory-related contingent payments of up to $40.0 million and commercial-related contingent payments of up to $54.0 million. For each product that incorporates or targets a licensed protein target, GSK is also obligated to pay us tiered low- to mid-single digit royalties on net sales of such product for the longer of the life of certain patents licensed to GSK covering such product or 12 years after the first commercial sale of such product.

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, referred to as the respiratory diseases collaboration, with Glaxo Group Limited, 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 plan to conduct up to six customized cell-based screens of our protein library under the respiratory diseases collaboration. The four-year research term will end in April 2016.

At the inception of the respiratory diseases collaboration, GSK made an upfront payment to us of $7.5 million and purchased shares of our preferred stock for $10.0 million. Through December 31, 2014, we have also received $8.6 million of research funding and we are eligible to receive up to an additional $4.3 million of research funding under the respiratory diseases collaboration through the remainder of the research term, which ends in April 2016.

In the course of conducting screens of our protein library in the respiratory diseases collaboration, we expect to discover proteins that may be potential drug targets or drug candidates for treating refractory asthma or COPD. Under the respiratory diseases collaboration, GSK has the right for limited periods of time to evaluate proteins identified in the screens we conduct and obtain an exclusive worldwide license to develop and commercialize products that incorporate or target the protein.

Prior to the time GSK exercises its right to obtain an exclusive worldwide license to a protein target, we will discuss and agree on Track 1 Targets, over which GSK will have sole responsibility for the further development and commercialization of products that incorporate or target such protein targets, and Track 2 Targets, for which we will develop biologics that incorporate or target such protein targets through to clinical proof of mechanism in either a Phase 1 clinical trial or Phase 2 clinical trial. We will take into consideration each party’s available resources and capabilities at the time in deciding which protein targets will be Track 1 Targets or Track 2 Targets, but subject to each party’s general right to alternate in such selection and with GSK to have the right to first select.

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For Track 1 Targets, GSK would have sole responsibility for the further development and commercialization of products that incorporate or target the protein, including with respect to preclinical studies, clinical development, manufacturing and commercialization, at GSK's cost and expense. For Track 2 Targets, we would have sole responsibility for the further development of biologic products that incorporate or target the protein, including with respect to preclinical studies, clinical development and manufacturing, at our cost and expense through agreed-upon proof-of-mechanism endpoints in a Phase 1 or Phase 2 clinical trial.

We are eligible to receive up to $124.3 million in potential target evaluation and selection fees and contingent payments with respect to each Track 1 Target. These potential fees and payments are composed of target evaluation and selection fees of up to $1.8 million, preclinical and development-related contingent payments of up to $28.5 million, regulatory-related contingent payments of up to $40.0 million and commercial-related contingent payments of up to $54.0 million. For each product that incorporates or targets a Track 1 Target, GSK is also obligated to pay us tiered low- to mid-single digit royalties on net sales of such product for the longer of the life of certain patents licensed to GSK covering such product or 10 years after the first commercial sale of such product. We cannot determine the date on which GSK's potential royalty payment obligations to us would expire because GSK has not yet elected to take an exclusive license to any evaluated protein target, and therefore we cannot identify related patents to any such relevant licensed protein 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 Track 2 Target. These potential fees and payments are composed of per target evaluation and selection fees of up to $1.8 million, a clinical proof of mechanism option exercise fee of up to $23.0 million, preclinical and development-related contingent payments of up to $36.5 million, regulatory-related contingent payments of up to $53.0 million and commercial-related contingent payments of up to $79.5 million. For each product that incorporates or targets a Track 2 Target, GSK is also obligated to pay us tiered high-single to low-double digit royalties on net sales of such product for the longer of the life of certain patents licensed to GSK covering such product or 10 years after the first commercial sale of such product.

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 plan to conduct up to five customized cell-based and in vivo screens of our protein library under the fibrosis and CNS collaboration. We currently expect to complete our initial research activities under the fibrosis and CNS collaboration by 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.

At the inception of the fibrosis and CNS collaboration, UCB made payments to us of $8.2 million. Through December 31, 2014, we received $5.7 million of technology access fees and research funding and we are eligible to receive up to an additional $3.2 million of technology access fees and research funding under the fibrosis and CNS collaboration through the end of the research term, which we expect to end in March 2016.

In the course of conducting screens of our protein library in the fibrosis and CNS collaboration we expect to discover proteins that may be potential drug targets or drug candidates for fibrosis-related immunologic diseases and CNS disorders. Under the fibrosis and CNS collaboration, UCB has the right for limited periods of time to evaluate proteins identified in the screens we conduct 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. 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 that 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. For each product that incorporates or targets a licensed protein target, UCB is also obligated to pay us tiered low- to mid-single digit royalties on net sales of such product for the longer of the life of certain patents covering such product or 10 years after the first commercial sale of such product. We cannot determine the date on which UCB's potential royalty payment obligations to us would expire because UCB has not yet elected to take an exclusive license to any evaluated protein target, and therefore we cannot identify related patents to any such relevant licensed protein target.

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The fibrosis and CNS 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.

BMS Immuno-oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement with BMS, which we refer to as the immuno-oncology research collaboration, 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, 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.

The initial three-year research term of the immuno-oncology research collaboration will end in March 2017. BMS has the option to extend the research term for two additional one-year terms.

In connection with entering into the immuno-oncology research collaboration, BMS made an upfront payment of $20.0 million to us. Through December 31, 2014, we received $3.4 million of research funding and are eligible to receive up to an additional $6.1 million of research funding under the immuno-oncology research collaboration through the end of the initial three-year research term. We will be eligible to receive up to $240.0 million per collaboration target in specified developmental, regulatory and commercialization contingent payments comprising 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 will also be eligible to receive up to $60.0 million in sales-based contingent payments per collaboration product.

For each commercialized product under the immuno-oncology research collaboration that is directed toward a target in the checkpoint pathways, BMS is also obligated to pay us tiered mid-single digit to low double-digit percentage royalties, subject to reduction in certain circumstances, on net sales of such product for the longer of (i) 12 years after the first commercial sale of such product, (ii) the life of certain patents licensed covering such product or (iii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such product expires. We cannot determine the date on which BMS's potential royalty payment obligations to us would expire because BMS has not yet commercialized any products under the immuno-oncology research collaboration, and we therefore cannot identify the date of the first commercial sale or any related patents covering such product.

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.

In connection with the immuno-oncology research collaboration agreement, 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.

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 FPA144. 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. We paid Galaxy an upfront license fee of $3.0 million in connection with our entry into the license agreement, which we paid in two equal installments in January 2012 and July 2012.

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Through December 31, 2014, we made milestone payments to Galaxy totaling $2.6 million. We are obligated to pay Galaxy additional milestone payments of up to $89.9 million comprising aggregate intellectual property-related milestone payments of up to $1.4 million, development-related milestone payments of up to $17.0 million for development in two indications, aggregate regulatory-related milestone payments of up to $41.5 million for two indications and aggregate commercial-related milestone payments of up to $30.0 million. We are also obligated to pay tiered royalties on net sales of FPA144 from the high-single digits to the low-double digits.

Our license agreement with Galaxy will remain in effect until the expiration of our royalty obligations under the license agreement 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 product in such country or 10 years after the first commercial sale of such product in such country. We cannot determine the date on which our royalty payment obligations to Galaxy would expire because no commercial sales of FPA144 have occurred and the last-to-expire relevant patent covering FPA144 in a given country may change in the future. Currently, Galaxy has an issued patent, which we have licensed, covering FPA144 in the United States that expires in 2029. Galaxy patents that may issue in other countries, including in Europe and Japan, from pending patent applications would expire in 2029. These patent expiration dates do not reflect any patent term extensions that may be available, which are not determinable at this time.

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 proceeding 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.

License Agreement with The Regents of the University of California

In September 2006, we entered into a license agreement with The Regents of the University of California, or the UC Regents, pursuant to which the UC Regents granted us an exclusive license under certain patents to develop and commercialize products, including FP-1039, and practice certain methods covered by the patents. Under the license agreement, we are obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product.

We are obligated to pay the UC Regents milestone payments of up to $0.8 million for the development and marketing approval of FP-1039 in cancer. We are also obligated to pay the UC Regents a low single-digit royalty on net sales of FP-1039 for the life of the relevant licensed patents. If we sublicense our rights under our license agreement with UC Regents, we would be obligated to pay the UC Regents a percentage of the total gross proceeds we receive in consideration of the grant of the sublicense, which total amount would be first reduced by the aggregate amount of certain research and development related expenses we have incurred. The portion of the total adjusted sublicense proceeds we would pay the UC Regents would be a mid-single digit percentage of the proceeds if such sublicense occurred prior to the first Phase 2 clinical trial of a licensed product, or a low-single digit percentage of the proceeds if such sublicense occurred after the initiation of the first Phase 2 clinical trial of a licensed product.

Our license agreement with the UC Regents will remain in effect until the expiration or abandonment of the last to expire of the licensed patents. We may terminate the license agreement for convenience in its entirety upon prior

written notice to the UC Regents. The UC Regents may terminate the license agreement in its entirety in the event of our uncured material breach of the license agreement. The license agreement will automatically terminate upon the filing of a petition for bankruptcy relief that is not dismissed within a set period of time.

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 FPA144 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 FPA144 antibody program. We are also obligated to pay BioWa-Lonza tiered royalties on net sales of FPA144 up to mid-single digit percentages of the proceeds of such sales.

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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 product on a country-by-country basis for the longer of the life of the licensed patents covering such product in such country or 10 years after the first commercial sale of such 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.

Non-exclusive License with Board of Trustees of the Leland Stanford Junior University

In February 2006, we entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University, or Stanford, pursuant to which Stanford granted us a non-exclusive license to use certain biological materials and a non-exclusive license to related patents. We use the licensed materials in the production of proteins in our protein library.

We are obligated to pay a non-material annual fee to maintain this license agreement. We have no milestone payment or royalty obligations under our license agreement with Stanford.

The license agreement has no fixed term. We may terminate the license agreement for convenience. Stanford may terminate the license agreement in the event of our uncured material breach.

Non-exclusive License with National Research Council of Canada

In December 2013, we entered into a license agreement with the National Research Council of Canada, or NRC, pursuant to which NRC granted us a non-exclusive license to use certain biological materials and a non-exclusive license to related patents. We use the licensed materials in the production of proteins in our protein library.

We have no milestone payment or royalty obligations under our license agreement with NRC.

The initial term of the license agreement expires on December 31, 2018, after which we may annually renew for additional one-year terms for a fee. The NRC may terminate the license agreement if we become bankrupt or insolvent, have a receiver appointed to continue our operations or resolve to wind up. We may terminate at any time with written notice. Either party may terminate the license agreement in the event of the other party’s uncured material breach.

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, novel biological discoveries, including new targets and applications, and other inventions 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 and 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 have entered into a non-exclusive license with BioWa-Lonza to use their Potelligent® CHOK1SV technology, which is necessary to produce our FPA144 antibody, and non-exclusive licenses with each of the NRC and Stanford to use materials and technologies that we use in the production of our protein library. 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.

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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 reduced 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 three most advanced programs are summarized below:

FPA008

Our FPA008 patent portfolio is wholly owned by us and includes an issued U.S. patent as well as pending U.S. and foreign patent applications covering compositions of matter, methods of use and biomarkers relating to FPA008. The issued U.S. composition of matter patent expires in 2031. Patents that may issue from the pending U.S. and foreign applications would expire between 2031 and 2033.

FPA144

Our patent portfolio for FPA144 includes patents and patent applications we exclusively licensed from Galaxy, as well as a pending U.S. and foreign patent applications wholly owned by us. The patent portfolio we exclusively licensed from Galaxy includes an issued U.S. patent as well as pending U.S. and foreign patent applications covering compositions of matter and methods of use of FPA144. The issued U.S. composition of matter patent expires in 2029. Patents that may issue from these pending U.S. and foreign applications would expire in 2029. Patents that may issue from the pending U.S. and foreign patent application wholly owned by us would expire in 2034.

FP-1039

Our patent portfolio for FP-1039 includes patents and patent applications wholly owned by us, as well as patents we exclusively license from UC Regents.

The FP-1039 patent portfolio that we wholly own includes issued patents and pending patent applications covering compositions of matter, methods of use, including certain combination therapies and dosing regimens, and biomarkers relating to FP-1039. This patent portfolio includes patents issued in the United States, Europe, Japan, Hong Kong, Australia and New Zealand. The issued U.S. patents covering composition of matter and methods for using FP-1039 expire in 2026 and 2031, respectively. The issued patent in Japan covering composition of matter for FP-1039 expires in 2026. The issued patents in Europe, Hong Kong, Australia and New Zealand covering composition of matter and methods of using FP-1039 expire in 2026. The FP-1039 patent portfolio that we wholly own also includes pending U.S. and foreign patent applications covering composition of matter and methods of use. Patents that may issue from these pending U.S. and foreign patent applications would expire between 2026 and 2034.

The FP-1039 patent portfolio also includes issued U.S. and foreign patents we exclusively license from the UC Regents that cover composition of matter and methods of producing FP-1039. These exclusively licensed patents include issued U.S. patents covering composition of matter and methods of producing FP-1039 that expire between 2019 and 2020.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application.

In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

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We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Manufacturing

We have process development and small-scale manufacturing capabilities. We generally perform cell line and process development for our product candidates and manufacture quantities of our drug candidates necessary to conduct preclinical studies of our investigational drug 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. GSK is responsible for the manufacture, at its cost and expense, of FP-1039 drug substance and filled drug product used in activities GSK undertakes under the FP-1039 license. 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 and we can manufacture commercial products. 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 because our lead candidates are still in preclinical or early clinical development. We generally expect to retain some commercial rights in the United States for our product candidates in specialty markets. Pursuant to our FP-1039 collaboration, we have a co-promotion right in the United States which, if exercised by us, will allow us to field a minority percentage of the total United States

sales force promotional effort (from GSK and us combined). If we exercise our option to co-promote FP-1039 in the United States prior to submission of a BLA, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell FP-1039 with GSK. 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 FP-1039 is being developed.

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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 FPA008, FPA144, FP-1039 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 Marketing Approval

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.

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Our planned clinical trials for our product candidates may not begin or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory approval to commence a study;
- reaching agreement with third-party clinical trial sites and their subsequent performance in conducting accurate and reliable studies on a timely basis;
- obtaining institutional review board, or IRB, approval to conduct a study at a prospective site;
- recruiting patients to participate in a study; and
- manufacturing or obtaining supply of the investigational product and related materials, such as companion diagnostics.

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 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 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 study 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 phases that 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 studies may also gain 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—studies 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.

Government regulation may delay or prevent marketing of product candidates for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approvals for any future product candidates on a timely basis, if at all. Success in early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval.

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The Biologic License Application Approval Process

In order to obtain approval to market a biologic in the United States, a biological license application, or 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, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the 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 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 the safe use of the biologic. 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 limitations on who may prescribe or dispense the biologic. 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.

Based on pivotal Phase 3 clinical trial results submitted in a BLA, 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 FDA's filing of the BLA rather than the standard 10 months. Priority review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial 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.

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.

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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 drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and 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 requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product 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 are free to prescribe any product approved by the FDA for any use, 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 for 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 a company promotes or distributes 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 Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions, which generally are 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. 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 providing 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.

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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.

Biologics Price Competition and Innovation Act of 2009

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the Public Health Service Act to create a new licensure framework for follow-on biologic products, or 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 relaying to some extent on the FDA's previous review and approval of the reference biologic to which the proposed product is similar. Previously, there had been no licensure pathway for such biosimilar products.

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.

On March 6, 2015, the FDA approved the first biosimilar, Zarxio (filgrastim-sndz), a leukocyte growth factor which referenced Amgen's filgrastim product, Neupogen. Because Neupogen was approved in 1991, Amgen had no remaining exclusivity. In contrast, the twelve-year marketing exclusivity and four-year data exclusivity provided to innovator products will be available for each of our biological product candidates, running from the date of each such product's first licensure.

FDA Regulation of Companion Diagnostics

As part of our clinical development plans, we are exploring the use of 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. In the United States, the FDA regulates the 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 of medical devices. 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. Some companion diagnostics, however, could potentially be cleared through 510(k) clearance.

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification demonstrating that the proposed device is "substantially equivalent" to a "predicate device," which is a previously 510(k) cleared Class I or Class II device, a pre-amendment Class III device for which the FDA has not yet called for PMA applications or a device that was in

commercial distribution before May 28, 1976. To demonstrate substantial equivalence, the applicant must show that the device has the same intended use and the same technological characteristics as the predicate, or if the device has different technological characteristics than the predicate, the device does not raise new questions of safety and effectiveness, and is at least as safe and effective as the predicate. The FDA's 510(k) clearance pathway usually takes from four to twelve months, but it can last longer. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA.

A product not eligible for 510(k) clearance must follow the PMA pathway, which requires proof that there is a reasonable assurance of a device's safety and efficacy to the FDA's satisfaction.

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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, or QSR, 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, although the process typically takes longer and may require several years to complete. 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 the 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 make 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 then the data submitted in an amendment to the PMA. Once granted, PMA may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

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 draft 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.

The FDA previously has required in vitro companion diagnostics intended to select the patients who will respond to the cancer treatment to obtain PMA simultaneously with approval of the drug. Based on the 2014 guidance, and the FDA's past treatment of companion diagnostics, we believe that the FDA will require PMA of one or more companion diagnostics to identify patient populations suitable for our product candidates. The review of these companion diagnostics in conjunction with the review of our product candidates involves coordination of review by the FDA's Center for Drug Evaluation and Research and by the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics Device Evaluation and Safety.

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, 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 individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is 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.

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Anti-Kickback, False Claims and Physician Payment Sunshine 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. These laws include the Federal Anti-Kickback Statute, false claims statutes, and the Federal Physician Payment Sunshine Act. We are subject to these laws and they may affect our business. The Federal Anti-Kickback Statute prohibits, among other things, persons 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 Healthcare Reform Act or PPACA, 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, PPACA 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 false claims statutes. 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. Several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, also may implicate the Federal False Claims Act. Federal False Claims Act violations may result in imprisonment, criminal fines, civil monetary damages and penalties 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. A number of states have Anti-Kickback Statutes that apply regardless of the payor.

In addition, the Federal Physician Payment Sunshine Act requires extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data. The system for reporting is called Open Payments and applies to pharmaceutical companies. Last year was the first year for reporting under the Open Payments system. 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, 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.

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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.

Patient Protection and Affordable Care Act

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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively 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. Among the provisions of the Affordable Care Act of importance to the pharmaceutical and medical device industries are the following:

- The Affordable Care Act increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, from 15.1% to 23.1% and from 11% to 13% of the average manufacturer price, or AMP, for most branded and generic drugs and biologic agents, respectively. The Affordable Care Act also added a new rebate calculation for “line extensions” (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products and potentially impacted manufacturers’ Medicaid Drug Rebate liability by modifying the statutory definition of AMP. PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits, to be phased-in by 2014.
- The Affordable Care Act expanded the types of entities eligible to receive discounted pricing through the 340B drug pricing program. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- The Affordable Care Act imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., “donut hole”) as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D.
- The Affordable Care Act imposes an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- The Affordable Care Act expanded healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, and added new government investigative powers, and enhanced penalties for noncompliance.
- The Affordable Care Act established the Physician Payment Sunshine Act (as referenced above) which now requires pharmaceutical and medical device manufacturers to track and report annually certain financial arrangements with

physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or other transfers of value" made or distributed to such entities, and it requires applicable manufacturers and applicable group purchasing organizations to report annually any ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members by the 90th day of each calendar year.

- The Affordable Care Act added a new requirement to annually report drug samples that manufacturers and distributors provide to physicians.
- A new Patient-Centered Outcomes Research Institute was established pursuant to PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- The Affordable Care Act created the Independent Payment Advisory Board which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.

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- The Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In 2012, the Supreme Court of the United States heard challenges to the constitutionality of certain provisions of the Affordable Care Act. The Supreme Court's decision upheld most of the Affordable Care Act. However, the Supreme Court struck down a provision in the Affordable Care Act that penalized states that choose not to expand their Medicaid programs through an increase in the Medicaid eligibility income limit from a state's current eligibility levels to 133% of the federal poverty limit. As a result of the Supreme Court's ruling, it is unclear whether states will expand their Medicaid programs by raising the income limit to 133% of the federal poverty level and whether there will be more uninsured patients in 2015 than anticipated when Congress passed the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there will be fewer insured patients overall. The reduction in the number of insured patients could impact our sales, business and financial condition.

Earlier this year, the Supreme Court of the United States heard a case in which it will decide whether the federal government has the authority to make subsidies available to millions of Americans who buy health insurance on federal Exchanges. The outcome of this case could adversely affect the ability of enrollees to continue their insurance coverage and consequently may affect the insurance coverage to certain individuals for our products. A decision is expected in June.

These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and, accordingly, our financial operations.

We anticipate that the Affordable Care Act and this subsequent legislation will result in additional downward pressure on coverage and the price that we receive for any approved product. Any reduction in reimbursement from Medicare and 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. In addition, it is possible that there will be further legislation or regulation that could materially affect our business, financial condition, and results of operations.

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 Two Corporate Drive, 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, 2014, we had 123 full-time employees and 1 part-time employee. Of these employees, 99 were primarily engaged in research and development activities and 44 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 Securities and Exchange Commission, or 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.

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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 have incurred net losses in nearly every year since our inception and anticipate that we will continue to incur net losses in the 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 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 year ended December 31, 2014, we reported a net loss of $37.4 million. As of December 31, 2014, we had an accumulated deficit of $189.0 million.

We expect to continue to incur significant losses for the foreseeable future and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors 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 profitable.

To date, we have not generated any revenues 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 a number of 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 and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
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launch and commercialize future product candidates for which we obtain marketing approval, if any, and if launched independently, successfully establish a sales force, marketing and distribution infrastructure;

- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for our or our partners' products, if any;
- establish, maintain and protect our intellectual property rights; 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 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 these products.

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Even if we generate revenues 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. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance additional product candidates into clinical trials and as we increase the number and size of our clinical trials. We believe that our existing cash and cash equivalents and marketable securities as of December 31, 2014, the net proceeds from our January 2015 public offering of our common stock, and the funding we expect to receive under existing collaboration agreements will fund our projected operating requirements into the first half of 2018. However, 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 requiring us to find new product candidates, or our product collaboration partners may not elect to pursue the development and commercialization of any of our product candidates that are subject to their respective agreements with us. Any of these events may increase our development costs more than we expect. 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 other than programs currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, 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 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 any product candidates or cease operations altogether;
- seek strategic alliances 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 any future 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 will have a material adverse effect on our business, operating results and prospects.

Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. 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 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 for such authorities to require that we 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, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;

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- 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 our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our 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 can generate a sufficient amount of revenue from our products, if ever, we expect to finance 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 result in dilution to our existing stockholders and/or increased fixed payment obligations. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would 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.

We plan to use our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue that may be generated from future operations. However, our ability to use NOL carryforwards could be limited as a result of issuance of equity securities.

We plan to use our current year operating losses to offset taxable income that may result from any revenue generated from future operations or corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. As a result, our use of federal NOL carryforwards could be limited by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we issue. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

Risks Related to Our Business and Industry

Three of our product candidates are in clinical development. We may not identify additional product candidates or identify or validate additional drug targets. If we do not identify additional product candidates or identify or validate additional drug targets or 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. To date, we have three product candidates, FPA008, FPA144 and FP-1039, in clinical development. Our ability to generate product revenues, which we do not expect will 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 clinical

development. The outcome of target discovery and validation efforts and preclinical studies may not predict the success of clinical trials. Moreover, preclinical data are often susceptible to varying interpretations and analyses and many companies that have believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed in clinical development. Our inability to successfully identify and validate new targets and complete preclinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

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If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce 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 future 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.

If we experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

We do not know whether any clinical trials will begin as planned, will need to be 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 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 clinical trial operations or 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 clinical trials at any time for safety issues or for any other reason;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators or failure to conduct the 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, manufacturing and delivery of the product candidates to the clinical sites;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects or disease progression;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Any inability of us or our partners to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

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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 sites;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- 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 drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

For example, we plan to conduct a Phase 1/2 clinical trial of FPA008 in patients with PVNS, which is a rare, locally aggressive CSF1-driven tumor of synovium for which there are no currently approved therapies. Very little data regarding the incidence and prevalence of PVNS exists and the data that has been published suggests that the incidence of PVNS may be as low as 1.8 per 1,000,000. We expect that the limited size of the PVNS patient population will limit patient enrollment rates. Also, we know that Plexxikon Inc. has clinically tested its PLX3397 product and Roche has clinically tested its RG7155 antibody in PVNS patients. If Plexxikon or Roche continue the clinical development of their products in PVNS, we would potentially compete with them for the enrollment in this rare patient population, which may adversely impact the rate of patient enrollment in and the timely completion of our planned Phase 1/2 clinical trial of FPA008 in PVNS. Also, although we believe selecting patients using companion diagnostics should increase the probability of success in our clinical trials of FPA144 and FP-1039 in gastric cancer and squamous non-small cell lung cancer, respectively, this will limit the number of patients eligible for enrollment.

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.

We may not successfully identify, test, develop or commercialize potential product candidates.

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 identify, test, develop and commercialize protein therapeutics, which we may develop ourselves or in-license from others. 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 for a number of reasons, including because:

- 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 in the particular disease indications we are pursuing, which may be challenging to validate because of the novelty of the target or we may fail to validate at all after further research work;
- we may need to rely on third parties to generate antibody candidates for our product candidate programs;
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we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of goods, cause delays or make the product candidates unmarketable;

- our product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- 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.

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If any of these events occur, we may be forced to abandon our development efforts for a program or 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 products is complex and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. 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 period of time to investigate and remedy 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; and
- 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. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

Certain raw materials necessary for the manufacture of our FPA008 and FPA144 products under our current manufacturing process, such as growth media, resins and filters, are available 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 trials or the regulatory approval of that product candidate.

We depend on third-party manufacturers for the manufacture of drug substance and drug product for clinical trials as well as on third parties for our supply chain. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates, which could harm our results of operations.

We have process development and small-scale 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.

Human Genome Sciences, Inc., which was acquired by GSK in August 2012, and which we refer to as GSK, is responsible for the manufacturing of FP-1039 for GSK's use in clinical trials. Under our license and collaboration agreement with GSK, we have the right to require GSK to manufacture and supply us with FP-1039 bulk drug substance and filled FP-1039 drug product. We have contracted with third parties for the manufacture of FPA008 and FPA144 bulk drug substance and drug product for Phase 1 clinical testing and labeling and distribution of FPA008 drug product for our Phase 1 clinical trial of FPA008.

We have not contracted with alternate suppliers in the event the current organizations we utilize 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 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 or products ourselves, including 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 because of 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 that is costly or damaging to us.

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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 preclinical studies and clinical trials and depends upon 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 the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate 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:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologic License Application or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the 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, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates 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. Results of our trials could reveal a high and unacceptable severity and 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 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 product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of 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;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;

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- the FDA may require the establishment or modification of REMS or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products 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 acceptance of the particular product candidate or otherwise materially harm the commercial prospects for the product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of our therapeutic product candidates.

We and certain of our partners plan to develop companion diagnostics for our therapeutic product candidates. We expect that, at least in some cases, the FDA and comparable foreign regulatory authorities may require the development and regulatory approval of a companion diagnostic as a condition to approving our therapeutic product candidates. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any agreements in place with any third party to develop or commercialize companion diagnostics for any of our therapeutic product candidates.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization.

If we or our partners, or any third parties that either of us engage to assist us, are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so:

- the development of our therapeutic product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our therapeutic product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any therapeutic product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our therapeutic product candidates.

If any of these events were to occur, our business would be harmed, possibly materially.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it 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. 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 a product’s indicated uses or marketing, or impose ongoing requirements for potentially costly

post-approval studies or post-market surveillance.

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In addition, manufacturers of drug products 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 agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the 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 agency 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 can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or other court actions to impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- 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 inhibit 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, are subject to enforcement letters, inquiries and 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 our products for off-label uses can also subject us 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 a 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 causing 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 share in 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 regarding certain sales practices promoting off-label drug uses involving fines in excess of $1.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim 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, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies 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.

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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 must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies 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 of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the 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. Further, 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 others and may significantly diminish the commercial prospects of that product candidate, and our business prospects could 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 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 us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through 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 and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Although there are no approved therapies that specifically target the signaling pathways 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 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 FP-1039, our lead product candidate, were approved for the treatment of squamous non-small cell lung cancer, it could face competition from currently approved and marketed products, including carboplatin, cisplatin, paclitaxel, docetaxel, gemcitabine and Tarceva ® (erlotinib). Further competition could arise from products currently in development, including several small molecules that act in the same pathway as FP-1039, including Novartis AG's BGJ-398, AstraZeneca plc's AZD-4547, Eli Lilly and Company's LY-2874455, ArQule Inc.'s ARQ-087, Clovis Oncology/Les Laboratoires Servier/EOS S.p.A.'s lucitanib, Incyte Corporation's INCB54828 and Janssen Pharmaceuticals, Inc.'s JNJ-42756493. Additionally, we could face competition from other agents, such as immuno-oncology agents including Bristol-Myers Squibb Company's Opdivo® (nivolumab), that are being developed to treat patients with squamous non-small cell lung cancer. Some of these programs have been advanced further in clinical development than FP-1039 and could receive approval before FP-1039 is approved, if it is approved at all.

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If FPA008 were approved for the treatment of rheumatoid arthritis, it could face competition from currently approved and marketed products, including Humira®(adalimumab), Remicade ® (infliximab), Simponi® (golimumab), CIMZIA (certolizumab pegol), Orencia® (abatacept), Actemra® (tocilizumab) and Enbrel ® (etanercept), or from products in development such as MorphoSys' and GSK's MOR103 antibody or Medimmune/AstraZeneca's mavrilimumab antibody, which act on some of the same cell types as FPA008. Further competition for FPA008 in cancer or PVNS could arise from products currently in development, including Daiichi Sankyo Co., Ltd./Plexxikon Inc.'s PLX3397 small molecule tyrosine kinase inhibitor, Roche's RG7155 antibody, or Lilly's IMC-CS4/LY3022855 antibody, MorphoSys and GSK's MOR103 antibody, each of which act in the same pathway as FPA008.

If FPA144 were approved for the treatment of gastric cancer, it could face competition from currently approved and marketed products, including 5-fluorouracil, capecitabine, doxorubicin, cisplatin and docetaxel or CYRAMZA TM (ramucirumab), and from products currently in development, including AstraZeneca plc's AZD-4547 and Bayer's BAY1179470, an FGFR2 antibody.

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;
- the 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;
- the ability to establish, maintain and protect intellectual property rights related to our product candidates;
- the 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 a number of factors, including:

- the efficacy and safety profile of the product candidate, as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- 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.

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Even if we commercialize any of our product candidates, these products 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 our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will 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 the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug 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 according to 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 approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

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 candidate for which we obtain marketing approval.

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In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that Medicare will cover in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In March 2010, President Obama signed into law 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, a law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs, effective the first quarter of 2010, and revising the definition of "average manufacturer price," or AMP, for reporting purposes, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service utilization, to Medicaid managed care utilization and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. The Centers for Medicare and Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid drug rebates to the utilization that occurs in the U.S. territories, such as Puerto Rico and the Virgin Islands. Also effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, because 340B pricing is determined based on AMP and Medicaid drug rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discounts to increase. Furthermore, as of 2011, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products and requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Notably, a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the Affordable Care Act, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President 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 of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have 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.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that 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 any product candidates or products that we may develop;
·termination of clinical trial sites or entire trial programs;
·injury to our reputation and significant negative media attention;

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- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to 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 insurance coverage for products 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 commercially reasonable product liability insurance for any products 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 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 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 for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits persons 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, or any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, 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 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 Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available

under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the 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 and applicable manufacturers and applicable group purchasing organizations to report annually to the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members; and

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- analogous state and foreign laws and regulations, 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 HIPAA, thus complicating compliance efforts.

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 may 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, 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 not to be in compliance with 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 in order to succeed.

During 2014, we experienced significant growth in our operations and plan to continue to grow our operations during 2015 as we expand the scope of our clinical activities, including the initiation in 2015 of a Phase 1/2 clinical trial of FPA008 in PVNS, the Phase 1a/1b clinical trial of FPA008 in combination with Opdivo (nivolumab) in six cancers, and our 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, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining 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, as a result, 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 that we compete against 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 be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business 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, third-party 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 pre-clinical 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 located 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 disasters 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 perform our obligations under our discovery collaborations and discover new targets.

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In addition, we are conducting a clinical trial in Europe. Political and economic relations between Russia and Ukraine are complex and recent conflicts have arisen between their governments. Political, ethnic, historical and other differences have on occasion given rise to tensions and, in certain cases, military conflict between these countries, which could adversely affect normal economic activity and disrupt the economies of neighboring regions. A significant portion of Europe's energy imports come from Russia, and a disruption of gas flow from Russia to countries in which we are conducting our clinical trial could interrupt our clinical trial and harm our business.

Risks Related to Our Dependence on Third Parties

We currently depend significantly on GSK for the development and commercialization of FP-1039. GSK's failure to timely develop and/or commercialize FP-1039 would result in a material adverse effect on our business and operating results.

We granted Human Genome Sciences, Inc., which was acquired by GSK, an exclusive license to develop, subject to certain rights retained by us, and commercialize FP-1039 for all companion diagnostic, therapeutic and prophylactic uses for humans in the United States, the European Union and Canada. Our development collaboration with GSK on FP-1039 may not be scientifically, medically or commercially successful due to a number of important factors, including the following:

- FP-1039 may fail to demonstrate sufficient safety or efficacy in clinical trials to support regulatory approval;
- GSK may be unable to successfully develop, test and obtain regulatory approval for a companion diagnostic;
- GSK may be unable to manufacture sufficient quantities of FP-1039 in a cost-effective manner;
- GSK may be unable to obtain regulatory approval to commercialize FP-1039 even if clinical and preclinical testing is successful;
- GSK may not be successful in obtaining sufficient reimbursement for FP-1039;
- the prevalence of the target population we may observe in clinical trials may be lower than what is reported in the literature, which would result in slower enrollment and a smaller potential commercial patient population than what we currently estimate for FP-1039; and
- existing or future products or technologies developed by competitors may be safer, more effective or more conveniently delivered than FP-1039.

In addition, we could be adversely affected by:

- GSK's failure to timely perform its obligations under our collaboration agreement;
- GSK's failure to timely or fully develop or effectively commercialize FP-1039; and
- a material contractual dispute between us and GSK.

In April 2014, GSK announced that it entered into an agreement for a three-part transaction with Novartis AG, or Novartis, pursuant to which GSK would, among other things, divest to Novartis its commercial oncology portfolio, related research and development activities and rights to its AKT inhibitor as well as grant Novartis certain commercialization rights for future oncology products. In connection with this transaction, GSK plans to refocus its oncology efforts to development in immuno-oncology and epigenetics. Because FP-1039 is not within GSK's area of focus for oncology, GSK may not dedicate as many resources on the development of FP-1039 as if FP-1039 was within GSK's area of focus.

Any of the foregoing could adversely impact the likelihood and timing of any milestone payments we are eligible to receive 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.

GSK can terminate our collaboration agreement under certain conditions and without cause, and in some cases on short notice. GSK could also separately pursue alternative potentially competitive products, therapeutic approaches or technologies as a means of developing treatments for the diseases targeted by FP-1039.

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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, our product candidates and programs may be deemed to be at too early a stage of development for collaborative efforts and/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 of the risk related to the development of any such product candidates.

We may not succeed in maintaining our current discovery collaborations, which would adversely affect our business plans.

We currently have ongoing discovery collaborations with GSK, UCB and BMS. As of December 31, 2014, we were eligible to receive up to an additional $13.6 million of research funding and technology access fees through 2017 under the GSK, UCB and BMS discovery collaborations. While we expect we will receive all of this funding and these fees, if GSK, UCB or BMS terminate any of our discovery collaborations, we may not receive all or any of this $13.6 million, which would adversely affect our business or financial condition.

We rely on third parties to conduct our clinical trials. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for or commercialize our product candidates in a timely manner or at all.

We rely on third-party CROs to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. 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 of our products in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators and 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 assure you 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 under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

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Our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether or not 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 the 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. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be adversely affected.

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 and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and 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 from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed. Other licenses may not give us such rights.

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 identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, 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 from or license to third parties and may have to rely on our licensors, licensees or collaborators. Therefore, 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 prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been 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 highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting, enforcing and defending patents on 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. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. 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 all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. 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 further, 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 protection, 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 our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims 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 the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or 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 patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could 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 the intellectual property that we own or license.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. 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 would weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

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Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include 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, and in particular, 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 our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. 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, to protect our or our licensors' or collaborators' trade secrets or to determine 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. The 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 upon 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 an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop 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.

Third-party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators 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 on commercially reasonable terms or at all. 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, 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 successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

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Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

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 identify, test, develop, manufacture, market and sell product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property, including patent rights, that are important or necessary to the use of our technologies or development or commercialization of our products. As a result, we are a party to a number of technology 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 FPA144 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 penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements 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 such third parties, including in oppositions, interferences, reexaminations, inter parties reviews or derivation proceedings before 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 related technology or developing or 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 on commercially reasonable terms or at all. 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, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. 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.

In May 2011, the European Patent Office, or the EPO, granted European Patent No. 2092069, or the '069 patent, to Aventis Pharma S.A., or Aventis. The '069 patent claimed soluble fibroblast growth factor receptor Fc fusion proteins having certain levels of glycosylation, some of which claims could have been relevant to our FP-1039 product candidate. In February 2012, we filed an opposition to the '069 patent. In March 2013, we attended oral proceedings before the Opposition Division of the EPO and presented our arguments regarding our opposition to the '069 patent. In April 2013, the Opposition Division of the EPO published an Interlocutory Decision regarding the outcome of the oral proceedings. In the Interlocutory Decision, the EPO maintained certain claims of the '069 patent covering FGFR2 fusion proteins, but not FGFR1 fusion proteins such as FP-1039. Although this proceeding has concluded, Aventis has pursued claims in other countries that are similar to those originally granted by the EPO in the '069 patent and we may need to initiate similar opposition or other legal proceedings in other jurisdictions with respect to patents that may issue with similar scope of claims as those originally granted in the '069 patent. If we unsuccessfully oppose Aventis' similar patents in a country, we could be required to obtain a license from Aventis to continue developing and commercializing FP-1039 in that country.

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We may be subject to claims by third parties asserting that our employees or we 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 these 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 prosecuting or defending 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 awarded to 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 on commercially reasonable terms or at all. Even if we successfully prosecute or 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 or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome 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 technology or information 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 initial public offering 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 $28.00 through March 17, 2015. 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:

·the success of competitive products or technologies;
·regulatory actions with respect to our products or our competitors' products;
·actual or anticipated changes in our growth rate relative to our competitors;
.

announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;

- results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- 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;

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- 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 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, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 28.3% 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.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002 requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to

compensation of our chief executive officer;

- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

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We may take advantage of these exemptions until we are no longer an "emerging growth company." We would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our initial public offering; (ii) the first fiscal year after our annual gross revenues are $1 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

We currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us under the JOBS Act so long as we qualify as an "emerging growth company." For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the Securities and Exchange Commission, or SEC, which may make it more difficult for investors and securities analysts to evaluate us. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

We incur increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and The NASDAQ Global Select Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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.

Some of the holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading 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.

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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 principle executive office is currently located in South San Francisco, California, and consists of 81,235 square feet of leased office and laboratory space, all of which is located in a single building, under a lease that expires on December 31, 2017. We believe that our existing facilities are 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.

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PART II

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

Market Information

Our common stock was traded on The NASDAQ Global Market under the symbol "FPRX" from our IPO on September 18, 2013 until January 2, 2014 when it began trading on The NASDAQ Global Select Market. Prior to our IPO, there was no public market for our common stock. 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 Market and the NASDAQ Global Select Market.

	High	Low
Year Ended December 31, 2014		
First Quarter	$23.33	$12.20
Second Quarter	20.40	11.90
Third Quarter	16.94	10.50
Fourth Quarter	28.00	11.41

	High	Low
Year Ended December 31, 2013		
Third Quarter (beginning September 18, 2013)	$16.00	$12.80
Fourth Quarter	17.75	8.02

As of March 11, 2015, we had 25,532,719 shares of common stock outstanding held by approximately 48 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.

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Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock since September 18, 2013, which is the date our common stock first began trading on the NASDAQ Global Market, to three indices: the NASDAQ Composite Index, the NASDAQ Biotechnology Index and the Russell 2000 Biotechnology Index. During 2014, Five Prime was included in the NASDAQ Biotechnology Index and therefore, beginning from 2014, we started comparing our stock performance with this 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
Five Prime (FPRX)	$ 100.00	$ 128.36	$ 206.42
NASDAQ Composite Index (IXIC)	$ 100.00	$ 110.39	$ 125.17
NASDAQ Biotechnology (NBI)	$ 100.00	$ 107.41	$ 144.04
Russell 2000 Biotechnology (RGUSHSBT)	$ 100.00	$ 104.58	$ 130.96

Recent Sales of Unregistered Securities

Except as previously reported in our Quarterly Report on 10-Q for the period ending March 31, 2014, there were no recent sales of unregistered securities

Initial Public Offering

Use of Proceeds

On September 23, 2013, we completed our IPO and issued 4,800,000 shares of our common stock at an initial offering price of $13.00 per share. On September 26, 2013, we sold an additional 720,000 shares of common stock directly to our underwriters when they exercised their over-allotment option in full at the initial offering price of $13.00 per share. We received net proceeds from the IPO of $63.8 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries. Jefferies LLC, BMO Capital Markets and Wells Fargo Securities, LLC acted as joint book-running managers and Guggenheim Securities, LLC acted as co-manager for the offering.

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Shares of our common stock began trading on the NASDAQ Global Market on September 18, 2013. The shares were registered under the Securities Act on Registration Statements on Form S-1 (File No. 333-190194), which was declared effective by SEC on September 17, 2013, and Registration Statement on Form S-1 (File No. 333-191222). There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus dated September 18, 2013, filed with the SEC pursuant to Rule 424(b)(4) pursuant to the Securities Act of 1933, as amended. As of December 31, 2014, we have used approximately $23.4 million of the net offering proceeds primarily to fund pre-clinical and clinical activities for FPA008 and FPA144.

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, 2014, 2013 and 2012 and the balance sheet data as of December 31, 2014 and 2013 from our audited financial statements appearing in this report. We have derived the statements of operations data for the years ended December 31, 2011 and 2010 and the balance sheet data as of December 31, 2012, 2011 and 2010 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)	2014	2013	2012	2011	2010
Statement of Operations Data:					
Collaboration revenue	$19,231	$13,791	$9,983	$64,916	$23,740
Operating expenses:					
Research and development	43,173	32,785	28,778	34,039	29,417
General and administrative	13,632	10,427	9,009	11,216	8,338
Total operating expenses	56,805	43,212	37,787	45,255	37,755
(Loss) income from operations	(37,574)	(29,421)	(27,804)	19,661	(14,015)
Interest income	210	62	88	114	58
Other income (expense), net	(60)	487	121	(65)	491
(Loss) income before benefit from income taxes	(37,424)	(28,872)	(27,595)	19,710	(13,466)
Benefit from income taxes	—	—	—	—	5
Net (loss) income	$(37,424)	$(28,872)	$(27,595)	$19,710	$(13,461)
Net income attributable to participating securities	—	—	—	18,823	—
Net (loss) income attributable to common stockholders	$(37,424)	$(28,872)	$(27,595)	$887	$(13,461)
Basic net (loss) income per share attributable to common	$(1.79)	$(5.23)	$(23.05)	$0.77	$(12.22)

stockholders [1]					
Diluted net (loss) income per share attributable to common stockholders [1]	$(1.79)	$(5.23)	$(23.05)	$0.72	$(12.22)
Weighted average shares of common stock outstanding used in computing basic net (loss) income per share [1]	20,865	5,523	1,197	1,152	1,102
Weighted average shares of common stock outstanding used in computing diluted net (loss) income per share [1]	20,865	5,523	1,197	1,904	1,102

[1] See Note 2 to our financial statements for an explanation of the method used to calculate basic and diluted net (loss) income per share of common stock and the weighted average number of shares used in computation of the per share amounts.

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	As of December 31,				
(in thousands)	2014	2013	2012	2011	2010
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$149,054	$75,722	$38,015	$50,743	$29,282
Working capital	131,443	63,835	26,017	39,950	17,990
Total assets	155,631	81,791	44,091	58,579	36,622
Preferred stock warrant liability	—	—	563	682	622
Convertible preferred stock	—	—	136,282	129,463	129,463
Total stockholders' equity (deficit)	85,205	58,026	(115,878)	(90,106)	(112,792)

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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 novel protein therapeutics to improve the lives of patients with serious diseases. We currently have three product candidates in clinical development covering multiple potential indications. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are still needed. In addition, we are pursuing companion diagnostics, where appropriate, for each of our lead programs to allow us to select patients most likely to benefit from treatment and therefore accelerate clinical development and improve patient care. Our most advanced product candidates are identified below.

- FPA008 is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are developing in rheumatoid arthritis and plan to clinically develop in pigmented villonodular synovitis, or PVNS, and in combination with nivolumab in multiple cancers.

- FPA144 is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are developing to treat patients with gastric (stomach) cancer.

- FP-1039/GSK3052230 is a fusion protein that "traps" and neutralizes cancer-promoting fibroblast growth factors, or FGFs, involved in cancer cell proliferation and new blood vessel formation that our partner, GlaxoSmithKline, or GSK, is developing to treat patients with squamous non-small cell lung cancer, or NSCLC, and malignant pleural mesothelioma.

We have a differentiated target discovery platform and library, which we believe encompasses substantially all of the body's medically important targets for protein therapeutics. This positions us to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and a growing focus of our research and development activities. We are applying all aspects of our biologics discovery platform, including cell-based screening, in vivo screening, receptor-ligand matching technologies and bioinformatics, in our immuno-oncology research program. We have identified novel targets that we believe could be useful in immuno-oncology and are actively validating these and looking for additional targets. We plan to generate therapeutic proteins, including antibodies or ligand traps, directed to the targets we identify and advance select candidates into pre-clinical development and eventually 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. We have incurred losses in each period since our inception in 2002, with the exception of the fiscal year ended 2011, primarily due 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, 2014 and 2013, we reported a net loss of $37.4 million and $28.9 million, respectively. As of December 31, 2014 and 2013, we had an accumulated deficit of $189.0 million and $151.6 million.

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 included elsewhere in this report.

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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 item(s) 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. We determine 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 we do not have VSOE or third party evidence of selling price for these deliverables. 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 exclusive 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 up-front and license fees are contingently refundable, we defer the recognition of the up-front 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.

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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 payable 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 payable 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 Financial Accounting Standards Board Accounting Standards Update 2010-17, 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.

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, 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.

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Stock-Based Compensation

We issue stock-based compensation awards to employees 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, less estimated forfeitures, 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 two to three years. Stock-based compensation expense related to restricted stock awards 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. Expected forfeiture rates for restricted stock awards are based on historical data, and compensation expense is adjusted for actual results.

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 model requires the input of various assumptions that require management to apply judgment and make assumptions and estimates, including with respect to:

- 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 we estimate 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 do not have significant trading history for our common stock. The peer group was selected on the basis of operational and economic similarity with our business operations. We plan to continue to use the guideline peer group volatility information until historical volatility of our common stock is relevant to measure expected volatility for future option grants;
- the assumed dividend yield, which is based on our expectation of not paying dividends for the foreseeable future; and
- 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,		
	2014	2013	2012
Expected term (years)	5.3-6.7	5.0-6.1	5.0-6.1
Expected volatility	85.0%	85.0%	85.0%
Risk-free interest rate	1.6-2.0%	0.8-2.0%	0.6-1.1%
Expected dividend yield	0.0%	0.0%	0.0%

The amount of stock-based compensation expense we recognize during a period is based on the value of the portion of the awards that we expect to ultimately vest. We estimate forfeitures for employee grants at the time of grant, and revise the estimates, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Ultimately,

the actual expense recognized over the vesting period will only represent those options that vest. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. For instance, if a revised forfeiture rate is lower than the previously estimated forfeiture rate, we make an adjustment that will result in an increase to the stock-based compensation expense recognized in our financial statements. To date, our forfeitures have been immaterial.

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 method and are subject to periodic remeasurement over the period during which the services are rendered.

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

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We expect our stock-based compensation expense to increase in future periods due to the potential increases in the value of our common stock and because we expect to issue additional stock option and other equity grants as compared to prior periods as our headcount increases.

Preferred Stock Warrant Liability

Prior to our IPO in September 2013, we classified freestanding warrants for shares that are either putable or redeemable as liabilities on the balance sheet at fair value. Therefore, the freestanding warrants that gave the holders the right to purchase our convertible preferred stock were liabilities that we recorded at estimated fair value. At the end of each reporting period, we recorded changes in fair value during the period as a component of other income (expense), net.

We continued to adjust the liability for changes in the estimated fair value of the warrants until the earlier of the exercise or expiration of the warrants to purchase shares of convertible preferred stock or the completion of a liquidation event, including the completion of our initial public offering, at which time we reclassified the liabilities to stockholders' deficit.

We used the Black-Scholes option pricing model and the probability-weighted expected return method, or PWERM, to estimate the fair value of the preferred stock warrant liability. Inputs we used in the Black-Scholes option pricing model to determine estimated fair value include the estimated fair value of the underlying convertible preferred stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the price of the underlying convertible preferred stock. Inputs we used in the PWERM approach to determine the estimated fair value included a risk-adjusted discount rate, probability-weighted outcomes and time to liquidity.

In June 2004, pursuant to the terms of an equipment loan and security agreement, we issued a fully exercisable warrant to the lender for the purchase of 2,304 shares of Series A convertible preferred stock at an exercise price of $12.30 per share. The warrant was automatically net exercised for a total of 768 shares on January 26, 2014.

In connection with the issuance of Series A convertible preferred stock in January and February 2005, we issued a warrant to purchase 81,300 shares of Series A convertible preferred stock at $12.30 per share to our preferred stock placement agent. During 2007, the warrant was canceled and replaced by the issuance of two warrants for 44,715 and 36,585 shares; all other terms remained unchanged. These warrants automatically exercised on a net issuance basis upon completion of our initial public offering in September 2013.

In connection with the completion of our IPO in September 2013, substantially all of the warrants were automatically net exercised for a total of 4,376 shares, pursuant to their terms. As a result of the net exercises, we recorded an $83,000 gain related to the change in fair value as part of other income, net on our statement of operations and reclassified the fair value of $57,000 to permanent equity. These warrants were remeasured using the intrinsic value of the warrant and the net settlement value based on the $13.00 per share initial public offering price. The remaining outstanding warrant to purchase Series A convertible preferred stock converted into a warrant to purchase 2,304 shares of common stock at $12.30 per share, expiring in January 2014. We remeasured the fair value of this remaining warrant through the date of the conversion to a common stock warrant and we recorded a $3,000 loss related to the change in fair value as part of other income, net on our statements of operations and reclassified the fair value of $6,000 to permanent equity.

The outstanding preferred stock warrants were converted to common stock warrants upon the completion of the IPO in September 2013 and were no longer subject to remeasurement following that time. The remaining issued and unexpired warrant to purchase 2,304 shares of common stock was unexercised as of December 31, 2013. The intrinsic value of the outstanding warrant as of December 31, 2013 was approximately $10,000, based on the closing price of $16.79 per share of our common stock as reported on The NASDAQ Global Market on December 31, 2013. There were no warrants outstanding at December 31, 2014.

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Financial Overview

Collaboration Revenue

We have not generated any revenue from product sales. Our revenue to date has been derived from upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaboration partners. We currently have research collaborations in muscle diseases and respiratory diseases and an FP-1039 product collaboration and license agreement with GSK, a fibrosis and CNS research collaboration with UCB Pharma S.A., or UCB, and an immuno-oncology research collaboration and clinical trial collaboration with BMS. For additional information on these collaborations, please see the section entitled “Business – Collaborations” located elsewhere in this report.

Summary Revenue by Collaboration Partner

The following is a comparison of collaboration revenue for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
(in millions)	2014	2013	2012
R&D Funding			
Respiratory Diseases Collaboration	$3.7	$2.9	$1.3
Muscle Diseases Collaboration	0.8	2.8	3.3
FP-1039 Product Collaboration	0.1	0.1	0.9
Fibrosis and CNS Collaboration	0.3	0.2	—
Immuno-oncology Research Collaboration	2.5	—	—
Other	0.1	0.2	0.1
Ratable Revenue Recognition			
Respiratory Diseases Collaboration	2.7	2.6	1.9
Muscle Diseases Collaboration	0.9	2.5	2.4
Fibrosis and CNS Collaboration	2.9	2.0	—
Immuno-oncology Research Collaboration	3.5	—	—
Milestone and Contingent Payments			
Muscle Diseases Collaboration	1.7	0.5	0.1
Total	$19.2	$13.8	$10.0

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 or any new collaborations we may enter into.

FP-1039 License and Collaboration with GSK

In March 2011, we entered into a license and collaboration agreement with Human Genome Sciences, Inc., which was acquired by GSK, referred to as the FP-1039 license.

We received an upfront payment of $50.0 million from GSK in connection with our entry into the FP-1039 license. GSK is obligated to pay us contingent payments of up to $435.0 million comprising aggregate development-related contingent payments of up to $70.0 million, aggregate regulatory-related contingent payments of up to $195.0 million, and aggregate commercial-related contingent payments up to $170.0 million. If certain manufacturing criteria are not met, these aggregate potential contingent payments could total up to $310.0 million, instead of $435.0 million. We are also eligible to receive tiered royalty payments from the low-double digits to the high-teens on net sales of FP-1039.

GSK is obligated to pay us for the costs of all FP-1039 related research and development activities we elect to undertake on behalf of GSK. GSK has paid us $3.4 million for our conduct of these activities through December 31, 2014.

GSK Muscle Diseases Collaboration

In July 2010, we entered into a research collaboration and license agreement, referred to as the muscle diseases collaboration, with GSK. In May 2011, we amended the muscle diseases collaboration to expand the research plan in scope and duration to include an additional cell-based screen and an in vivo screen using our Rapid In Vivo Protein Production System, or RIPPS®, technology.

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At the inception of the muscle diseases collaboration, GSK made an upfront payment to us of $7.0 million and purchased shares of our Series A-2 convertible preferred stock for $7.5 million, of which we considered $3.0 million to be an implied premium. The implied premium was accounted for as revenue in the same manner as the upfront payment and allocated to the deliverables under the research collaboration agreement. Through December 31, 2014, we received $9.9 million in research funding under this agreement, which ended in May 2014. The deferred revenue related to this agreement had been fully recognized in 2014 as we completed our obligation to provide research services.

In September 2014, GSK exercised its option under the muscle diseases collaboration to obtain an exclusive, worldwide license to an undisclosed muscle disease target that we identified using our proprietary target discovery platform and paid us $1.5 million fee. In addition, we are entitled to receive up to $122.5 million in milestone payments as well as royalties on net sales of products related to the target. The milestone payments consist of preclinical and development-related contingent payments of up to $28.5 million, regulatory-related contingent payments of up to $40.0 million and commercial-related contingent payments of up to $54.0 million. 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 the protein.

GSK Respiratory Diseases Collaboration

In April 2012, we entered into a research collaboration and license agreement, referred to as the respiratory diseases collaboration, with GSK.

In April 2014, we amended our respiratory diseases collaboration to provide GSK with an option to elect to include additional screening assays under the research plan. The amendment allowed GSK to terminate any additional screening assay it elects under the research plan within six months of so electing, which termination right lapsed unexercised in October 2014. Concurrent with the amendment, GSK exercised its option and expanded the research plan to include two additional screening assays. In connection with GSK’s exercise of its option, we are entitled to receive up to $1.0 million in additional research funding in 16 equal quarterly payments for each additional screening assay, for a total of up to $2.0 million in additional research funding for both additional screening assays, of which we received $1.0 million as of December 31, 2014.

At the inception of the respiratory diseases collaboration, GSK paid us an upfront technology access payment of $7.5 million and purchased from us shares of our Series A-3 convertible preferred stock for $10.0 million, of which we considered $3.1 million to be an implied premium. The implied premium was accounted for as revenue in the same manner as the upfront payment and allocated to the deliverables under the research collaboration agreement. Through December 31, 2014, we received $8.6 million of research funding and we are eligible to receive up to an additional $4.3 million of research funding under this collaboration through the remainder of the research term, which ends in April 2016. We had deferred revenue of $4.3 million related to this agreement as of December 31, 2014, which we expect to recognize through the second quarter of 2016 as we complete our obligation to provide research services. We expect to receive $2.7 million and $1.6 million in 2015 and 2016, respectively, as we complete our obligation to provide research services.

We are eligible to receive up to $124.3 million in potential target evaluation and selection fees and contingent payments with respect to each Track 1 Target. These fees and payments are composed of target evaluation and selection fees up to $1.8 million, preclinical and development-related contingent payments of up to $28.5 million, regulatory-related contingent payments of up to $40.0 million and commercial-related contingent payments of up to $54.0 million. 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 the 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 Track 2 Target. These fees and payments are composed of target evaluation and selection fees of up to $1.8 million, a clinical proof of mechanism option exercise fee of up to $23.0 million, preclinical and development-related contingent payments of up to $36.5 million, regulatory-related contingent payments of up to $53.0 million and commercial-related contingent payments of up to $79.5 million. 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 the Track 2 Target.

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UCB Fibrosis and CNS Collaboration

In March 2013, we entered into a research collaboration and license agreement, referred to as the fibrosis and CNS collaboration.

At the inception of the fibrosis and CNS collaboration, UCB made payments to us of $8.2 million. In 2014, we received a $2.2 million technology fee and $1.0 million of research funding from UCB. We are eligible to receive up to an additional $3.2 million of technology access fees and research funding under the fibrosis and CNS collaboration through January 2016. As of December 31, 2014, we had deferred revenue of $6.5 million related to this agreement. We expect to receive research payments and technology fees of $3.0 million in 2015 and $0.2 million in 2016. We expect to recognize revenue of $3.0 million in each of 2015, 2016 and 2017.

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.

BMS Immuno-Oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement, referred to as the immuno-oncology research collaboration, with BMS.

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, 2014, we received $3.4 million of research funding and we are eligible to receive up to an additional $6.1 million of research funding under this collaboration through the remainder of the research term, which ends in March 2016, based on the research activities currently planned under the research plan.

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 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 will recognize in the same manner as the $20.0 million up-front payment.

During 2014, we recognized $6.0 million of revenue under the immuno-oncology research collaboration. As of December 31, 2014, we had deferred revenue relating to the immuno-oncology research collaboration of $19.7 million.

BMS Clinical Trial Collaboration

In November 2014, we entered into a clinical trial collaboration agreement with BMS, referred to as the clinical trial collaboration, to evaluate the safety, tolerability and preliminary efficacy of combining our FPA008 antibody with BMS's nivolumab antibody, which we refer to together as the combined therapy, for patients with non-small cell lung cancer, melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma.

Pursuant to the terms of the agreement, we are responsible for conducting the Phase 1a/1b clinical trial of the combined therapy, which we expect to begin by the second half of 2015. In addition, either we or BMS may, by mutual agreement, expand the scope of the clinical trial collaboration to study additional tumor types using the combined therapy.

BMS is responsible for all third party expenses that are directly attributable to the conduct of activities under the development plan, other than manufacturing activities. For manufacturing costs related to FPA008, we are responsible for the full expense of the manufacture and supply of FPA008 for any Phase 1a clinical study under the development plan and each party will be responsible for one half of the full expense of the manufacture and supply of FPA008 for any other clinical study under the development plan. BMS is responsible for the full expense of the manufacture and supply of nivolumab for any clinical study under the clinical trial collaboration. Each party will be responsible for its own internal costs, including internal personnel costs, incurred in the conduct of activities under the development plan.

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Under the terms of the agreement, BMS paid us a one-time fee of $30.0 million in December 2014. If a change of control of FivePrime closes prior to the initial results date, defined as the earlier date that (i) certain dose escalation and pharmacodynamics conditions are met in the planned Phase 1a portion of the first clinical study of the combined therapy; or (ii) the first subject is dosed in the Phase 1b portion of the first clinical study of the combined therapy, then if,

- immediately prior to such change of control, the acquirer in such change of control (or any of its affiliates) owns or controls an anti-PD-1 or anti-PD-L1 antagonist that is then in clinical development for use in treating cancer or is then being commercialized for use in treating cancer;
- BMS is using commercially reasonable efforts in the performance and fulfillment of its activities under the clinical trial collaboration;
- the parties are developing or pursuing the development of the combined therapy under the clinical trial collaboration; and
- a change of control of BMS has not occurred,

we would be obligated to pay to BMS the lesser of (x) $30.0 million or (y) 10% of the aggregate purchase price paid to us or our stockholders at the closing of such change of control (with any contingent consideration being risk-adjusted and discounted).

As of December 31, 2014, we recorded the one-time fee of $30.0 million paid by BMS as deferred revenue. Once the one-time fee is no longer contingently refundable, we will recognize the revenue ratably, using a cumulative catch up method, over the estimated performance period of approximately three years. We will periodically evaluate our estimated performance period based on the progress made under the collaboration. No revenue related to this collaboration has been recognized as of December 31, 2014.

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 have a research and development team that designs, manages and evaluates the results of all of our research and development activities. We conduct nearly all of the core target discovery and early research and preclinical activities internally and rely on third parties, such as CROs, and clinical manufacturing organizations, or CMOs, for the execution of certain of our research and development activities, such as toxicology studies and drug substance and drug product manufacturing and the conduct of clinical trials. We account for research and development costs on a program-by-program basis. Costs associated with the early phases of research and discovery are often related to improving our discovery platform and are not necessarily allocable to a specific target. We assign costs for such activities to a distinct non-program related project code. We allocate research management, overhead, common usage laboratory supplies and facility costs on a fulltime equivalent basis.

The following is a comparison of research and development expenses for the years ended December 31, 2014, 2013 and 2012:

(in millions)	Year Ended December 31, 2014	2013	2012
Product programs:			
FPA008	$8.3	$9.0	$4.5
FPA144	11.6	5.3	4.8
FP-1039	0.5	0.9	1.0
Early preclinical programs, collectively	0.4	2.9	8.3
Subtotal pipeline	20.8	18.1	18.6
Discovery collaborations	13.8	10.3	7.0
Early research and discovery	8.6	4.4	3.2
Total research and development expenses	$43.2	$32.8	$28.8

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We expect that most of the research and development expenses we incur that relate to our internal programs will continue to relate to activities to support our FPA008 and FPA144 clinical programs and our immuno-oncology research and discovery efforts. We expect our research and development expenses to increase as we advance our development programs further and advance additional drug candidates into clinical development, in particular as we increase the number and size of our clinical trials and as we expand our internal immuno-oncology discovery and research efforts. We expect that our FPA008 development-related expenses will increase at a faster rate than our other internal program research and development expenses as we advance FPA008 into a Phase 1/2 clinical trial in PVNS and a Phase 1a/1b clinical trial in six cancers in mid-2015.

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.

FP-1039 entered Phase 1b clinical development in July 2013, FPA008 entered Phase 1 clinical development in October 2013, FPA144 entered Phase 1 clinical development in December 2014 and our other product candidates are in preclinical development. 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, tax and legal services, including intellectual property-related legal services.

We expect our general and administrative expenses to increase as we expand our operations to support our increased research and development activities and due to increasing the amount of space we lease in our corporate headquarters building. Also, we expect our intellectual property-related legal expenses, including those related to preparing, filing, prosecuting and maintaining patent applications, 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 revaluation of the preferred stock warrant liability and the gain or loss on the disposal of property and equipment, if any. Upon the completion of our IPO in September 2013, the preferred stock warrant liability was reclassified to additional paid-in capital and we no longer record any related periodic fair value adjustment.

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Results of Operations

Comparison for the Years Ended December 31, 2014 and 2013

	Year Ended December 31,	
(in millions)	2014	2013
Collaboration revenue	$19.2	$13.8
Operating expenses:		
Research and development	43.2	32.8
General and administrative	13.6	10.4
Total operating expenses	56.8	43.2
Interest income	0.2	0.1
Other (expense) income, net	(0.1)	0.4
Net loss	$(37.4)	$(28.9)

Collaboration Revenue

Collaboration revenue increased by $5.4 million, or 39.1%, to $19.2 million in 2014 from $13.8 million in 2013. This increase was primarily due to the $6.0 million in revenue recognized under our immuno-oncology research collaboration with BMS entered into in March 2014, a $1.5 million payment in connection with GSK's taking a commercial license to an undisclosed muscle disease target under our muscle diseases collaboration, a $1.0 million increase in revenue recognized under our fibrosis and CNS collaboration with UCB entered into in March 2013 and a $0.9 million increase in revenue recognized under our respiratory diseases collaboration with GSK, which was offset primarily by a $3.9 million decrease in revenue from our muscle diseases collaboration with GSK, the research term of which ended in July 2013.

Research and Development

Our research and development expenses increased by $10.4 million, or 31.7%, to $43.2 million in 2014 from $32.8 million in 2013. This increase was primarily due to an increase of $6.3 million related to advancing our FPA144 program into a phase 1 clinical trial, including $2.6 million of milestone costs under our exclusive license agreement with Galaxy Biotech, LLC, a $4.2 million increase in early research and discovery costs related to expanding our immuno-oncology efforts, and a $3.5 million increase in our discovery collaboration costs due to entering into the immuno-oncology research collaboration with BMS in March 2014 and the fibrosis and CNS collaboration with UCB in March 2013, which was offset by a decrease of $0.7 million in costs related to our FPA008 program primarily due to manufacturing costs incurred during 2013 and a decrease of $2.5 million in costs incurred in our early preclinical programs due to a reduction in the number of programs we are actively pursuing.

General and Administrative

Our general and administrative expenses increased by $3.2 million, or 30.8%, to $13.6 million in 2014 from $10.4 million in 2013, primarily due to a $1.9 million increase in public company-related expenses, a $0.5 million increase in stock-based compensation costs, a $0.6 million increase in cash compensation costs, and a $0.2 million increase in

recruiting and relocation costs related to hiring additional research and development staff.

Other (Expense) Income, Net

Other expense, net, was $60,000 for 2014 and was primarily due to a loss on disposal of equipment. Other income, net, was $0.4 million in 2013 and was primarily related to the re-measurement of the preferred stock warrant liability in 2013. The entire preferred stock warrant liability was reclassified to permanent equity as a result of the closing of our IPO in September 2013.

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Comparison of the Years Ended December 31, 2013 and 2012

	Year Ended December 31,	
(in millions)	2013	2012
Collaboration revenue	$13.8	$10.0
Operating expenses:		
Research and development	32.8	28.8
General and administrative	10.4	9.0
Total operating expenses	43.2	37.8
Interest income	0.1	0.1
Other income, net	0.4	0.1
Net income (loss) before income taxes	$(28.9)	$(27.6)

Collaboration Revenue

Collaboration revenue increased by $3.8 million, or 38.0%, to $13.8 million in 2013 from $10.0 million in 2012. This increase was primarily due to the $2.3 million increase in revenue recognized under our respiratory diseases collaboration with GSK entered into in April 2012, and the recognition of $2.2 million of revenue under our fibrosis and CNS collaboration with UCB entered into in March 2013, offset by a reduction in reimbursed clinical costs of $0.8 million for research and development we completed in 2012 under our FP-1039 license and collaboration agreement with GSK.

Research and Development

Our research and development expenses increased by $4.0 million, or 13.9%, to $32.8 million in 2013 from $28.8 million in 2012. This increase was primarily due to an increase of $4.5 million related to our FPA008 program mainly for clinical trial costs and the manufacture of drug substance and drug product for our Phase 1 clinical trial, a $0.5 million increase related to advancing our FPA144 program and a $3.3 million increase in discovery collaboration costs due to entering into the fibrosis and CNS collaboration in March 2013 and the respiratory diseases collaboration in April 2012, which was offset by a $4.2 million decrease in early preclinical program expenses due to a reduction in the number of preclinical programs we were actively pursuing.

General and Administrative

Our general and administrative expenses increased by $1.4 million, or 15.6%, to $10.4 million in 2013 from $9.0 million in 2012, primarily due to $0.7 million for activities related to preparing to become a public company, a $0.2 million increase in stock-based compensation charge resulting from modification accounting in 2013, and a $0.1 million increase in intellectual property legal fees.

Other Income, Net

Other income, net increased to income of $0.4 million in 2013 from a $0.1 million of expense in 2012. This increase primarily reflects the decrease in estimated fair value of the preferred stock warrant liability and remeasurement through the date of the closing of our initial public offering.

Liquidity and Capital Resources

On September 23, 2013, we completed our IPO, which resulted in the sale of 4,800,000 shares of our common stock at a price of $13.00 per share. On September 26, 2013, the underwriters of our IPO exercised their over-allotment option in full to purchase an additional 720,000 shares of common stock at a price of $13.00 per share. We received net proceeds from our IPO of $63.8 million after deducting underwriting discounts, offering expenses and commissions paid by us. In connection with our IPO, two outstanding preferred stock warrants net exercised and all of our outstanding convertible preferred stock automatically converted to common stock on a one-for-one ratio on September 23, 2013.

On February 12, 2014, we completed an underwritten public offering of our common stock, which resulted in the sale of 3,450,000 shares, at a price of $12.50 per share, including the full exercise of the underwriters' option to purchase an additional 450,000 shares of common stock. We received net proceeds from the offering of $40.1 million after deducting underwriting discounts and offering expenses paid by us.

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On March 14, 2014, we entered into the immuno-oncology research collaboration with BMS. Under the immuno-oncology research collaboration agreement, BMS paid us an upfront payment of $20.0 million in April 2014. Also, in connection with the immuno-oncology research collaboration agreement, BMS purchased 994,352 shares of our common stock at a price of $21.16, for an aggregate purchase price of $21.0 million.

As of December 31, 2014, we had $15.3 million in cash and cash equivalents and $133.8 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury, and U.S. government agencies securities with maturities of 18 months or less.

On January 12, 2015, we completed an underwritten public offering of our common stock, which resulted in the sale of 3,829,994 shares of our common stock, at a price of $22.00 per share, including the partial exercise of the underwriters' option to purchase additional shares of common stock. We received net proceeds of $78.7 million, after underwriting discounts, structuring fees and estimated offering expenses paid by us.

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 achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time. Our rights to payment under our collaboration agreements are our only committed external source 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 manufacturing, laboratory and related supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and contract manufacturers 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 source 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.

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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, 2014, the net proceeds received from our January 2015 underwritten public offering of our common stock, and the funding that we expect to receive under our existing collaborations will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2018, without giving effect to any potential contingent payments we may receive under our collaboration agreements or entering into any new collaboration or license agreements. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Cash Flows

The following is a summary of cash flows for the years ended December 31, 2014, 2013 and 2012:

	Year Ended December 31,		
(in millions)	2014	2013	2012
Net cash provided by (used in) operating activities	$15.3	$(25.3)	$(18.4)
Net cash (used in) provided by investing activities	(69.4)	(42.2)	18.5
Net cash provided by financing activities	61.2	64.3	6.9

Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was $15.3 million during the year ended December 31, 2014. The net loss of $37.4 million was offset by non-cash charges of $1.6 million for depreciation and amortization, $3.4 million for stock-based compensation expense, and $1.5 million for amortization of premium on marketable securities. The net change in operating assets and liabilities was $46.2 million, primarily due to $45.5 million of deferred revenue primarily related to the $20.0 million upfront fee we received in April 2014 from our entry into the immuno-oncology research collaboration with BMS and the $30.0 million one-time fee we received in December 2014 from our entry into the clinical trial collaboration with BMS.

Net cash used in operating activities was $25.3 million during the year ended December 31, 2013. The net loss of $28.9 million was offset by non-cash charges of $1.7 million for depreciation and amortization, $2.1 million for stock-based compensation expense, $0.4 million for amortization of premium on marketable securities and a $0.5 million non-cash gain for the revaluation of preferred stock warrant liabilities. The net change in operating assets and liabilities was $0.2 million.

Net cash used in operating activities was $18.4 million during the year ended December 31, 2012. The net loss of $27.6 million was offset by non-cash charges of $1.6 million for depreciation and amortization, $1.7 million for stock-based compensation expense, $0.5 million for amortization of premium on marketable securities and a $0.1 million non-cash gain for the revaluation of preferred stock warrant liabilities. The net change in operating assets and liabilities was $5.4 million.

Net cash provided by operating activities increased by $40.6 million in 2014 compared to 2013. The increase was primarily due to the $20.0 million upfront fee we received in April 2014 from our entry into the immuno-oncology research collaboration with BMS and the $30.0 million one-time fee we received in December 2014 from our entry

into the clinical trial collaboration with BMS. The $6.9 million increase in net cash used in operating activities in 2013 compared to 2012 is primarily due to a $1.3 million increase in net loss and an increase in recognition of non-cash ratable revenue in 2013.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by or used in investing activities for the periods presented primarily relates to the purchases and maturities of marketable securities. Net cash used in investing activities in 2014 increased primarily due to purchases of marketable securities with the upfront and one-time fees received from the two BMS collaboration agreements noted above and the net proceeds from our underwritten public offering of our common stock in February 2014. Net cash used in investing activities in 2013 increased primarily due to purchases of marketable securities with the proceeds from our IPO. Purchases of property and equipment were $1.6 million, $0.8 million and $0.7 million during the years ended December 31, 2014, 2013 and 2012, respectively. The property and equipment purchases consisted primarily of purchases of laboratory equipment to support our research and development activities.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities was $61.2 million during the year ended December 31, 2014, primarily related to the net proceeds of $40.1 million from our underwritten public offering of our common stock in February 2014 and BMS's purchase of 994,352 shares of our common stock at a price of $21.16 per share, for an aggregate purchase price of $21.0 million, in March 2014 in connection with the immuno-oncology research collaboration, of which $2.4 million was considered to be an implied premium and was allocated to the deliverables under the immuno-oncology research collaboration, resulting in $18.6 million being allocated to common stock. Additionally, we received $2.5 million from employee stock option exercises and stock purchases in 2014.

Net cash provided by financing activities was $64.3 million during the year ended December 31, 2013, primarily related to the net proceeds from our IPO of $63.8 million. Additionally, we received $0.4 million from employee stock option exercises in 2013.

Net cash provided by financing activities was $6.9 million during the year ended December 31, 2012 primarily related to the sale of preferred stock. In April 2012, we sold 0.4 million shares of Series A-3 convertible preferred stock to GSK for proceeds of $10.0 million, of which $3.1 million was considered to be an implied premium and was allocated to the deliverables under the respiratory diseases collaboration, resulting in $6.8 million being allocated to the Series A-3 convertible preferred stock. Additionally, we received $0.1 million from employee stock option exercises in 2012.

Contractual Obligations and Contingent Liabilities

The following table summarizes our significant contractual obligations as of December 31, 2014:

(in millions) Contractual Obligations	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating leases [1]	$ 9.9	$ 3.1	$ 6.8	$ —	$ —
Total obligations	$ 9.9	$ 3.1	$ 6.8	$ —	$ —

[1] Represents future minimum lease payments under non-cancelable operating leases in effect as of December 31, 2014 for our facilities 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 $117.4 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; and
- 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.

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.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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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, 2014 and 2013, we had cash and cash equivalents and marketable securities of $149.1 million and $75.7 million, respectively, consisting of bank deposits, interest-bearing money market accounts, U.S. Treasury and U.S. government agency securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and marketable securities and the low 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 at 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, 2014, 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 Securities and Exchange Commission’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, 2014, 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.

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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, 2014 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 the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2014.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for “emerging growth companies.”

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.

Item 9B. Other Information.

None.

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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.

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PART IV

Item 15. Exhibits, 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.

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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: March 18, 2015 /s/ Lewis T. Williams
Lewis T. Williams

President and Chief Executive Officer

(Principal Executive Officer)

Date: March 18, 2015 /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 Lewis T. Williams 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/ Lewis T. Williams, M.D., Ph.D. Lewis T. Williams, M.D., Ph.D.	Chief Executive Officer, President and Director (Principal Executive Officer)	March 18, 2015

/s/ Marc. L. Belsky Marc L. Belsky	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2015
/s/ Brian G. Atwood Brian G. Atwood	Chairman of the Board	March 18, 2015
/s/ Franklin M. Berger Franklin M. Berger	Director	March 18, 2015
/s/ Fred E. Cohen, M.D., D.Phil. Fred E. Cohen, M.D., D.Phil.	Director	March 18, 2015
/s/ R. Lee Douglas R. Lee Douglas	Director	March 18, 2015
/s/ Peder K. Jensen, M.D. Peder K. Jensen, M.D.	Director	March 18, 2015
/s/ Aron Knickerbocker Aron Knickerbocker	Senior Vice President, Chief Business Officer and Director	March 18, 2015
/s/ Mark D. McDade Mark D. McDade	Director	March 18, 2015
/s/ William Ringo William Ringo	Director	March 18, 2015

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Five Prime Therapeutics, Inc.

Financial Statements

Years ended December 31, 2014, 2013 and 2012

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Report of Independent Registered Public Accounting Firm

The Board of Directors and

Stockholders of Five Prime Therapeutics, Inc.

We have audited the accompanying balance sheets of Five Prime Therapeutics, Inc. (the "Company") as of December 31, 2014 and 2013, and the related statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Jose, California

March 18, 2015

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Five Prime Therapeutics, Inc.

Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$15,267	$8,161
Marketable securities	133,787	67,561
Receivable from collaborative partners	410	296
Prepaid and other current assets	1,794	1,640
Total current assets	151,258	77,658
Property and equipment, net	3,794	3,744
Other long-term assets	579	389
Total assets	$155,631	$81,791
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,096	$348
Accrued personnel-related expenses	4,618	2,957
Other accrued liabilities	1,531	2,056
Deferred revenue, current portion	11,938	7,913
Deferred rent, current portion	632	549
Total current liabilities	19,815	13,823
Deferred revenue, long-term portion	48,628	7,123
Deferred rent, long-term portion	1,514	2,146
Other long-term liabilities	469	673
Commitments and Contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 21,680,494 and 16,842,134 shares issued and outstanding at December 31, 2014 and 2013, respectively	22	17
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Additional paid-in capital	274,180	209,580
Accumulated other comprehensive income	1	3
Accumulated deficit	(188,998)	(151,574)
Total stockholders' equity	85,205	58,026
Total liabilities and stockholders' equity	$155,631	$81,791

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

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Five Prime Therapeutics, Inc.

Statements of Operations

(In thousands except per share amounts)

	Year Ended December 31,		
	2014	2013	2012
Collaboration revenue	$19,231	$13,791	$9,983
Operating expenses:			
Research and development	43,173	32,785	28,778
General and administrative	13,632	10,427	9,009
Total operating expenses	56,805	43,212	37,787
Loss from operations	(37,574)	(29,421)	(27,804)
Interest income	210	62	88
Other (expense) income, net	(60)	487	121
Net loss	(37,424)	$(28,872)	$(27,595)
Net loss per share attributable to common stockholders:			
Basic	$(1.79)	$(5.23)	$(23.05)
Diluted	$(1.79)	$(5.23)	$(23.05)
Weighted-average shares used to compute net loss per share attributable to common stockholders:			
Basic	20,865	5,523	1,197
Diluted	20,865	5,523	1,197

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

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Five Prime Therapeutics, Inc.

Statements of Comprehensive Loss

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Net loss	$(37,424)	$(28,872)	$(27,595)
Other comprehensive loss:			
Net unrealized loss on marketable securities	(2)	(4)	(3)
Comprehensive loss	$(37,426)	$(28,876)	$(27,598)

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

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Five Prime Therapeutics, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2011	9,547,466	$129,463	1,161,781	$ 1	$4,990	$ 10	$(95,107)	$(90,106)
Issuance of Series A3 convertible preferred stock for cash at $26.20 per share, net of issuance costs of $35 and a fair value adjustment of $3,146	381,693	6,819	—	—	—	—	—	—
Issuance of common stock under equity incentive plans	—	—	64,208	—	105	—	—	105
Stock-based compensation expense related to employee and director option grants	—	—	—	—	1,655	—	—	1,655
Nonemployee stock-based compensation expense	—	—	—	—	66	—	—	66
Other comprehensive loss	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(27,595)	(27,595)
Balances at December 31, 2012	9,929,159	136,282	1,225,989	1	6,816	7	(122,702)	(115,878)
Conversion of preferred stock to common stock	(9,929,159)	(136,282)	9,929,159	10	136,272	—	—	136,282
	—	—	5,520,000	6	63,843	—	—	63,849

Issuance of common stock upon initial public offering, net of issuance costs								
Issuance of common stock under equity incentive plans	—	—	162,610	—	440	—	—	440
Reclassification of warrant liability to additional paid-in capital upon conversion of warrant to purchase Series A convertible preferred stock to warrant to purchase common stock	—	—	—	—	6	—	—	6
Issuance of common stock upon automatic net exercise of warrant	—	—	4,376	—	57	—	—	57
Stock-based compensation expense related to employee and director option grants	—	—	—	—	2,067	—	—	2,067
Nonemployee stock-based compensation expense	—	—	—	—	79	—	—	79
Other comprehensive loss	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(28,872)	(28,872)
Balances at December 31, 2013	—	—	16,842,134	17	209,580	3	(151,574)	58,026
Issuance of common stock upon follow-on offering, net of issuance costs	—	—	3,450,000	3	40,096	—	—	40,099
Issuance of common stock in connection with immuno-oncology research collaboration	—	—	994,352	1	18,628	—	—	18,629

Issuance of common stock under equity incentive plans	—	—	393,240	1	2,458	—	—	2,459
Issuance of common stock upon automatic net exercise of warrant	—	—	768	—	—	—	—	—
Stock-based compensation expense related to employee and director option grants	—	—	—	—	3,284	—	—	3,284
Nonemployee stock-based compensation expense	—	—	—	—	134	—	—	134
Other comprehensive loss	—	—	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	—	—	(37,424)	(37,424)
Balances at December 31, 2014	—	$—	21,680,494	$ 22	$274,180	$ 1	$(188,998)	$85,205

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

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Five Prime Therapeutics, Inc.

Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Operating activities			
Net loss	$(37,424)	$(28,872)	$(27,595)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,552	1,694	1,643
Loss (gain) on disposal of property and equipment	41	—	(5)
Stock-based compensation expense	3,418	2,146	1,721
Amortization of premium on marketable securities	1,491	432	538
Revaluation of preferred stock warrant liability	—	(500)	(119)
Changes in operating assets and liabilities:			
Receivable from collaborative partners	(114)	101	449
Prepaid, other current assets, and other long-term assets	(579)	(981)	372
Accounts payable	701	(209)	196
Accrued personnel-related expenses	1,661	707	(19)
Payable to collaborative partner	—	—	(3,000)
Deferred revenue	45,530	280	7,379
Deferred rent	(549)	247	457
Other accrued liabilities and other long-term liabilities	(463)	(375)	(414)
Net cash provided by (used in) operating activities	15,265	(25,330)	(18,397)
Investing activities			
Purchases of marketable securities	(158,674)	(79,776)	(45,419)
Maturities of marketable securities	90,955	38,403	64,636
Purchases of property and equipment	(1,643)	(807)	(737)
Change in restricted cash	—	—	38
Net cash (used in) provided by investing activities	(69,362)	(42,180)	18,518
Financing activities			
Proceeds from issuances of common stock, net of issuance costs	58,728	63,849	—
Proceeds from issuances of convertible preferred stock, net of issuance costs)	—	—	6,819
Proceeds from issuances of common stock under equity incentive plans	2,459	440	105
Deferred offering costs	16	—	—
Payments under capital lease obligation	—	(9)	(15)
Net cash provided by financing activities	61,203	64,280	6,909
Net increase (decrease) in cash and cash equivalents	7,106	(3,230)	7,030
Cash and cash equivalents at beginning of year	8,161	11,391	4,361

Cash and cash equivalents at end of year	$15,267	$8,161	$11,391
Supplemental schedule of noncash financing activities			
Accrued and deferred offering costs	$144	$—	$—

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

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FIVE PRIME THERAPEUTICS, INC.

Notes to Financial Statements

December 31, 2014

1. Business

Five Prime Therapeutics, Inc. (we, us, our, or the Company) is a clinical-stage biotechnology company focused on discovering and developing novel protein therapeutics. Protein therapeutics are antibodies or drugs developed from extracellular proteins or protein fragments that block disease processes, including cancer and inflammatory diseases. 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.

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 and reported as a separate component of stockholders’ 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. The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on short-term investments is included 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, and does not invest in mortgage-backed securities or mortgage loans.

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.

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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, 2014			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$9,996	$9,996	$—	$ —
U.S. Treasury securities	130,786	130,786	—	—
U.S. government agency securities	3,001	—	3,001	—
Total cash equivalents and marketable securities	$143,783	$140,782	$3,001	$ —

	December 31, 2013		
		Basis of Fair Value Measurements	
	Total	Level 1	Level 2

				Level 3
Assets				
Money market funds	$6,456	$6,456	$—	$ —
U.S. Treasury securities	18,852	18,852	—	—
U.S. government agency securities	48,709	—	48,709	—
Total cash equivalents and marketable securities	$74,017	$25,308	$48,709	$ —

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Prior to the Company's initial public offering, or IPO, in September 2013, we had outstanding warrants which were classified as a liability and remeasured to fair value each reporting period using the Black-Scholes option-pricing model. Inputs used to determine estimated fair value include the estimated fair value of the underlying stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the price of the underlying stock. As of December 31, 2012, the warrants were remeasured assuming volatility of 85%, a remaining term of 2.1 years and a risk free interest rate of approximately 0.3%. In connection with the completion of the Company's IPO, substantially all of the warrants were automatically net exercised for a total of 4,376 shares, pursuant to the terms of the warrants. As a result of the net exercises, we recorded an $83,000 gain related to the change in fair value as part of other income, net on our statement of operations and reclassified the fair value of $57,000 to permanent equity. These warrants were remeasured using the intrinsic value of the warrant and the net settlement value based on the $13.00 per share IPO price. The remaining outstanding warrant to purchase Series A convertible preferred stock converted into a warrant to purchase 2,304 shares of common stock at $12.30 per share. We remeasured the fair value of these remaining warrants through the date of the conversion to a common stock warrant and we recorded a $3,000 loss related to the change in fair value as part of other income, net on our statement of operations and reclassified the fair value of $6,000 to permanent equity. The common stock warrant was automatically net exercised for a total of 768 shares on January 26, 2014.

The change in the estimated fair value of the Level 3 preferred stock warrant liability on a recurring basis is summarized below (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Balance, beginning of year	$—	$563	$682
Change in fair value recorded in other expense, net	—	(500)	(119)
Exercises	—	(57)	—
Conversion of preferred stock warrant to common stock warrant and reclassification to permanent equity	—	(6)	—
Balance, end of year	$—	$—	$563

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. The carrying value of long-lived assets is reviewed for impairment whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss is recognized 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, 2014, there have been no such impairment losses.

Preferred Stock Warrant Liability

Freestanding warrants for shares that are either putable or redeemable are classified as liabilities on the balance sheet at fair value. Therefore, the freestanding warrants that give the holders the right to purchase our convertible preferred stock are liabilities that are recorded at estimated fair value. At the end of each reporting period, changes in fair value during the period are recorded as a component of other income (expense), net.

We adjusted the liability for changes in the estimated fair value of the warrants until the earlier of the exercise or expiration of the warrants to purchase shares of convertible preferred stock or the completion of a liquidation event, including the completion of an initial public offering, at which time the liabilities were reclassified to stockholders' equity (deficit).

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.

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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. We determine the estimated selling price for deliverables within each agreement using vendor-specific objective evidence (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 we do not have VSOE or third party evidence of selling price for these deliverables.

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 exclusive 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 up-front and license fees are contingently refundable, we defer the recognition of the up-front 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 payable 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 payable 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.

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We have elected to adopt the Financial Accounting Standards Board Accounting Standards Update 2010-17, 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 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.

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 stocks and stock options. For restricted stock awards, 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 are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate prevesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

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 bases 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. 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.

Net Loss Per Share of Common Stock

We compute basic net loss per common share by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. We did not include potentially dilutive securities consisting of options and restricted stock awards, or RSAs, to purchase common stock, preferred stock warrants, common stock warrants and convertible preferred stock in the diluted net loss per common share calculations for all periods presented because the inclusion of such shares would have had an antidilutive effect. The convertible preferred stock contained certain participation rights.

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

	Year Ended December 31,		
	2014	2013	2012
Convertible preferred stock	—	7,209	9,824
Options and RSAs to purchase common stock	2,388	2,338	2,347
Warrants to purchase convertible preferred stock	—	61	87
Warrants to purchase common stock	—	1	—
	2,388	9,609	12,258

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers.” ASU 2014-09 supersedes the revenue recognition requirements in “Topic 605, Revenue Recognition” and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective retrospectively for annual or interim reporting periods beginning after December 15, 2016, with early application not permitted. We are currently evaluating the effect the adoption of ASU 2014-09 will have on our financial statements.

3. Cash Equivalents and Marketable Securities

The following is a summary of our cash equivalents and marketable securities at December 31, 2014 and 2013 (in thousands):

	December 31, 2014			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$9,996	$ —	$ —	$9,996
U.S. Treasury securities	130,785	18	(17)	130,786
U.S. government agency securities	3,001	—	—	3,001
	143,782	18	(17)	143,783
Less: cash equivalents	(9,996)	—	—	(9,996)
Total marketable securities	$133,786	$ 18	$ (17)	$133,787

	December 31, 2013			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$6,456	$ —	$ —	$6,456
U.S. Treasury securities	18,848	4	—	18,852
U.S. government agency securities	48,709	3	(3)	48,709
	74,013	7	(3)	74,017
Less: cash equivalents	(6,456)	—	—	(6,456)
Total marketable securities	$67,557	$ 7	$ (3)	$67,561

As of December 31, 2014, 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	$129,232	$129,239
In one to two years	14,550	14,544
Total marketable securities	$143,782	$143,783

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We determined that the gross unrealized losses of $17,000 on our marketable securities as of December 31, 2014 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, 2014. 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,	
	2014	2013
Computer equipment and software	$1,269	$1,097
Furniture and fixtures	731	694
Laboratory equipment	9,978	9,596
Leasehold improvements	2,173	2,173
	14,151	13,560
Less: accumulated depreciation and amortization	(10,357)	(9,816)
Property and equipment, net	$3,794	$3,744

5. Preferred Stock and Common Stock Warrant

In June 2004, pursuant to the terms of an equipment loan and security agreement, we issued a fully exercisable warrant to the lender for the purchase of 2,304 shares of Series A convertible preferred stock at an exercise price of $12.30 per share. In connection with the completion of the Company’s IPO in September 2013, the warrant converted into a warrant to purchase 2,304 shares of common stock at $12.30 per share. We remeasured the fair value of these remaining warrants through the date of the conversion to a common stock warrant and we recorded a $3,000 loss related to the change in fair value as part of other income, net on our statement of operations and reclassified the fair value of $6,000 to permanent equity. The warrant was automatically net exercised for a total of 768 shares on January 26, 2014.

In connection with the issuance of Series A convertible preferred stock in January and February 2005, we issued a warrant to purchase 81,300 shares of Series A convertible preferred stock at $12.30 per share to our preferred stock placement agent. During 2007, the warrant was canceled and replaced by the issuance of two warrants for 44,715 and 36,585 shares; all other terms remained unchanged. In connection with the completion of our IPO in September 2013, the warrants were automatically net exercised for a total of 4,376 shares, pursuant to the terms of the warrants. As a result of the net exercises, we recorded an $83,000 gain related to the change in fair value as part of other income, net on our statement of operations and reclassified the fair value of $57,000 to permanent equity. These warrants were remeasured using the intrinsic value of the warrant and the net settlement value based on the $13.00 per share IPO price.

6. Convertible Preferred Stock

In connection with the completion of our IPO in September 2013, all outstanding shares of convertible preferred stock converted into 9,929,159 shares of common stock.

7. Stockholders' Equity (Deficit)

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.

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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. As of December 31, 2014, 3,358,568 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, and nonstatutory stock options may be granted with an exercise price of not less than 85% of the estimated fair value of the common stock on the date of grant. 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 IPO, our Board determined the estimated fair value of our common stock. For all stock options granted after the completion of our IPO in September 2013, the fair value for our underlying common stock is determined using the closing price as reported on The NASDAQ Global Market or The NASDAQ Global Select Market, as applicable, 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.

RSAs may be granted for no consideration (other than par value of the shares of stock). The fair value of RSAs is based upon the closing price of our common stock on the date of grant. RSAs generally vest over two to three years and are nontransferable until the awards are vested.

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, 2014, 334,561 shares of common stock were available for issuance under the ESPP.

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 Intristic Value (in thousands)
Balance at January 1, 2014	2,236,997	$ 6.09		
Options granted	824,895	$ 11.71		
Options exercised	(307,272)	$ 5.47		
Options forfeited	(68,182)	$ 7.70		

Options expired	(1,626)	$ 1.23		
Balance at December 31, 2014	2,684,812	$ 7.85		
Options exercisable at December 31, 2014	1,409,621	$ 6.13	5.76	$ 29,424
Options vested and expected to vest at December 31, 2014	2,643,893	$ 7.81	7.26	$ 50,727

The weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2014, 2013 and 2012 was $8.39, $5.05 and $4.06 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was $4.2 million, $1.1 million and $0.3 million, respectively.

We recorded stock-based compensation expense to employees and directors of approximately $2.9 million, $2.1 million and $1.7 million for the years ended December 31, 2014, 2013 and 2012, respectively. Stock-based compensation expense related to options granted to individual service providers who are not employees or directors was approximately $134,000, $79,000 and $66,000 for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, there was $8.0 million of total unrecognized compensation expense related to nonvested employee and director stock options that we expect to recognize over a weighted-average period of 3.0 years.

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Restricted Stock Awards

Restricted stock awards, or 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 Company has granted RSAs to certain employees starting 2013.

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, 2014	1,000	$ 15.64
RSAs granted	26,500	$ 12.30
RSAs vested	(3,500)	$ 14.09
RSAs forfeited	—	$ —
Unvested balance at December 31, 2014	24,000	$ 12.18

The total fair value on the date of vesting of RSAs vested in 2014 and 2013 was $54,000 and $0. There were no RSAs granted prior to 2013.

As of December 31, 2014, there was $0.3 million of unrecognized compensation cost related to unvested RSAs that we expect to recognize over a weighted-average period of 2.5 years.

Employee Stock Purchase Plan

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. No shares were issued under the ESPP in 2013. We issued a total of 83,860 shares under the ESPP in 2014.

The compensation expense related to the ESPP was $339,000 and $42,000 for the years ended December 31, 2014 and 2013, respectively. There was no compensation expense incurred prior to 2013. As of December 31, 2014, there was $0.1 million of unrecognized compensation cost related to the ESPP, which we expect to recognize over 4.5 months.

Stock-Based Compensation

Employee stock-based compensation expense recognized was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Total stock-based compensation expense recognized was as follows:

	Years Ended December 31		
(in thousands)	2014	2013	2012
Research and development	$1,761	$968	$705
General and administrative	1,657	1,178	1,016
Total	$3,418	$2,146	$1,721

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The fair value of each award was estimated 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,		
	2014	2013	2012	2014	2013	2012
Expected term (years)	5.3-6.7	5.0-6.1	5.0-6.1	0.5	0.5	—
Expected volatility	85.0%	85.0%	85.0%	49.0 - 83.0%	62.0%	—
Risk-free interest rate	1.6-2.0%	0.8-2.0%	0.6-1.1%	0.1%	0.1%	—
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	—

The expected term of options granted represents the period of time that options granted are expected to be outstanding and was determined by calculating the midpoint between the date of vesting and the contractual life of each option. The expected term of the ESPP rights is equal to the six-month look-back period. Volatility for options granted is based on the average historical volatility of a peer group of public companies over the expected term. The peer group was selected on the basis of operational and economic similarity with our principal business operations. 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.

8. Employee Benefit Plans

We sponsor a 401(k) plan that stipulates that eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100% of eligible compensation on a pre-tax basis. Through December 2014, we have not elected to match employee contributions as permitted by the plan. We pay the administrative costs for the plan.

9. Collaborative Research and Development Agreements GlaxoSmithKline

Muscle Diseases Collaboration

In July 2010, we entered into a research collaboration and license agreement, referred to as the muscle diseases collaboration with GlaxoSmithKline LLC, or GSK, to identify potential drug targets and drug candidates to treat

skeletal muscle diseases. Under the terms of the agreement, we received an upfront technology access payment of $7.0 million in August 2010. The $7.0 million upfront technology access payment was recorded as deferred revenue, which we initially began recognizing over the initial three-year research period under the agreement.

In May 2011, we amended the agreement to expand the research plan in scope and duration to include an additional cell-based screen and an in vivo screen using our RIPPS technology. Under the amendment, GSK agreed to provide an additional $6.3 million of research funding over a three-year research program term beginning on the date of the expansion. We received $0 million, $1.5 million and $4.2 million of research funding in the years ended December 31, 2014, 2013 and 2012, respectively, related to research we performed under the muscle diseases collaboration. Due to this amendment, in May 2011 we revised our estimate of our substantive performance period under this collaboration to extend through the end of this additional research term and began recognizing the remaining unamortized portion of the upfront payment over this revised period into May 2014.

We were eligible to receive certain option and selection payments related to targets identified in the collaboration. We are also eligible to receive payments for the achievement of certain development activities and royalties on the sales of products related to targets GSK selected for exclusive development.

We were eligible to receive up to $1.8 million of option and selection payments per target when GSK claimed and selected a target for further development. In accordance with ASU No. 2010-17, we concluded that these payments under the agreement with GSK were substantive and accounted for these milestones under the milestone method of revenue recognition.

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In accordance with ASU No. 2010-17, we determined that the remaining contingent payments under the agreement with GSK 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 GSK do not meet the definition of a milestone under ASU 2010-17 because the achievement of these events is solely dependent on GSK'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 this arrangement. If there are no remaining performance obligations under the arrangement at the time the contingent payment is triggered, the contingent payment would be recognized as revenue in full upon the triggering event.

In connection with the agreement, GSK purchased 329,597 shares of our Series A-2 convertible preferred stock at a price of $22.76 per share, resulting in net cash proceeds to us of $7.5 million. We determined that the purchase price of $22.76 per share exceeded the estimated fair value of the Series A-2 convertible preferred stock by $3.0 million and, therefore, recorded the $3.0 million as revenue in the same manner as the upfront technology access payment.

In December 2012, GSK selected a protein therapeutic target for further evaluation. The related selection fee of $0.3 million was received in 2013. In September 2013, we and GSK entered into an agreement to extend the evaluation period for this protein therapeutic target by approximately eight months. In connection with the extension of the evaluation period, GSK paid a $0.2 million extension fee, which had been fully recognized in revenue over the eight-month extension period in 2014.

In October 2013, GSK exercised its right to reserve for further evaluation several protein therapeutic targets for muscle diseases that we discovered pursuant to this agreement with GSK. In connection with reserving these targets for further evaluation, GSK paid us a selection fee of $0.3 million in 2013. In September, 2014, GSK exercised its option to license an undisclosed muscle disease target that we identified. We granted GSK an exclusive, worldwide license to products containing or directed to the target. We received a payment of $1.5 million in connection with the option exercise

Total revenue recognized under this arrangement was $3.4 million for the year ended December 31, 2014 and $5.8 million for the years ended December 31, 2013 and 2012. As of December 31, 2013, we had deferred revenue relating to this collaboration agreement of $1.9 million. As of December 31, 2014, the deferred revenue related to this agreement had been fully recognized as we completed our obligation to provide research services.

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, 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.

Respiratory Diseases Collaboration

In April 2012, we entered into research collaboration and license agreement, referred to as 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 initially planned to conduct up to six customized cell-based screens of our protein library under this agreement. The four-year research term will end in April 2016. Under the terms of the agreement, GSK paid us an upfront technology access payment of $7.5 million in April 2012.

We applied ASU No. 2009-13, 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 arrangement consideration should be recognized in the same manner as the final deliverable, which is the research service. The $7.5 million upfront technology access payment was recorded as deferred revenue and is being recognized over the initial four-year research period under the agreement. In addition, GSK agreed to pay us $10.5 million of research funding over the research program term.

In April 2014, we amended the agreement with GSK. Pursuant to the original agreement, GSK has an option to elect to include additional screening assays under the research plan. The amendment allowed GSK to terminate any additional screening assay it elects under the research plan within six months of so electing, which termination right lapsed unexercised in October 2014. Concurrent with the amendment, GSK exercised its option and expanded the research plan to include two additional screening assays. In connection with GSK's exercise of its option, we are entitled to receive up to $1.0 million in additional research funding in 16 equal quarterly payments for each additional screening assay, for a total of up to $2.0 million in additional research funding for both additional screening assays, of which we have received $1.0 million as of December 31, 2014. In the years ended December 31, 2014, 2013 and 2012, we received $3.9 million, $3.4 million and $1.3 million, respectively, of research funding related to all research being performed under the respiratory diseases collaboration.

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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 $1.8 million of option and selection payments for each target claimed and selected for further development. In addition, prior to the time GSK exercises its right to obtain an exclusive worldwide license to a protein target, we and GSK will discuss and agree on Track 1 Targets, for which GSK will have sole responsibility for the further development and commercialization of products that incorporate or target the protein targets, and Track 2 Targets, 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 Phase 2 clinical trial. We and GSK will take into consideration each party's available resources and capabilities at the time in deciding which protein targets will be Track 1 Targets or Track 2 Targets, but subject to each party's general right to alternate in such selection, with GSK having the right to first select. For each Track 2 Target, we are eligible to receive a $4.0 million milestone payment upon initiation of the first GLP toxicology study, a $6.5 million milestone payment upon the initiation of Phase 1 clinical trial and a $11.0 million milestone payment upon the initiation of Phase 2 clinical trial. We are also eligible to receive a $14.0 million option exercise milestone if GSK exercises its option to develop a Track 2 Target prior to the initiation of Phase 2 clinical trial or a $23.0 million option exercise milestone if GSK exercises after the initiation of Phase 2 clinical trial for the Track 2 Targets. Substantive uncertainty exists at the inception of the agreement as to whether any of these milestones will be achieved because of the numerous variables that may affect our ability to identify targets that GSK would be interested in further evaluating or with respect to which GSK would develop products. In accordance with ASU No. 2010-17, we concluded that these milestones under the agreement with GSK are substantive and will be accounted for under the milestone method of revenue recognition.

In accordance with ASU No. 2010-17, we determined that the remaining contingent payments under the agreement with GSK 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 GSK do not meet the definition of a milestone under ASU 2010-17 because the achievement of these events is solely dependent on GSK'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 this arrangement. If there are no remaining performance obligations under the arrangement at the time the contingent payment is triggered, the contingent payment would be recognized as revenue in full upon the triggering event.

In connection with the agreement, 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.

Total revenue recognized under this arrangement was $6.4 million, $5.6 million and $3.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014 and 2013, we had deferred revenue relating to this collaboration agreement of $4.3 million and $6.8 million, respectively. Additionally, GSK is obligated to reimburse us for certain specialized research and development costs associated with the screens under the agreement. As of December 31, 2014 and 2013, the receivable from GSK under the agreement related to such costs was $0.3 million and $0.1 million, respectively.

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, 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 with Human Genome Sciences, Inc., which was acquired by GSK in 2012, and which we refer to as the FP-1039 license. Pursuant to the agreement we granted GSK an exclusive license to develop and commercialize our FP-1039 product and other FGFR1 fusion proteins for multiple cancers in the United States, the European Union and Canada. Under the terms of the agreement, GSK paid us an upfront license fee of $50.0 million. We received full payment of the $50.0 million upfront license fee in March 2011. The agreement also calls for tiered double-digit percentage royalty payments on net sales. GSK has exclusive rights to develop and commercialize FP-1039 for all indications in the United States, the European Union and Canada. We have an option to co-promote FP-1039 in the United States and retain development and commercialization rights in territories outside the United States, the European Union and Canada.

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We applied ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, in evaluating the appropriate accounting for this agreement. In accordance with this guidance, 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 this agreement. However, since all of the deliverables were fully delivered by December 31, 2011, the $50.0 million upfront license fee associated with the deliverables was entirely recognized as revenue in 2011.

Additionally, GSK is obligated to reimburse us for all future research and development costs associated with FP-1039 incurred by us in the conduct of research and development activities on behalf of GSK. At the time we entered into the FP-1039 license, we agreed to perform services for the conduct of the then-concluding Phase 1 clinical trial. We also elected to conduct a Phase 2 clinical trial of FP-1039 in endometrial cancer for which we were reimbursed by GSK. The Phase 2 clinical trial was terminated in January 2012 and we are no longer conducting any activities with respect to this trial. Additionally, GSK is obligated to pay us for the costs of other FP-1039 related research and development activities we elect to undertake on behalf of GSK. Revenue from GSK related to these development costs associated with FP-1039 is recognized as we incur these costs. For the years ended December 31, 2014, 2013 and 2012, we recognized $0.1 million, $0.1 million and $0.9 million, respectively, in revenue from GSK related to development costs associated with FP-1039.

GSK is obligated to pay us certain amounts contingent upon the achievement of pre-specified development, regulatory and commercial criteria, which could total approximately $435.0 million. 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 GSK do not meet the definition of a milestone under ASU 2010-17 because the achievement of these milestones is solely dependent on GSK’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.

The agreement will terminate upon the expiration of the royalty terms of any products that result from the collaboration. In addition, GSK may terminate this agreement at any time with advance written notice, and either party may terminate this agreement for the other party’s material breach if such party fails to cure the breach or upon certain insolvency events.

UCB Pharma S.A.

In March 2013, we and UCB Pharma, S.A., or UCB, entered into a research collaboration and license agreement to identify potential biologics targets and therapeutics in the areas of fibrosis-related immunologic diseases and central nervous system disorders. We plan to conduct up to five customized cell-based and in vivo screens of our protein library under this agreement. We currently expect to complete our initial research activities under this agreement by 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.

We applied ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, in evaluating 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 arrangement consideration in the same manner as the final deliverable, which is research service.

Under the terms of the agreement, UCB paid us an upfront payment of $6.0 million in March 2013. In addition, UCB agreed to pay us a $6.6 million technology fee, of which we received $2.2 million in each of the years 2014 and 2013.

The remaining $2.2 million technology access fee is due on the second anniversary of this agreement. UCB also agreed to pay us $2.0 million of research funding during the second and the third years of the research program term, of which we received $1.0 million in 2014. We recorded the $6.0 million upfront payment, $4.4 million technology access payment and $1.0 million of research funding as deferred revenue, which we will recognize over the initial five-year research period under the agreement.

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 offer to UCB in the collaboration. Substantive uncertainty exists at the inception of the agreement as to whether any of these fees will be received because of the numerous variables that may affect our ability to identify targets that UCB would be interested in further evaluating or with respect to which UCB would develop products. In accordance with ASU No. 2010-17, we concluded that these fees under the agreement with UCB are substantive and will be accounted for under the milestone method of revenue recognition.

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In accordance with ASU No. 2010-17, we determined that the remaining contingent payments under the agreement with UCB 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 ASU 2010-17 because the achievement of these events solely depends on UCB'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 this arrangement. If we have no remaining performance obligations under the arrangement at the time the contingent payment is triggered, we would recognize the contingent payment as revenue in full upon the triggering event.

For the years ended December 31, 2014 and 2013, we recognized $3.2 million and $2.2 million of revenue, respectively, under this arrangement. As of December 31, 2014 and 2013, we have deferred revenue relating to this collaboration agreement of $6.5 million and $6.2 million, respectively. Additionally, UCB is obligated to reimburse us for certain specialized research and development costs associated with the screens under the agreement. As of December 31, 2014 and 2013, the receivable from UCB under the agreement related to such costs was $0.1 million and $0.2 million, respectively.

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.

Bristol-Myers Squibb Company

Research Collaboration and License Agreement

In March 2014, we entered into a research collaboration and license agreement, referred to as the immuno-oncology research collaboration, with Bristol-Myers Squibb Company, or 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 will have an option to take exclusive licenses to additional targets we may identify in these checkpoint pathways during the course of the immuno-oncology research collaboration.

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 and expect to receive $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 may 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.

We applied the FASB Accounting Standards Update, or ASU, No. 2009-13, 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. The $20.0 million upfront payment was recorded as deferred revenue and is being recognized over the five-year research period under the collaboration. In addition, BMS agreed to pay us $9.5 million of research funding over the initial three-year research program term. We received $3.4 million of research funding in 2014 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.

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In accordance with ASU No. 2010-17, Milestone Method of Revenue Recognition, 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 ASU 2010-17 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 to be recognized in the same manner as the $20.0 million up-front payment.

For the year ended December 31, 2014, we recognized $6.0 million of revenue under the immuno-oncology research collaboration. As of December 31, 2014, we had deferred revenue relating to the immuno-oncology research collaboration of $19.7 million.

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.

Clinical Trial Collaboration Agreement

In November 2014, we entered into a clinical trial collaboration agreement with BMS, referred to as the clinical trial collaboration, to evaluate the safety, tolerability and preliminary efficacy of combining our FPA008 antibody with BMS's nivolumab antibody, which we refer to together as the combined therapy, as a potential treatment option for patients with non-small cell lung cancer, melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma.

Pursuant to the terms of the agreement, we are responsible for conducting the clinical phase 1a/1b study. In addition, either BMS or we may, by mutual agreement, expand the scope of the clinical trial collaboration to study additional tumor types using the combined therapy.

Under the terms of the agreement, BMS paid us a one-time fee of $30.0 million in December 2014. If a change of control of FivePrime closes prior to the initial results date, defined as the earlier date that (i) certain dose escalation and pharmacodynamics conditions are met in the planned Phase 1a portion of the first clinical study of the combined therapy; or (ii) the first subject is dosed in the Phase 1b portion of the first clinical study of the combined therapy, then if,

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immediately prior to such change of control, the acquirer in such change of control (or any of its affiliates) owns or controls an anti-PD-1 or anti-PD-L1 antagonist that is then in clinical development for use in treating cancer or is then being commercialized for use in treating cancer;

- BMS is using commercially reasonable efforts in the performance and fulfillment of its activities under the clinical trial collaboration;
- the parties are developing or pursuing the development of the combined therapy under the clinical trial collaboration; and
- a change of control of BMS has not occurred,

we would be obligated to pay to BMS the lesser of (x) $30.0 million or (y) 10% of the aggregate purchase price paid to us or our stockholders at the closing of such change of control (with any contingent consideration being risk-adjusted and discounted).

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We applied the ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, in evaluating the appropriate accounting for the clinical trial collaboration. In accordance with this guidance, we concluded that we should account for the clinical trial collaboration as a single unit of accounting because the delivered items did not have stand-alone value and recognize the clinical trial collaboration consideration in the same manner as the final deliverable, which is conducting the clinical phase 1a/1b study. The $30.0 million one-time fee is contingently refundable upon certain change of control events prior to the initial results date. The one-time fee was not considered to be fixed or determinable as of December 31. 2014 and was recorded as deferred revenue as of December 31, 2014. Once the one-time fee is considered fixed or determinable, we will start recognizing revenue ratably, using a cumulative catch up method, over the estimated performance period of approximately three years. We will periodically evaluate the estimated performance period based on the progress made under the collaboration. No revenue related to this collaboration has been recognized as of December 31, 2014.

Unless earlier termination by either party, the clinical trial collaboration will continue until the date that is 90 days after the completion of all clinical trials under the agreement, the delivery of all study data by both parties and the completion of all obligations under the clinical trial collaboration. Either party may terminate the agreement with written notice (i) if the other party is in material breach and such breach has not been cured within the applicable cure period, (ii) if either party deems it necessary to protect the safety, health or welfare of the subjects enrolled in a clinical trial or (iii) 90 days following the commencement of a clinical hold.

10. 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 (fibroblast growth factor receptor 2) monoclonal antibodies. Under the terms of the agreement, we agreed to pay Galaxy an upfront license payment of $3.0 million. The upfront payment was paid 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 is in an early stage of development, and the underlying technology has no alternative future uses, the entire upfront payment was recorded 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. We made milestone payments to Galaxy totaling $2.6 million in 2014. No milestone payment was made prior to 2014.

11. Income Taxes

No income tax expense was recorded for the years ended December 31, 2014, 2013 and 2012.

A reconciliation of the federal statutory income tax rate to our effective income tax rate is as follows (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Federal statutory income tax rate	$(13,098)	$(10,105)	$(9,658)
Nondeductible stock compensation	(501)	455	386
Nontaxable equity premiums	(504)	(532)	(452)
Deferred tax assets not benefitted	14,075	10,338	9,750
Other permanent items	28	(156)	(26)
Income tax expense	$—	$—	$—

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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,	
	2014	2013
Net operating loss carryforwards	$73,722	$59,552
Research and development credit	8,685	6,564
Reserves and accruals	7,233	5,936
Total deferred tax assets	89,640	72,052
Less: valuation allowance	(89,640)	(72,052)
Net deferred tax assets	$—	$—

Realization of deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, net deferred tax assets have been fully offset by a valuation allowance. Our valuation allowance increased by approximately $17.6 million and $12.1 million during 2014 and 2013, respectively. We have established a full valuation allowance against our deferred tax assets due to the uncertainty surrounding the realization of such assets. We evaluate on a periodic basis the recoverability of deferred tax assets and the need for a valuation allowance. At such time that it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced.

At December 31, 2014, we had approximately $179.7 million and $205.9 million of federal and state net operating loss carryforwards, respectively, available to offset future taxable income. The net operating loss carryforwards begin to expire in 2024 for federal and 2015 for state purposes. We also had approximately $6.9 million and $5.6 million of federal and state tax credits, respectively, available to offset future tax. These credits begin to expire in 2023 for federal purposes, and state research and development tax credits can be carried forward indefinitely.

Utilization of the net operating loss and credit carryforwards may be subject to substantial annual limitation due to ownership change provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. To the extent net operating loss carryforwards, when realized, relate to non-qualified stock option deductions, the resulting benefits will be credited to stockholders' equity.

As of December 31, 2014 and 2013, we had no accrued interest or penalties related to income taxes, and no such interest and penalties have been incurred through December 31, 2014. As of December 31, 2014, no significant increases or decreases are expected to our uncertain tax positions within the next 12 months. A reconciliation of our unrecognized tax benefits for the years ended December 31, 2014, 2013 and 2012, is as follows (in thousands):

	Unrecognized Income Tax Benefits
Balance as of January 1, 2012	$ 1,457
Additions for current year tax positions	78

Balance as of December 31, 2012	1,535
Additions for prior year tax positions	27
Additions for current year tax positions	219
Balance as of December 31, 2013	1,781
Additions for prior year tax positions	11
Additions for current year tax positions	445
Balance as of December 31, 2014	$ 2,237

We file U.S. and state income tax returns with varying statutes of limitations. The tax years from inception in 2001 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.

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12. Commitments and Contingencies

Operating Leases

In March 2010, we entered into office and laboratory facility lease agreements, which we refer to collectively as the lease, for a facility located in South San Francisco, California. The lease enables us to utilize the facility through December 31, 2017, with an option to extend the term for an additional three years. In November 2014, we entered into an amendment to the lease, which we refer to as the lease amendment, to amend certain terms of the lease and to increase the amount of space leased. The lease amendment will be effective as of March 1, 2015 and expire on December 31, 2017, which is coterminous with the expiration of the lease. In addition, the amendment contains a $0.2 million one-time improvement allowance for costs of leasehold improvements from the landlord. The lease and the lease amendment require us to pay rent as well as additional amounts for operating expenses and maintenance.

The minimum annual rent under the lease is subject to increases based on stated rental adjustment terms. For financial reporting purposes, rent expense is recognized on a straight-line basis over the term of the leases. Accordingly, rent expense recognized in excess of rent paid is reflected as deferred rent. Deferred rent totaled $2.1 million and $2.7 million at December 31, 2014 and 2013, respectively. In addition, the lease contains a $1.7 million incentive in the form of reimbursement or payments from the landlord for a portion of the costs of leasehold improvements we make to the facility. We made these improvements and received the benefit of the $1.7 million incentive in 2010. The assets purchased with the incentive are included in property and equipment, net in the accompanying balance sheets as of December 31, 2014 and 2013, respectively. The incentive is being recognized as a reduction of rental expense on a straight-line basis over the term of the underlying leases. The unamortized leasehold improvement incentive totaled $0.7 million and $0.9 million as of December 31, 2014 and 2013, respectively, of which $0.5 million and $0.7 million is included in other long-term liabilities in the accompanying balance sheets as of December 31, 2014 and 2013, respectively.

Rent expense for each of the years ended December 31, 2014, 2013 and 2012 was $1.9 million. The estimated future minimum commitments under our lease are as follows (in thousands):

Year ending December 31:	
2015	$3,108
2016	3,363
2017	3,461
Total estimated minimum payments	$9,932

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 the 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.

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13. Selected Quarterly Financial Information (Unaudited)

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

	Quarter Ended			
Quarterly Results of Operations	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
	(Unaudited)			
Revenue	$3,546	$4,981	$ 6,059	$4,645
Net loss	(8,644)	(9,866)	(7,088)	(11,826)
Basic and diluted net loss per share	(0.46)	(0.46)	(0.33)	(0.55)

	Quarter Ended			
Quarterly Results of Operations	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
	(Unaudited)			
Revenue	$2,975	$3,549	$ 3,482	$ 3,785
Net loss	(7,047)	(7,274)	(7,234)	(7,317)
Basic and diluted net loss per share	(5.73)	(5.82)	(2.74)	(0.43)

Basic and diluted net 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 loss per share amounts.

14. Subsequent Events

Follow-on Public Offering

In January 2015, we closed an underwritten public offering of 3,829,994 shares of our common stock and received net proceeds of $78.7 million, after underwriting discounts, structuring fees and estimated offering expenses.

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EXHIBIT INDEX

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	Seventh Amended and Restated Investor Rights Agreement by and among the company and the investors named therein, dated as of April 16, 2012 (incorporated herein by reference to Exhibit 10.1 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.2+	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).
10.3+	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).
10.4+	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).
10.5+	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).
10.6+	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).

10.7+	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).
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 September 4, 2009 (incorporated herein by reference to Exhibit 10.9 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.12+	Offer Letter Agreement by and between the company and Julie Hambleton, dated as of November 19, 2012 (incorporated herein by reference to Exhibit 10.11 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 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).
10.14+	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).
10.15+	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).

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Exhibit No.	Description
10.16+	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).
10.17+	Executive Severance Benefits Agreement by and between the company and Julie Hambleton, dated as of December 3, 2012 (incorporated herein by reference to Exhibit 10.16 to the company's Registration Statement on Form S-1 (File No. 333-193491), filed with the SEC on January 22, 2014).
10.18+	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).
10.19+	Amendment No. 1 to the Executive Severance Benefits Agreement by and between the company and Marc L. 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).
10.20+	Stock Option Grant Notice by and between the company and Aron M. Knickerbocker, dated as of December 16, 2009 (incorporated herein by reference to Exhibit 10.28 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 to Stock Option by and between the company and Aron M. Knickerbocker, dated as of March 15, 2011 (incorporated herein by reference to Exhibit 10.29 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.22+	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).
10.23	Lease by and between the company and Britannia Biotech Gateway Limited Partnership, dated as of March 22, 2010 (incorporated herein by reference to Exhibit 10.26 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.24	First Amendment to Lease by and between the company and Britannia Biotech Gateway Limited Partnership, dated as of November 13, 2014 (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 November 14, 2014).

10.25	Sublease by and between the company and AMGEN SF, LLC, dated as of March 22, 2010 (incorporated herein by reference to Exhibit 10.27 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).
10.26†	Research Collaboration and License Agreement by and between the company and UCB Pharma S.A., dated as of March 14, 2013 (incorporated herein by reference to Exhibit 10.17 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).
10.27†	Amendment No. 1 to the Research Collaboration and License Agreement by and between the company and UCB Pharma S.A., dated as of June 5, 2014 (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 August 7, 2014).
10.28†	License and Collaboration Agreement by and between the company and Human Genome Sciences, Inc., dated as of March 16, 2011 (incorporated herein by reference to Exhibit 10.18 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).
10.29†	Respiratory Diseases Research Collaboration and License Agreement by and between the company and Glaxo Group Limited, dated as of April 11, 2012 (incorporated herein by reference to Exhibit 10.19 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).
10.30†	Amendment No. 1 to the Respiratory Diseases Research Collaboration and License Agreement by and between the company and Glaxo Group Limited, dated as of August 9, 2012 (incorporated herein by reference to Exhibit 10.20 to the company's Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on July 26, 2013).

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Exhibit No.	Description
10.31†	Amendment No. 2 to the Respiratory Diseases Research Collaboration and License Agreement by and between the company and Glaxo Group Limited, dated as of April 9, 2014 (incorporated herein by reference to Exhibit 10.1 to the company's to the company's Quarterly Report on Form 10-Q (File No. 001-36070), filed with the SEC on August 7, 2014).
10.32†	Research Collaboration and License Agreement by and between the company and GlaxoSmithKline LLC, dated as of July 29, 2010 (incorporated herein by reference to Exhibit 10.21 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).
10.33†	Amendment No. 1 to the Research Collaboration and License Agreement by and between the company and GlaxoSmithKline LLC, dated as of May 17, 2011 (incorporated herein by reference to Exhibit 10.22 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).
10.34†	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).
10.35†	Exclusive License Agreement by and between the company and the Regents of the University of California, dated as of September 7, 2006 (incorporated herein by reference to Exhibit 10.24 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†	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).
10.37†	Non-Exclusive License Agreement by and between the company and the Board of Trustees of the Leland Stanford Junior University, dated as of February 1, 2006 (incorporated herein by reference to Exhibit 10.32 to the company's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-190194), filed with the SEC on August 23, 2013).
10.38†	Amendment No. 1 to the License Agreement effective February 1, 2006 by and between the company and Stanford University, dated as of January 22, 2010 (incorporated herein by reference to Exhibit 10.33 to the company's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-190194), filed with

	the SEC on August 23, 2013).
10.39†	Agreement by and between the company and National Research Council of Canada, effective December 3, 2013 (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 December 9, 2013).
10.40†	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).
10.41†	Stock Purchase Agreement, dated March 14, 2014, by and between the company and Bristol-Myers Squibb Company (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 March 19, 2014).
10.42*††	Clinical Trial Collaboration Agreement, dated as of November 21, 2014, by and between the company and Bristol-Myers Squibb Company.
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.

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Exhibit No.	Description
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**	Financial statements from the Annual Report on Form 10-K of the company for the year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Comprehensive (Loss) Income, (iii) the Statements of Convertible Preferred Stock and Stockholders' Deficit, (iv) the Statements of Cash Flows and (v) Notes to Financial Statements.

* 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.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

+ 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.