FIVE PRIME THERAPEUTICS INC
Form 10-Q
November 12, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended September 30, 2014

or

¨ TRANSITION REPORTS 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)

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 (§ 232.405 of this chapter) 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 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 Exchange Act Rule 12b-2) Yes ¨ No x

As of October 31, 2014, the number of outstanding shares of the registrant's common stock was 21,550,672.

TABLE OF CONTENTS

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q 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, 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 quarterly report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. While we believe that each of these studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal company research is reliable and the market definitions we use are appropriate, neither such research nor these definitions have been verified by any independent source.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Condensed Balance Sheets

(In thousands)

	SEPTEMBER 30, 2014	DECEMBER 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 13,128	$ 8,161
Marketable securities	116,854	67,561
Receivable from collaborative partners	91	296
Prepaid and other current assets	1,775	1,640
Total current assets	131,848	77,658
Property and equipment, net	3,979	3,744
Other long-term assets	431	389
Total assets	$ 136,258	$ 81,791
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 672	$ 348
Accrued personnel-related expenses	3,106	2,957
Other accrued liabilities	2,235	2,056
Deferred revenue, current portion	11,676	7,913
Deferred rent, current portion	611	549
Total current liabilities	18,300	13,823
Deferred revenue, long-term portion	20,920	7,123
Deferred rent, long-term portion	1,672	2,146
Other long-term liabilities	504	673
Commitments		
Stockholders' equity:		
Common stock	22	17
Preferred stock	—	—
Additional paid-in capital	271,952	209,580
Accumulated other comprehensive income	60	3
Accumulated deficit	(177,172)	(151,574)
Total stockholders' equity	94,862	58,026
Total liabilities and stockholders' equity	$ 136,258	$ 81,791

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

4

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Operations

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Collaboration revenue	$6,059	$3,482	$14,586	$10,006
Operating expenses:				
Research and development	9,803	8,193	30,602	24,708
General and administrative	3,360	2,607	9,664	7,385
Total operating expenses	13,163	10,800	40,266	32,093
Loss from operations	(7,104)	(7,318)	(25,680)	(22,087)
Interest income	57	7	148	35
Other income (expense), net	(41)	77	(66)	497
Net loss	$(7,088)	$(7,234)	$(25,598)	$(21,555)
Basic and diluted net loss per common share	$(0.33)	$(2.74)	$(1.24)	$(12.60)
Shares used to compute basic and diluted net loss per common share	21,521	2,637	20,619	1,711

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Comprehensive Loss

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	$(7,088)	$(7,234)	$(25,598)	$(21,555)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable securities	19	—	60	(6)
Comprehensive loss	$(7,069)	$(7,234)	$(25,538)	$(21,561)

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statement of Cash Flows

(In thousands)

	Nine Months Ended September 30,	
	2014	2013
	(Unaudited)	
Operating activities		
Net loss	$(25,598)	$(21,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,154	1,288
Loss on disposal of property and equipment	41	-
Stock-based compensation expense	2,230	1,554
Amortization of premium on marketable securities	1,075	272
Revaluation of preferred stock warrant liability	-	(500)
Changes in operating assets and liabilities:		
Receivable from collaborative partners	205	14
Prepaid, other current assets, and other long-term assets	(539)	(2)
Accounts payable	324	467
Accrued personnel-related expenses	149	(154)
Deferred revenue	17,560	2,677
Deferred rent	(412)	189
Other accrued liabilities and other long-term liabilities	373	18
Net cash used in operating activities	(3,438)	(15,732)
Investing activities		
Purchases of marketable securities	(121,016)	(12,078)
Maturities of marketable securities	70,705	29,435
Purchases of property and equipment	(1,430)	(633)
Net cash (used in) provided by investing activities	(51,741)	16,724
Financing activities		
Proceeds from public offering of common stock, net	40,099	64,887
Proceeds from the sale of common stock to collaborative partner	18,629	—
Proceeds from issuance of common stock under equity incentive plans	1,418	387
Payments under capital lease obligation	—	(9)
Net cash provided by financing activities	60,146	65,265
Net increase in cash and cash equivalents	4,967	66,257
Cash and cash equivalents at beginning of period	8,161	11,391
Cash and cash equivalents at end of period	$13,128	$77,648
Supplemental schedule of noncash financing activities		
Accrued and deferred offering costs	$—	$1,026

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

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements

September 30, 2014

1. Description of 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.

Unaudited Interim Financial Information

The accompanying financial information as of September 30, 2014 is unaudited. The Condensed Financial Statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that our management considers necessary for the fair statement of the results of operations for the interim periods covered and of the financial condition of the Company at the date of the interim balance sheet. The December 31, 2013 Condensed Balance Sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or GAAP. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying Condensed Financial Statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the U.S. Securities and Exchange Commission.

Follow-on Public Offering

In February 2014, we completed a public offering of 3,450,000 shares of our common stock, or our Follow-on Public Offering, which included shares we issued pursuant to our underwriters' exercise of their over-allotment option. We received net proceeds of $40.1 million, after underwriting discounts, commissions and offering expenses, from the Follow-on Public Offering.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions about future events that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements as well as reported amounts of revenue and expenses during the reporting period. Actual results could differ materially from those estimates.

Reclassifications

We have reclassified certain prior period amounts to conform to the current period presentation. We reclassified certain liabilities, primarily those related to unbilled receipts, from accounts payable to other accrued liabilities on our balance sheets and made related conforming reclassifications on our statements of cash flows.

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; 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.

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

The following table summarizes, for assets recorded at fair value, the respective fair values and the classifications by level of input within the fair value hierarchy defined above (in thousands):

	SEPTEMBER 30, 2014			
		BASIS OF FAIR VALUE MEASUREMENTS		
	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets				
Money market funds	$8,925	$8,925	$—	$ —
U.S. Treasury securities	106,330	106,330	—	—
U.S. government agency securities	10,524	—	10,524	—
Total cash equivalents and marketable securities	$125,779	$115,255	$10,524	$ —

	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	$ —

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 stock options, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Convertible preferred stock	—	9,174	—	9,675
Options to purchase common stock	2,404	2,235	2,253	2,235
Warrants to purchase preferred stock	—	75	—	79
Warrants to purchase common stock	—	2	—	2
	2,404	11,486	2,253	11,991

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 (in thousands):

	SEPTEMBER 30, 2014			
	AMORTIZED COST BASIS	UNREALIZED GAINS	UNREALIZED LOSSES	ESTIMATED FAIR VALUE
	(unaudited)			
Money market funds	$8,925	$ —	$ —	$ 8,925
U.S. Treasury securities	106,274	57	(1)	106,330
U.S. government agency securities	10,520	4	—	10,524
	125,719	61	(1)	125,779
Less: cash equivalents	(8,925)	—	—	(8,925)
Total marketable securities	$116,794	$ 61	$ (1)	$ 116,854

	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 September 30, 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
	(unaudited)	
Debt securities maturing:		
In one year or less	$96,527	$96,574
In one to two years	29,192	29,205
Total marketable securities	$125,719	$125,779

We determined that the gross unrealized losses of $1,000 on our marketable securities as of September 30, 2014 were temporary in nature. 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 September 30, 2014. There were no sales of available-for-sale securities in any of the periods presented.

4. Equity Incentive Plans

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 TERM
Balance at December 31, 2013	2,236,997	$ 6.09	
Options granted	780,195	$ 11.62	
Options exercised	(188,439)	$ 5.29	
Options forfeited	(59,623)	$ 7.63	
Balance at September 30, 2014	2,769,130	$ 7.67	
Options exercisable	1,440,891	$ 6.03	6.00

As of September 30, 2014, there were 3,393,083 shares of common stock available for future issuance under our 2013 Omnibus Incentive Plan.

Stock-Based Compensation

We calculate employee stock-based compensation expense based on awards ultimately expected to vest reduced by estimated forfeitures. We estimate forfeitures at the time of grant and revise forfeitures, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$383	$261	$1,112	$661
General and administrative	471	258	1,118	893
Total	$854	$519	$2,230	$1,554

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Expected term (years)	5.4-6.7	5.3-6.1	5.3-6.7	5.0-6.1
Expected volatility	85%	85%	85%	85%
Risk-free interest rate	1.7-2.0%	1.4-1.6%	1.6-2.0%	0.8-1.6%
Expected dividend yield	0%	0%	0%	0%

As of September 30, 2014, we had $8.4 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 3.1 years.

5. Collaborative Research and Development Agreements

Bristol-Myers Squibb Company

On March 14, 2014, we entered into a research collaboration and license agreement, referred to as the immuno-oncology 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 collaboration. We received an upfront payment of $20.0 million from BMS in April 2014 in connection with our entry into the immuno-oncology 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 collaboration as a single unit of accounting and recognize the immuno-oncology 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 $2.3 million of research funding during the nine months ended September 30, 2014 related to research we performed under the immuno-oncology collaboration.

We are eligible to receive certain contingent payments with respect to each target subject to the immuno-oncology collaboration and royalties on sales of products related to such targets, if any.

In accordance with ASU No. 2010-17, Milestone Method of Revenue Recognition, we determined that the remaining contingent payments under the immuno-oncology 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 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 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 the three and nine months ended September 30, 2014, we recognized $2.0 million and $4.1 million, respectively, of revenue under the immuno-oncology collaboration. As of September 30, 2014, we had deferred revenue relating to the immuno-oncology collaboration of $20.6 million.

The immuno-oncology collaboration will terminate upon the expiration of all payment obligations under the collaboration. In addition, BMS may terminate the immuno-oncology 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 party fails to cure the breach or immediately upon certain insolvency events.

GlaxoSmithKline

Respiratory Diseases Discovery Collaboration

In April 2014, we amended our research collaboration and license agreement, referred to as the respiratory diseases collaboration, with Glaxo Group Limited, or GSK, that we originally entered into in April 2012 to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease function. Pursuant to the respiratory diseases collaboration, GSK has an option to elect to include additional screening assays under the research plan. The amendment allows GSK to terminate any additional screening assay it elects under the research plan within nine 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 $0.5 million as of September 30, 2014.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2013 included in our Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission (SEC) on March 26, 2014.

Overview

Five Prime Therapeutics, Inc. (we, us, our, FivePrime 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 for cancer and inflammatory diseases. We have developed a library of more than 5,700 human extracellular proteins, which we believe represent substantially all of the body's medically important targets for protein therapeutics. We screen this comprehensive library with our proprietary high-throughput protein screening technologies to identify new targets for protein therapeutics. This platform has allowed us to develop a pipeline of novel product candidates for cancer and inflammatory diseases and to generate $274.7 million under our collaboration arrangements through September 30, 2014.

We currently have two product candidates in clinical development and we expect to announce the initiation of a Phase 1 clinical trial of a third product candidate by the end of 2014. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are needed. In addition, we are pursuing companion diagnostics 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 candidate, FP-1039/GSK3052230, or FP-1039, is a protein therapeutic that "traps" and neutralizes cancer-promoting fibroblast growth factors, or FGFs, involved in cancer cell proliferation and new blood vessel formation. We have completed a Phase 1 clinical trial, and our partner, GlaxoSmithKline, or GSK, is conducting a three-arm Phase 1b clinical trial in squamous non-small cell lung cancer, or NSCLC, patients with abnormally high levels of FGFR1 and malignant pleural mesothelioma, or MPM, patients. We expect clinical results from the dose escalation phase from one or two arms of this trial by the end of 2014.

Our second clinical-stage product, FPA008, is an antibody that inhibits colony stimulating factor-1 receptor, or CSF1R, which we are developing to treat patients with inflammatory diseases, including rheumatoid arthritis, or RA. 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 commonly involved in the aberrant immune response and inflammatory processes seen in some chronic inflammatory conditions, such as RA. We began a Phase 1 clinical trial for FPA008 in October 2013 and expect preliminary data, including inflammation and bone turnover biomarker data, from the healthy volunteer portion of this trial by the end of 2014. We plan to begin dosing RA patients in this Phase 1 clinical trial by the end of 2014. We expect to commence clinical development of FPA008 in solid tumors in 2015.

We are also developing FPA144, an antibody that inhibits FGF receptor 2b, or FGFR2b, to treat patients with gastric cancer and potentially other solid tumors. In preclinical studies, FPA144 was highly effective in blocking the growth of gastric tumors that had abnormally high levels of FGFR2b. We plan to begin enrolling patients in a Phase 1 clinical trial for FPA144 by the end of 2014. We plan to initially test escalating doses of FPA144 in patients with solid tumors and, after dose escalation, begin treating gastric cancer patients with FGFR2 gene-amplified or FGFR2b over-expressing tumors.

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, due to collaboration revenues from product candidates under collaboration agreements with third parties. For the nine months ended September 30, 2014 and for the year ended December 31, 2013, we reported a net loss of $25.6 million and $28.9 million, respectively. As of September 30, 2014, we had an accumulated deficit of $177.2 million.

Our management's discussion and analysis of our financial condition and results of operations are based upon our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, which we prepared in accordance with GAAP for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended, or the Exchange Act.

Third Quarter 2014 and Other Recent Highlights

GSK continues to actively enroll all three arms of the Phase 1b clinical trial of FP-1039. We expect to have preliminary findings from at least one of the arms by year end 2014.

We initiated Part 3 of the Phase 1 clinical trial of FPA008 in RA patients. Part 3 of this trial begins with open-label dose escalation of FPA008 before advancing into randomized double-blind, placebo-controlled testing in patients with active RA who are on methotrexate background therapy.

We filed an IND in late September 2014 to initiate a Phase 1 clinical trial of FPA144 in gastric cancer patients and have been granted permission to move into clinical studies. We expect to announce first patient enrolled in this trial by the end of 2014.

During the third quarter, GSK exercised its option under our muscle disease collaboration to license an undisclosed muscle disease target that we identified using our proprietary target discovery platform. 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 and 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.

In October 2014, we announced the expansion of our respiratory diseases research collaboration with GSK. The scope of the collaboration was broadened to include two additional respiratory disease discovery programs for a six-month evaluation period and GSK subsequently committed to continue these for an additional 18 months. We will receive an aggregate of $2.0 million in research funding for this expansion, $0.5 million of which we have already received. We will also be eligible to receive up to $193.8 million in potential option exercise fees and milestone payments, as well as tiered royalties on global net sales for each product resulting from a selected drug target under the respiratory disease research collaboration.

In October 2014, we appointed Robert Sikorski, M.D., Ph.D., as Vice President of Global Clinical Development. Dr. Sikorski is in charge of overseeing the global clinical development activities for our product candidates.

In October 2014, we appointed William Ringo, a strategic advisor at Sofinnova Ventures, to our Board of Directors. The addition of Mr. Ringo increased the number of directors to nine.

Product Pipeline

The following table summarizes key information about our three most advanced product candidates:

PRODUCT CANDIDATE	INDICATION	COMMERCIAL RIGHTS	STAGE OF DEVELOPMENT AND ANTICIPATED MILESTONES
FP-1039	FGFR1 gene-amplified tumors, e.g., squamous NSCLC, and FGF-2 overexpressing tumors, e.g., MPM	GlaxoSmithKline: U.S., EU and Canada Five Prime: Co-promote in U.S.; retained rest of world rights	Phase 1b clinical trial underway, consisting of Arms A and B in squamous NSCLC and Arm C in MPM; two of the three arms are nearing completion of the dose escalation phase, which will allow us to choose a dose for expansion that is tolerable in combination with standard chemotherapy.
FPA008	Rheumatoid arthritis; other inflammatory and fibrotic diseases and cancer	Five Prime: Global	Phase 1 clinical trial underway; part 3 initiated with open-label dose escalation in RA patients. Preliminary Phase 1 clinical trial data from healthy volunteers expected by end of 2014. Advancement to dosing in RA patients expected by the end of 2014. Expect to commence clinical development in solid tumors in 2015.
FPA144	FGFR2 gene-amplified or FGFR2b protein over-expressing tumors, e.g., gastric cancer	Five Prime: Global	Received IND clearance for Phase 1 clinical trial. Expect to announce first patient enrolled by the end of 2014.

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 collaboration with BMS.

Summary Revenue by Collaboration Partner

The following is a comparison of collaboration revenue for the three and the nine months ended September 30, 2014 and 2013:

(in millions)	THREE MONTHS ENDED SEPTEMBER 30, 2014	2013	NINE MONTHS ENDED SEPTEMBER 30, 2014	2013
R&D Funding				
Respiratory Diseases Collaboration	$ 0.9	$ 0.7	$ 2.6	$ 2.1
Muscle Diseases Collaboration	—	0.7	0.8	2.3
FP-1039 Product Collaboration	0.1	—	0.1	0.1
Fibrosis and CNS Collaboration	—	0.1	0.1	0.1
Immuno-oncology Collaboration	0.9	—	1.7	—
Other	—	—	0.1	0.1
Ratable Revenue Recognition				
Respiratory Diseases Collaboration	0.7	0.7	2.0	2.0
Muscle Diseases Collaboration	—	0.6	0.9	1.8
Fibrosis and CNS Collaboration	0.8	0.6	2.2	1.4
Immuno-oncology Collaboration	1.1	—	2.4	—
Milestone and Contingent Payments				
Muscle Diseases Collaboration	1.6	0.1	1.7	0.1
Total	$ 6.1	$ 3.5	$ 14.6	$ 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.

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 approximate the revenue recognized under these agreements. Research and development costs consist of salaries and benefits, including associated stock-based compensation, lab supplies and facility costs, as well as fees paid to other entities that conduct certain research and development activities, including manufacturing, on our behalf.

We are conducting research and development activities on several oncology and inflammatory disease targets and products.

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 clinical research organizations, or CROs, and clinical manufacturing organizations, or CMOs, for the execution of certain of our research and development activities, such as toxicology studies, 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. In the early phases of research and discovery, our costs are often related to improving our discovery platform or preliminary screening activities 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 full-time equivalent basis.

The following is a comparison of research and development expenses for the three and the nine months ended September 30, 2014 and 2013:

(in millions)	THREE MONTHS ENDED SEPTEMBER 30, 2014	2013	NINE MONTHS ENDED SEPTEMBER 30, 2014	2013
Product programs:				
FP-1039	$ —	$ 0.2	$ 0.3	$ 0.7
FPA008	2.3	2.6	6.1	7.5
FPA144	1.9	1.2	8.6	3.8
Early preclinical programs, collectively	—	0.4	0.3	2.5
Subtotal pipeline	4.2	4.4	15.3	14.5
Product and discovery collaborations	3.7	2.7	9.7	7.5
Early research and discovery	1.9	1.1	5.6	2.7
Total research and development expenses	$ 9.8	$ 8.2	$ 30.6	$ 24.7

We expect our research and development expenses to increase as we expand our internal cancer immunotherapy discovery and research efforts, 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. We began a Phase 1 clinical trial for FPA008 in October 2013 and expect to begin a Phase 1 clinical trial for FPA144 in selected patients by the end of 2014. 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, our most-advanced product candidate entered Phase 1b clinical development in July 2013, FPA008 entered Phase 1 clinical development in October 2013, we expect FPA144 to begin enrolling patients in a Phase I clinical trial by the end of 2014 and our other product candidates are in preclinical development; therefore, 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 Income (Expense), Net

Other income (expense), 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.

Critical Accounting Policies and Estimates

We based our management's discussion and analysis of financial condition and results of operations upon our unaudited condensed financial statements, which we prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed financial statements and in Note 1 to our audited financial statements contained in our Annual Report on Form 10-K, or our Annual Report, as filed with the Securities and Exchange Commission, or SEC, on March 26, 2014. There have been no significant or material changes in our critical accounting policies during the nine months ended September 30, 2014, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in our Annual Report.

Results of Operations

Comparison for the Three Months Ended September 30, 2014 and 2013

	THREE MONTHS ENDED SEPTEMBER 30,	
(in millions)	2014	2013
Collaboration revenue	$6.1	$3.5
Operating expenses:		
Research and development	9.8	8.2
General and administrative	3.4	2.6
Total operating expenses	13.2	10.8
Interest income	—	—
Other income (expense), net	—	0.1
Net loss	$(7.1)	$(7.2)

Collaboration Revenue

Collaboration revenue increased by $2.6 million, or 74.3%, to $6.1 million for the three months ended September 30, 2014 from $3.5 million for the three months ended September 30, 2013. This increase was primarily due to a $1.5 million payment in connection with the option exercise on an undisclosed muscle disease target by GSK under our muscle diseases collaboration, $2.0 million in revenue recognized under our immuno-oncology collaboration with BMS entered into in March 2014, a $0.3 million increase in revenue recognized under our fibrosis and CNS collaboration with UCB entered into in March 2013, a $0.2 million increase in revenue recognized under our respiratory diseases collaboration with GSK, offset by a $1.3 million decrease in research related 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 $1.6 million, or 19.5%, to $9.8 million for the three months ended September 30, 2014 from $8.2 million for the three months ended September 30, 2013. This increase was primarily due to an increase of $0.7 million related to advancing our FPA144 program towards a phase 1 clinical trial, a $0.8 million increase in early research and discovery costs related to cancer immunotherapy and a concurrent decrease of $0.4 million in costs related to other early preclinical program expenses due to a reduction in the number of programs we are actively pursuing, and a $1.0 million increase in discovery collaboration costs due to entering into our immuno-oncology collaboration with BMS in March 2014 and the fibrosis and CNS collaboration with UCB in March 2013.

General and Administrative

Our general and administrative expenses increased by $0.8 million, or 30.8%, to $3.4 million for the three months ended September 30, 2014 from $2.6 million for the three months ended September 30, 2013, primarily due to a $0.5 million increase in public company-related expenses and $0.1 million increase in stock-based compensation costs.

Other Income (Expense), Net

Other expense, net, was $41,000 for the three months ended September 30, 2014 and was primarily due to a loss on disposal of equipment. Other income, net, was $0.1 million for the three months ended September 30, 2013 and primarily relates to the re-measurement of the preferred stock warrant liability. The entire preferred stock warrant liability was reclassified to permanent equity as a result of the closing of our IPO in September 2013.

Comparison for the Nine Months Ended September 30, 2014 and 2013

	NINE MONTHS ENDED SEPTEMBER 30,	
(in millions)	2014	2013
Collaboration revenue	$14.6	$10.0
Operating expenses:		
Research and development	30.6	24.7
General and administrative	9.7	7.4
Total operating expenses	40.3	32.1
Interest income	0.1	—
Other income (expense), net	—	0.5
Net loss	$(25.6)	$(21.6)

Collaboration Revenue

Collaboration revenue increased by $4.6 million, or 46.0%, to $14.6 million for the nine months ended September 30, 2014 from $10.0 million for nine months ended September 30, 2013. This increase was primarily due to a $1.5 million payment in connection with the option exercise on an undisclosed muscle disease target by GSK under our muscle diseases collaboration, $4.1 million in revenue recognized under our immuno-oncology collaboration with BMS entered into in March 2014, a $0.8 million increase in revenue recognized under our fibrosis and CNS collaboration with UCB entered into in March 2013, a $0.3 million increase in revenue recognized under our respiratory diseases collaboration with GSK, offset by a $2.4 million decrease in research related 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 $5.9 million, or 23.9%, to $30.6 million for the nine months ended September 30, 2014 from $24.7 million for the nine months ended September 30, 2013. This increase was primarily due to an increase of $4.8 million, including $1.5 million of milestone costs under our exclusive license agreement with Galaxy Biotech, LLC, related to advancing our FPA144 program towards a phase 1 clinical trial, a $2.9 million increase in early research and discovery costs related to cancer immunotherapy and a $2.2 million increase in our discovery collaboration costs due to entering into the immuno-oncology collaboration with BMS in March 2014 and the fibrosis and CNS collaboration with UCB in March 2013, offset by a decrease of $1.4 million in costs related to our FPA008 program primarily due to manufacturing costs incurred during the first nine months of 2013 and a decrease of $2.2 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 $2.3 million, or 31.1%, to $9.7 million for the nine months ended September 30, 2014, from $7.4 million for the nine months ended September 30, 2013, primarily due to a $1.7 million increase in public company-related expenses and legal fees, including legal fees related to the immuno-oncology collaboration with BMS, and a $0.6 million increase in stock-based compensation costs.

Other Income (Expense), Net

Other expense, net, was $66,000 for the nine months ended September 30, 2014 and was primarily due to a loss on disposal of equipment. Other income, net, was $0.5 million for the nine months ended September 30, 2013 and primarily relates to the re-measurement of the preferred stock warrant liability. The entire preferred stock warrant liability was reclassified to permanent equity as a result of the closing of our IPO in September 2013.

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 the IPO of $63.8 million after deducting underwriting discounts and commissions paid by us. In connection with the 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 basis on September 23, 2013.

On February 12, 2014, we completed our Follow-on Public Offering, 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, offering expenses and commissions paid by us.

On March 14, 2014, we entered into the immuno-oncology collaboration with BMS to carry out a research program to discover and further understand targets in two immune checkpoint pathways using our target discovery platform and discover and pre-clinically develop compounds suitable for development for human therapeutic uses against targets in these checkpoint pathways. Under the immuno-oncology collaboration agreement, BMS made an upfront payment of $20.0 million to us in April 2014. In connection with the immuno-oncology 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.

Since our inception and through September 30, 2014, we have raised an aggregate of $474.1 million to fund our operations, including $190.2 million under our collaboration agreements, $66.7 million from our IPO, $40.5 million from our Follow-on Public Offering, $84.5 million from the sale of common stock and convertible preferred stock to discovery collaboration partners, $89.9 million from the sale of convertible preferred stock to parties other than our discovery collaboration partners and $2.3 million from the sale of our common stock other than in connection with our IPO or Follow-On Public Offering. As of September 30, 2014, we had $13.1 million in cash and cash equivalents and $116.9 million of marketable securities invested in a U.S. Treasury money market fund, U.S. Treasuries and U.S. government agencies securities with maturities of 18 months or less.

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 through collaboration arrangements and, if necessary, equity or debt financings. 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 arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of September 30, 2014 and funding that we expect to receive under our existing collaborations will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2016, without giving effect to any potential contingent payments we may receive under our existing collaboration agreements or any new collaboration agreements that we may enter into. 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 nine months ended September 30, 2014 and 2013:

(in millions)	NINE MONTHS ENDED SEPTEMBER 30, 2014	2013
Net cash used in operating activities	$(3.4)	$(15.7)
Net cash (used in) provided by investing activities	(51.7)	16.7
Net cash provided by financing activities	60.1	65.3

Net Cash Used in Operating Activities

Net cash used in operating activities was $3.4 million during the nine months ended September 30, 2014. The net loss of $25.6 million was offset by non-cash charges of $1.2 million for depreciation and amortization, $2.2 million for stock-based compensation expense and $1.1 million for amortization of premium on marketable securities. The net change in operating assets and liabilities was $17.7 million, including $17.6 million of deferred revenue primarily related to the $20.0 million payment received from a collaborative partner in April 2014. Net cash used in operating activities was $15.7 million during the nine months ended September 30, 2013. The net loss of $21.6 million was offset by non-cash charges of $1.3 million for depreciation and amortization, $1.6 million for stock-based compensation expense, $0.3 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 $3.2 million, including $2.7 million of deferred revenue primarily related to the $6.0 million upfront payment and $2.2 million technology access fee received from the fibrosis and CNS collaboration with UCB in March 2013.

The decrease in cash used in operating activities for the nine months ended September 30, 2014, as compared to September 30, 2013, was primarily due to our entry into the immuno-oncology collaboration with BMS in March 2014, in connection with which we received an upfront fee of $20.0 million in April 2014.

Net Cash (Used in) Provided by Investing Activities

Net cash (used in) provided by investing activities for the periods presented primarily relates to the purchases and maturities of marketable securities. Purchases of property and equipment were $1.4 million for the nine months ended September 30, 2014 and $0.6 million for the nine months ended September 30, 2013. The property and equipment purchases consisted primarily of purchases of laboratory equipment to support our research and development activities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $60.1 million during the nine months ended September 30, 2014 primarily related to the Follow-on Public Offering of our common stock, which resulted in the sale of 3,450,000 shares of common stock at a price of $12.50 per share, which resulted in cash proceeds of $40.1 million after deducting underwriting discounts and commissions and expenses. Also, in connection with the immuno-oncology collaboration, BMS purchased 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, of which $2.4 million was considered to be an implied premium and

was allocated to the deliverables under the immuno-oncology collaboration, resulting in $18.6 million being allocated to common stock. Additionally, we received $1.4 million from employee stock option exercises for the nine months ended September 30, 2014.

Net cash provided by financing activities of $65.3 million during the nine months ended September 30, 2013 primarily reflects our completion of our IPO which resulted in the sale of 4,800,000 shares of our common stock at a price of $13.00 per share and the underwriters of our IPO exercising their over-allotment option in full to purchase an additional 720,000 shares of common stock at a price of $13.00 per share.

Contractual Obligations and Contingent Liabilities

During the nine months ended September 30, 2014, there were no material changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report.

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.

Item 3. 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 September 30, 2014, we had cash and cash equivalents and marketable securities of $130.0 million consisting of bank deposits, interest-bearing money market accounts, U.S. Treasuries 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 therefore we do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures. Management, including our President and Chief Executive Officer and Senior Vice President and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, the President and Chief Executive Officer and Senior Vice President and Chief Financial Officer concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Exchange Act is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the President and Chief Executive Officer and Senior Vice President and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 to collaboration revenues from product candidates that we partnered. For the nine months ended September 30, 2014, we reported a net loss of $25.6 million. As of September 30, 2014, we had an accumulated deficit of $177.2 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;
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.

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 our 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 the funding we expect to receive under existing collaboration agreements will fund our projected operating requirements into the fourth quarter of 2016. 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;

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, FP-1039, FPA008 and FPA144, 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.

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 in our Phase 1 clinical trial for FP-1039 and in preclinical studies for our other 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.

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.

There is significant competition for recruiting cancer and rheumatoid arthritis patients in clinical trials, and we or our partners may be unable to timely enroll the patients we need 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;
- 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.

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.

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.

28

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 the 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;
- 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.

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 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.

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 and Janssen Pharmaceuticals, Inc.'s JNJ-42756493. Additionally, we could face competition from other agents, such as cancer immunotherapeutics, 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.

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) and Enbrel ® (etanercept). Further competition could arise from products currently in development, including Daiichi Sankyo Co., Ltd./Plexxikon Inc.'s PLX5622 and PLX3397 products, Roche's RG7155 antibody, Janssen's JNJ-40346527, Lilly's IMC-CS4/LY3022855 antibody, MorphoSys and GSK's MOR103 antibody, and Medimmune and AstraZeneca's mavrilimumab antibody, each of which act in the same pathway as FPA008. If FPA008 were approved in other indications, such as other inflammatory disorders, fibrotic disorders or cancer, we could face competition in those settings as well.

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, all of which are available as generics. Further competition could arise from Eli Lilly and Company's CYRAMZA TM (ramucirumab) product 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.

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.

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;
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, 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, 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

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.

To succeed, we must 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.

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 our most advanced product candidate, 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.

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.

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

In addition to our current FP-1039 development collaboration with GSK, a part of our strategy is to enter into additional product development collaborations in the future, 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 effort 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 or establishing and maintaining new discovery collaborations, which would adversely affect our business plans.

Since 2006, we have entered into seven discovery collaborations with Boehringer Ingelheim GmbH, or Boehringer, Centocor Research and Development Inc., or Centocor, GSK, Pfizer, UCB and BMS, under which we have developed and conducted cell-based and in vivo screens using our protein discovery platform. These discovery collaborations

have provided us with approximately $136.8 million in non-equity funding through September 30, 2014, and allowed us to be less reliant on equity financing during this period. We currently have ongoing discovery collaborations with GSK, UCB and BMS. As of September 30, 2014, we were eligible to receive up to an additional $15.8 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 $15.8 million, which would adversely affect our business or financial condition. The research obligations under each of our discovery collaborations with Boehringer, Centocor, Pfizer and GSK have ended. We have no ongoing performance obligations and do not expect to receive any significant additional payments under these discovery collaborations for the foreseeable future.

We plan to continue to seek out discovery collaboration partners and engage in discussions with pharmaceutical and biotechnology companies regarding potential new discovery collaborations. We expect that we will enter into additional discovery collaborations from time to time; however, we expect that we will enter into new discovery collaborations with less frequency than in the last several years, during which we entered into one new discovery collaboration per year. We face significant competition in seeking appropriate discovery collaboration partners, including from these partners' internal research organizations, and the negotiation process is time-consuming and complex. Our failure to continue to enter into new discovery collaborations may require us to obtain financing earlier or in greater amounts than we currently plan.

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.

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.

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.

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.

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. We and Aventis had the right until September 18, 2013 to appeal the Opposition Division’s April 2013 decision; however, neither we nor Aventis appealed this decision and 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.

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 $22.99 through November 11, 2014. 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;
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 September 30, 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 32.1% 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 shareholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding shareholder 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.

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.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds

Initial Public Offering

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 approximately $63.8 million, after deducting underwriting discounts and commissions of approximately $5.0 million and expenses of approximately $2.9 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.

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 (Registration Nos. 333-190194 and 333-191222).

There has been no material change in the planned use of proceeds from our IPO 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.

As of September 30, 2014, we have used approximately $18.1 million of the net offering proceeds from our IPO primarily to fund pre-clinical and clinical activities for FPA008 and pre-clinical activities for FPA144.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which are incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, 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: November 12, 2014	/s/ Lewis T. Williams Lewis T. Williams President and Chief Executive Officer (Principal Executive Officer)
Date: November 12, 2014	/s/ Marc L. Belsky Marc L. Belsky Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

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), as 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), as 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 Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on September 4, 2013).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2014, formatted in XBRL (extensible Business Reporting Language): (i) the Consolidated Balance Sheets; ii) the Consolidated Statements of Comprehensive Income; (iii) the Consolidated Statements of Stockholders' Deficit; (iv) the Consolidated Statements of Cash Flow; and (v) Notes to Consolidated Financial Statements.

*Filed herewith.