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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2013

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 ☐ 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 ☒ 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	☒ (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 ☒

As of October 31, 2013, the number of outstanding shares of the registrant's common stock was 16,833,697.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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," "would," "project," "plan," "expect," or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- our or our partners' ability to advance drug candidates into, and successfully complete, clinical trials alone or in combination with other drugs;
- the frequency of *FGFR1* gene amplification in various patient populations;
- 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.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Condensed Balance Sheets
(In thousands)

	SEPTEMBER 30 2013	DECEMBER 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 77,648	$ 11,391
Marketable securities	8,989	26,624
Receivable from collaborative partners	383	397
Prepaid and other current assets	866	689
Total current assets	87,886	39,101
Property and equipment, net	3,976	4,631
Other long-term assets	184	359
Total assets	$ 92,046	$ 44,091
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,760	$ 2,470
Accrued personnel-related expenses	2,096	2,250
Other accrued liabilities	685	303
Preferred stock warrant liability	—	563
Deferred revenue, current portion	9,015	7,498
Deferred rent, current portion	354	—
Total current liabilities	15,910	13,084
Deferred revenue, long-term portion	8,418	7,258
Deferred rent, long-term portion	2,283	2,448
Other long-term liabilities	729	897
Commitments		
Convertible preferred stock	—	136,282
Stockholders' equity (deficit):		
Common stock	17	1
Preferred stock	—	—
Additional paid-in capital	208,945	6,816
Accumulated other comprehensive income	1	7
Accumulated deficit	(144,257)	(122,702)
Total stockholders' equity (deficit)	64,706	(115,878)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 92,046	$ 44,091

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Collaboration revenue	$ 3,482	$ 2,862	$ 10,006	$ 7,059
Operating expenses:				
Research and development	8,193	6,510	24,708	21,300
General and administrative	2,607	2,257	7,385	6,696
Total operating expenses	10,800	8,767	32,093	27,996
Loss from operations	(7,318)	(5,905)	(22,087)	(20,937)
Interest income	7	21	35	70
Other income, net	77	26	497	85
Net loss	$ (7,234)	$(5,858)	$(21,555)	$(20,782)
Basic and diluted net loss per common share	$ (2.74)	$ (4.85)	$ (12.60)	$ (17.46)
Shares used to compute basic and diluted net loss per common share	2,637	1,207	1,711	1,190

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,	
	2013	2012	2013	2012
Net loss	$ (7,234)	$ (5,858)	$(21,555)	$(20,782)
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities	—	9	(6)	(6)
Comprehensive loss	$ (7,234)	$ (5,849)	$(21,561)	$(20,788)

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,	
	2013	2012
	(Unaudited)	
Operating activities		
Net loss	$ (21,555)	$ (20,782)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,288	1,226
Gain on disposal of property and equipment	—	(5)
Stock-based compensation expense	1,554	1,237
Amortization of premium on marketable securities	272	416
Revaluation of preferred stock warrant liability	(500)	(82)
Changes in operating assets and liabilities:		
Receivable from collaborative partners	14	767
Prepaid, other current assets, and other long-term assets	(2)	211
Accounts payable	467	(519)
Accrued personnel-related expenses	(154)	(431)
Payable to collaborative partner	—	(3,000)
Deferred revenue	2,677	8,193
Deferred rent	189	373
Other accrued liabilities and other long-term liabilities	18	(208)
Net cash used in operating activities	(15,732)	(12,604)
Investing activities		
Purchases of marketable securities	(12,078)	(36,058)
Maturities of marketable securities	29,435	48,636
Purchases of property and equipment	(633)	(501)
Restricted cash	—	38
Net cash provided by investing activities	16,724	12,115
Financing activities		
Proceeds from issuances of common stock	64,887	—
Issuances of convertible preferred stock proceeds (net of issuance costs)	—	6,819
Proceeds from exercise of stock options	387	77
Payments under capital lease obligation	(9)	(11)
Net cash provided by financing activities	65,265	6,885
Net increase in cash and cash equivalents	66,257	6,396
Cash and cash equivalents at beginning of period	11,391	4,361
Cash and cash equivalents at end of period	$ 77,648	$ 10,757
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, 2013

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, 2013 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, 2012 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 for the year ended December 31, 2012 included in the Company's prospectus filed pursuant to Rule 424(b)(4) on September 18, 2013 with the U.S. Securities and Exchange Commission.

Initial Public Offering

In September 2013, we completed our initial public offering of shares of our common stock, or IPO, pursuant to which we issued 5,520,000 shares of common stock, which includes shares we issued pursuant to our underwriters' exercise of their over-allotment option, and received net proceeds of $63.9 million, after underwriting discounts, commissions and estimated offering expenses. In addition, in connection with the completion of our IPO, all convertible preferred stock converted into common stock.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Reverse Stock Split

On September 4, 2013, the Company effected a 1-for-12.3 reverse stock split. All information in this report relating to the number of shares, price per share and per share amounts of stock gives retroactive effect to the 1-for-12.3 reverse stock split of the Company's stock.

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, were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data.

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

2. Summary of Significant Accounting Policies (continued)

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. As of December 31, 2012, our Level 3 liability consists of a preferred stock warrant liability that we measured at estimated fair value.

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

	SEPTEMBER 30, 2013			
		BASIS OF FAIR VALUE MEASUREMENTS		
	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets				
Money market funds	$75,463	$75,463	$ —	$ —
U.S. government agency securities	9,740	—	9,740	—
Total cash equivalents and marketable securities	$85,203	$75,463	$ 9,740	$ —

	DECEMBER 31, 2012			
		BASIS OF FAIR VALUE MEASUREMENTS		
	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
Assets				
Money market funds	$ 6,910	$ 6,910	$ —	$ —
U.S. Treasury securities	3,577	3,577	—	—
U.S. government agency securities	23,047	—	23,047	—
Total cash equivalents and marketable securities	$33,534	$10,487	$23,047	$ —
Liability				
Preferred stock warrant liability	$ 563	$ —	$ —	$ 563

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

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

2. Summary of Significant Accounting Policies (continued)

The change in the estimated fair value of the preferred stock warrant liability is summarized below (in thousands):

	NINE MONTHS ENDED SEPTEMBER 30,	
	2013	2012
Balance, beginning	$ 563	$ 682
Change in fair value recorded in other income, net	(500)	(82)
Exercises	(57)	—
Conversion of preferred stock warrant to common stock warrants and reclassification to permanent equity	(6)	—
Balance, ending	$ —	$ 600

As of September 30, 2012, the fair value of the above warrants was determined using the following assumptions:

Risk-free interest rate	0.1-0.4%
Estimated term (years)	2.3
Volatility	85.0%

Net Loss Per Share of Common Stock

We compute basic net loss per common share 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, the preferred stock warrants, the common stock warrant 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 contains certain participation rights.

For the three months and nine months ended September 30, 2013 and 2012, we excluded the following securities from the calculation of diluted net loss per share as the effect would have been antidilutive (in thousands):

	SEPTEMBER 30,	
	2013	2012
Convertible preferred stock	—	9,929
Options to purchase common stock	2,235	2,526
Warrants to purchase common stock	2	—
Warrants to purchase convertible preferred stock	—	88
	2,237	12,543

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

3. Cash Equivalents and Marketable Securities

The following is a summary of our cash equivalents and marketable securities (in thousands):

	SEPTEMBER 30, 2013			
	AMORTIZED COST BASIS	UNREALIZED GAINS	UNREALIZED LOSSES	ESTIMATED FAIR VALUE
		(unaudited)		
Money market funds	$ 75,463	$ —	$ —	$ 75,463
U.S. government agency securities	9,739	1	—	9,740
	85,202	1	—	85,203
Less: cash equivalents	(76,214)	—	—	(76,214)
Total marketable securities	$ 8,988	$ 1	$ —	$ 8,989

	DECEMBER 31, 2012			
	AMORTIZED COST BASIS	UNREALIZED GAINS	UNREALIZED LOSSES	ESTIMATED FAIR VALUE
Money market funds	$ 6,910	$ —	$ —	$ 6,910
U.S. Treasury securities	3,576	1	—	3,577
U.S. government agency securities	23,041	6	—	23,047
	33,527	7	—	33,534
Less: cash equivalents	(6,910)	—	—	(6,910)
Total marketable securities	$ 26,617	$ 7	$ —	$ 26,624

As of September 30, 2013 and December 31, 2012, the contractual maturities of our marketable securities were less than one year. There were no sales of available-for-sale securities in any of the periods presented.

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

4. Conversion of Convertible Preferred Stock

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

5. Equity Incentive Plans

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

As of September 30, 2013, the total number of shares of common stock available for issuance under the 2013 Plan was 3,500,000, which includes the 1,069,985 shares of common stock that were available for issuance under the Prior Plans as of the effective date of the 2013 Plan. Unless our Board provides otherwise, beginning on January 1, 2014, and continuing until the expiration of the 2013 Plan, the total number of shares of common stock available for issuance under the 2013 Plan will automatically increase annually on January 1 by 4% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year. As of September 30, 2013, no shares of common stock were subject to outstanding awards under the 2013 Plan.

In September 2013, our stockholders approved the 2013 Employee Stock Purchase Plan, or the ESPP, which became effective as of September 23, 2013. We have reserved a total of 250,000 shares of common stock for issuance under the ESPP. Unless our Board provides otherwise, beginning on January 1, 2014, and continuing until the expiration of the ESPP, the total number of shares of common stock available for issuance under the ESPP will automatically increase annually on January 1 by the lesser of (i) 1% of the total number of issued and outstanding shares of common stock as of December 31 of the immediately preceding year, or (ii) 300,000 shares of common stock. As of September 30, 2013, we have not issued any shares of common stock under the ESPP.

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

5. Equity Incentive Plans (continued)

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

		OPTIONS OUTSTANDING	
	NUMBER OF SHARES AVAILABLE FOR GRANT	NUMBER OF SHARES	WEIGHTED-AVERAGE EXERCISE PRICE PER SHARE
Balance at December 31, 2012	451,349	2,545,231	$ 5.17
Options authorized	2,876,226	—	—
Options granted	(547,909)	547,909	$ 6.87
Options exercised	—	(138,484)	$ 2.79
Options forfeited	53,246	(53,246)	$ 6.87
Options expired	667,088	(667,088)	$ 4.10
Balance at September 30, 2013	3,500,000	2,234,322	$ 6.00
Options exercisable		1,196,206	$ 5.34

As of September 30, 2013, options to purchase 2,177,736 shares of common stock were outstanding that are vested and therefore exercisable with a weighted-average exercise price of $5.98 per share and a weighted-average remaining contractual term of 7.5 years. As of September 30, 2013, the weighted-average remaining contractual term for outstanding options that are vested and therefore exercisable was 6.3 years. The aggregate intrinsic value of options outstanding was $15.9 million. The aggregate intrinsic value of outstanding options that are exercisable was $9.3 million. We calculated the aggregate intrinsic value as the difference between the exercise price of the options and the closing price of common stock of $13.10 per share as of September 30, 2013.

Stock Based Compensation

We calculated 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 revised, 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,	
	2013	2012	2013	2012
Research and development	$ 261	$ 177	$ 661	$ 480
General and administrative	258	315	893	757
Total	$ 519	$ 492	$1,554	$1,237

In February 2013, we amended stock options held by our former CEO to extend the post-termination exercise period for the former CEO's outstanding vested options from 18 months to 20 months, which resulted in additional incremental stock-based compensation of $157,000 in the first quarter of 2013.

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

5. Equity Incentive Plans (continued)

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 weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Expected term (years)	5.3-6.1	5.0-6.1	5.0-6.1	5.0-6.1
Expected volatility	85%	85%	85%	85%
Risk-free interest rate	1.4-1.6%	0.6-0.8%	0.8-1.6%	0.6-1.1%
Expected dividend yield	0%	0%	0%	0%

As of September 30, 2013, we had $4.6 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 2.9 years.

6. Collaborative Research and Development Agreements

UCB Pharma S.A.

In March 2013, we and UCB Pharma S.A., or UCB, entered into a research collaboration and license agreement to identify potential biologics targets and therapeutics in the areas of fibrosis-related inflammatory diseases and central nervous system disorders. We plan to conduct five customized cell-based and *in vivo* screens of our protein library under this agreement. We currently expect to complete our initial research activities under this agreement by March 2016. Upon the completion of those research activities, UCB has up to a two-year evaluation period during which we may be obligated to perform additional services at the request of UCB.

We applied the Financial Accounting Standards Board Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, in evaluating the appropriate accounting for this agreement. In accordance with this guidance, we concluded that we should account for the arrangement as a single unit of accounting and recognize the arrangement consideration in the same manner as the final deliverable, which is research service.

Under the terms of the agreement, UCB paid us an upfront payment of $6.0 million in March 2013. In addition, we received $2.2 million of a $6.6 million technology access fee in March 2013. The remaining $4.4 million technology access fee is due in two equal installments on the first and second anniversaries of this agreement. UCB also agreed to pay us $2.0 million of research funding during the second and the third years of the research program term. We recorded the $6.0 million upfront payment and $2.2 million technology access payment as deferred revenue, which we will recognize over the initial five-year research period under the agreement.

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

We are eligible to receive up to $0.4 million of target evaluation and selection fees with respect to each target we offer to UCB in the collaboration. Substantive uncertainty exists at the inception of the agreement as to whether any of these fees will be received because of the numerous variables that may affect our ability to identify targets that UCB would be interested in further evaluating or with respect to which UCB would develop products. In accordance with ASU No. 2010-17, we concluded that these fees under the agreement with UCB are substantive and will be accounted for under the milestone method of revenue recognition.

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements (continued)

6. Collaborative Research and Development Agreements (continued)

In accordance with ASU No. 2010-17, we determined that the remaining contingent payments under the agreement with UCB do not constitute milestone payments and will not be accounted for under the milestone method of revenue recognition. The events leading to these payments under the agreement with UCB do not meet the definition of a milestone under ASU 2010-17 because the achievement of these events solely depends on UCB's performance. Any revenue from these contingent payments would be subject to an allocation of arrangement consideration and would be recognized over any remaining period of performance obligations, if any, relating to this arrangement. If we have no remaining performance obligations under the arrangement at the time the contingent payment is triggered, we would recognize the contingent payment as revenue in full upon the triggering event.

During the three and nine months ended September 30, 2013, we recognized $0.6 million and $1.4 million, respectively, of revenue under this arrangement. As of September 30, 2013, we have deferred revenue relating to this collaboration agreement of $6.8 million.

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

GlaxoSmithKline

Muscle Diseases Discovery Collaboration

In July 2010, we entered into a research collaboration and license agreement with GlaxoSmithKline LLC, or GSK US, to identify potential drug targets and drug candidates to treat skeletal muscle diseases. In December 2012, GSK US selected a protein target for further evaluation under the collaboration agreement. In September 2013, we and GSK US entered into an agreement to extend by approximately eight months the evaluation period for this protein target. In connection with the extension of the evaluation period, GSK US agreed to pay a $0.2 million extension fee. We are recognizing the $0.2 million extension fee over the eight-month extension period, which we recorded as accounts receivable as of September 30, 2013.

7. Subsequent Events

In October 2013, GSK US exercised its right to reserve for further evaluation several protein therapeutic targets for muscle diseases that we discovered in our muscle diseases discovery collaboration with GSK US. In connection with reserving these targets for further evaluation, GSK US will pay us a selection fee of $0.3 million.

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, 2012, included in our prospectus dated September 18, 2013, filed with the U.S. Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus").

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 cancer and inflammatory diseases. We have developed a library of more than 5,600 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 over $222 million under our collaboration arrangements.

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. 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 year ended December 31, 2012 and nine months ended September 30, 2013, we reported a net loss of $27.6 million and $21.6 million, respectively. As of September 30, 2013, we had an accumulated deficit of $144.3 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 accounting principles generally accepted in the United States of America, or GAAP, for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended.

Third Quarter 2013 and Other Recent Highlights

In July 2013, GlaxoSmithKline (GSK), our collaborator for FP-1039/GSK3052230, initiated a three-arm Phase 1b clinical trial in patients with abnormally high levels of FGFR1. GSK has dosed patients in two of the arms. GSK has activated five clinical sites of the approximately 20 planned and continues to activate additional clinical site. Activation of additional sites should allow for acceleration in the rate of patient screening and enrollment in the Phase 1b clinical trial. We expect preliminary Phase 1b clinical data by the second half of 2014.

On September 17, 2013, our registration statements on Form S-1 (File Nos. 333-190194 and 333-191222) relating to our initial public offering (IPO) of common stock became effective. Our IPO closed on September 23, 2013 at which time we sold 4,800,000 shares of our common stock. 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. We received cash proceeds of $63.9 million from the IPO, net of underwriting discounts and commissions and expenses paid by us.

In October 2013, we announced the first in human administration of FPA008 in a Phase 1 clinical trial. FPA008 is an antibody that binds to the colony stimulating factor-1 receptor (CSF1R), thus preventing interaction with its two ligands, CSF1 and IL34, the latter being a novel cytokine discovered at Five Prime. Inhibition of CSF1R in this manner results in inhibition of monocyte-macrophage cells, which contribute to the inflammatory process in many diseases, and in bone-resorbing osteoclasts, which cause bone erosion. FPA008 is being developed for its potential benefit in the treatment of inflammatory diseases, such as rheumatoid arthritis (RA). The first cohort of healthy volunteer subjects was successfully dosed in the Phase 1 clinical trial, which is a randomized, double-blind, placebo-controlled, single- and multiple-ascending dose study in healthy volunteers and subjects with active rheumatoid arthritis. The study will be conducted in three parts to assess the safety, pharmacokinetic (PK), and pharmacodynamic (PD) profiles of the molecule. The first two parts assess single ascending doses (SAD) and multiple ascending doses (MAD) of FPA008 in healthy volunteer subjects. In the third part of the Phase 1, preliminary efficacy and pharmacodynamics of FPA008 in patients with moderate to severe RA disease activity will also be evaluated. We expect to complete dosing of the healthy volunteer portion of the Phase 1 clinical trial of FPA008 in the second half of 2014 and progress to dosing in RA patients by the end of 2014. We anticipate having preliminary healthy volunteer data from the first two parts by the end of 2014.

In September 2013, we and GSK US entered into an agreement to extend by approximately eight months the evaluation period for a protein target for muscle disease that GSK US had previously paid to reserve for evaluation. In connection with the extension of the evaluation period, GSK US agreed to pay a $0.2 million extension fee.

In October 2013, GSK US exercised its right to reserve for further evaluation several protein therapeutic targets for muscle diseases that we discovered in our muscle diseases discovery collaboration with GSK US. In connection with reserving these targets for further evaluation, GSK US will pay us a selection fee of $0.3 million.

In October 2013, we entered into a license agreement with ADC Therapeutics Sarl (ADCT) of Lausanne, Switzerland under which we granted ADCT the right to develop and commercialize antibody-drug conjugates incorporating any of our fully human monoclonal antibodies to an undisclosed protein target expressed on the surface of certain cancer cells.

In October 2013, Aron Knickerbocker was added to our Board of Directors and we promoted Marc Belsky to the position of Chief Financial Officer.

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 non-small cell lung cancer	**GlaxoSmithKline**: U.S., EU and Canada **Five Prime**: Co-promote in U.S.; retained rest of world rights	• Completed Phase 1 clinical trial • In Phase 1b clinical development • Preliminary Phase 1b clinical data expected by the second half of 2014
FPA008	Rheumatoid arthritis; other inflammatory diseases	**Five Prime**: Global	• In Phase 1 clinical development • Preliminary Phase 1 clinical trial data from healthy volunteers expected by end of 2014
FPA144	*FGFR2* gene-amplified tumors, e.g., gastric cancer	**Five Prime**: Global	• Phase 1 clinical trial planned to commence by the end of 2014 • Preliminary Phase 1 clinical trial data expected by end of 2015

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, including GlaxoSmithKline, GSK US, Glaxo Group Limited, or GSK UK, and UCB Pharma S.A., or UCB.

Summary Revenue by Collaboration Partner

The following is a comparison of collaboration revenue for the three and the nine months ended September 30, 2013 and 2012:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
(in millions)	2013	2012	2013	2012
R&D Funding				
Glaxo Group Limited	$ 0.7	$ 0.7	$ 2.1	$ 0.7
GlaxoSmithKline LLC	0.7	0.8	2.3	2.5
GlaxoSmithKline.	—	0.1	0.1	0.8
UCB Pharma S.A.	0.1	—	0.1	—
Other	—	—	0.1	0.1
Ratable Revenue Recognition				
Glaxo Group Limited	0.7	0.7	2.0	1.2
GlaxoSmithKline LLC	0.6	0.6	1.8	1.8
UCB Pharma S.A.	0.6	—	1.4	—
Milestone and Contingent Payments				
GlaxoSmithKline LLC	0.1	—	0.1	—
Total	$ 3.5	$ 2.9	$ 10.0	$ 7.1

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.

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 and are not necessarily allocable to a specific target. We assign costs for such activities to a distinct non-program related project code. We allocate research management, overhead, common usage laboratory supplies, and facility costs on a fulltime equivalent basis.

The following is a comparison of research and development expenses for the three and the nine months ended September 30, 2013 and 2012:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
(in millions)	**2013**	**2012**	**2013**	**2012**
Product programs:				
FP-1039	$ 0.2	$ —	$ 0.7	$ 0.7
FPA008	2.6	0.7	7.5	3.1
FPA144	1.2	1.5	3.8	3.1
Early preclinical programs, collectively	0.4	1.7	2.5	6.8
Subtotal pipeline	4.4	3.9	14.5	13.7
Product and discovery collaborations	2.7	2.0	7.5	5.1
Early research and discovery	1.1	0.6	2.7	2.5
Total research and development expenses	$ 8.2	$ 6.5	$ 24.7	$ 21.3

We expect our overall research and development expenses to increase as we advance our development programs further, 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, 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 scientific and clinical success of each drug candidate, as well as ongoing assessment 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, intellectual property, contract, 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 that our general and administrative expenses will increase for the foreseeable future as we incur additional costs associated with being a publicly-traded company, including legal, auditing and filing fees, additional insurance premiums, investor relations expenses and general compliance and consulting expenses. Also, we expect our intellectual property related legal expenses, including relating to preparing, filing, prosecuting and maintaining patents 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 IPO, 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

Our management's discussion and analysis of financial condition and results of operations are based upon our unaudited condensed financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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 in 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 the Prospectus. There have been no significant or material changes in our critical accounting policies during the three months or nine months ended September 30, 2013, 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 the Prospectus.

Results of Operations

Comparison for the Three Months Ended September 30, 2013 and 2012

	THREE MONTHS ENDED SEPTEMBER 30,	
(in millions)	**2013**	**2012**
Collaboration revenue	$ 3.5	$ 2.9
Operating expenses:		
Research and development	8.2	6.5
General and administrative	2.6	2.3
Total operating expenses	10.8	8.8
Interest income	—	—
Other income, net	0.1	—
Net loss	$ (7.2)	$ (5.9)

Collaboration Revenue

Collaboration revenue increased by $0.6 million, or 20.7%, to $3.5 million for the three months ended September 30, 2013 from $2.9 million for three months ended September 30, 2012. This increase for the three months ended September 30, 2013 was primarily due to the recognition of $0.7 million of revenue under our research collaboration and license agreement, referred to as the fibrosis and CNS collaboration, with UCB entered into in March 2013, offset by a $0.1 million decrease in revenue from our research collaboration and license agreement, referred to as the muscle diseases collaboration, with GSK US, whose original term ended in July 2013.

Research and Development

Our research and development expenses increased by $1.7 million, or 26.2%, to $8.2 million for the three months ended September 30, 2013 from $6.5 million for the three months ended September 30, 2012. This increase was primarily due to an increase of $1.9 million related to our FPA008 program, a $0.7 million increase in our discovery collaboration costs due to entering into the fibrosis and CNS collaboration in March 2013 and the research collaboration and license agreement, referred to as the respiratory diseases collaboration, with GSK UK in April 2012, a $0.5 million increase in early research and discovery programs, primarily cancer immunotherapy, offset by a decrease of $1.3 million in costs incurred in our early preclinical programs due to a reduction in the number of programs we were actively pursuing.

General and Administrative

Our general and administrative expenses increased by $0.3 million, or 13.0%, to $2.6 million for the three months ended September 30, 2013, from $2.3 million for the three months ended September 30, 2012, primarily due to a $0.1 million increase in intellectual property legal fees and $0.2 million for activities related to preparing to become a public company.

Other Income, Net

Other income, net, increased to $77,000 for the three months ended September 30, 2013 from $26,000 for the three months ended September 30, 2012. This increase primarily relates to the re-measurement of the preferred stock warrant liability through the date of the closing of our IPO.

Comparison for the Nine Months Ended September 30, 2013 and 2012

	NINE MONTHS ENDED SEPTEMBER 30,	
(in millions)	**2013**	**2012**
Collaboration revenue	$ 10.0	$ 7.1
Operating expenses:		
Research and development	24.7	21.3
General and administrative	7.4	6.7
Total operating expenses	32.1	28.0
Interest income	—	—
Other income, net	0.5	0.1
Net loss	$ (21.6)	$ (20.8)

Collaboration Revenue

Collaboration revenue increased by $2.9 million, or 40.8%, to $10.0 million for the nine months ended September 30, 2013 from $7.1 million for nine months ended September 30, 2012. This increase for the nine months ended September 30, 2013 was primarily due to the $2.2 million increase in revenue recognized under our respiratory diseases collaboration with GSK UK entered into in April 2012, and the recognition of $1.5 million of revenue under our fibrosis and CNS collaboration with UCB entered into in March 2013, offset by a reduction in reimbursed clinical costs of $0.7 million for research and development we completed in 2012 under our FP-1039 license and collaboration agreement with GSK.

Research and Development

Our research and development expenses increased by $3.4 million, or 16.0%, to $24.7 million for the nine months ended September 30, 2013 from $21.3 million for the nine months ended September 30, 2012. This increase was primarily due to an increase of $4.4 million related to our FPA008 program primarily for the manufacture of drug substance and drug product for our Phase 1 clinical trial, a $0.7 million increase related to advancing our FPA144 program, a $2.4 million increase in discovery collaboration costs due to entering into the fibrosis and CNS collaboration in March 2013 and the respiratory diseases collaboration in April 2012, offset by a $4.3 million decrease in early preclinical program expenses due to a reduction in the number of programs we were actively pursuing.

General and Administrative

Our general and administrative expenses increased by $0.7 million, or 10.4%, to $7.4 million for the nine months ended September 30, 2013, from $6.7 million for the nine months ended September 30, 2012, primarily due to a $0.2 million increase in stock-based compensation, a $0.1 million increase in intellectual property legal fees and $0.2 million for activities related to preparing to become a public company.

Other Income, Net

Other income, net, increased to $0.5 million for the nine months ended September 30, 2013 from $0.1 million for the nine months ended September 30, 2012. This increase primarily reflects the decrease in estimated fair value of the preferred stock warrant liability and re-measurement through the date of the closing of our IPO.

Liquidity and Capital Resources

On September 23, 2013, we completed an IPO of our common stock, which resulted in the sale of 4,800,000 shares 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 before expenses from the IPO of $66.7 million after deducting underwriting discounts and commissions paid by us. In connection with the IPO, two preferred stock warrants net exercised and all of our outstanding convertible preferred stock automatically converted to common stock on a one-for-one ratio on September 23, 2013.

Since our inception and through September 30, 2013, we have raised an aggregate of $379.6 million to fund our operations, including $158.8 million under our collaboration agreements, $66.7 million from our IPO, $63.5 million from the sale of 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 $0.7 million from the sale of common stock. As of September 30, 2013, we had $77.6 million in cash and cash equivalents and $9.0 million of marketable securities invested in a U.S. Treasury money market fund, and U.S. government agencies securities with maturities less than one year.

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 payments 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 interest 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, 2013, and research funding that we expect to receive under our existing collaborations, will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2015, without giving effect to any potential contingent payments we may receive under our collaboration agreements or entering into any new collaboration agreements. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Cash Flows

The following is a summary of cash flows for the nine months ended September 30, 2013 and 2012:

	NINE MONTHS ENDED SEPTEMBER 30,	
(in millions)	**2013**	**2012**
Net cash used in operating activities	($ 15.7)	($ 12.6)
Net cash provided by investing activities	16.7	12.1
Net cash provided by financing activities	65.3	6.9

Net Cash Used in Operating Activities

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 decrease in operating assets and liabilities of $3.2 million is primarily due to a $2.7 million decrease in deferred revenue due to amortization of upfront payments from research collaborations. Net cash used in operating activities was $12.6 million during the nine months ended September 30, 2012. The increase in cash used in operating activities in the nine months ended September 30, 2013 is due to lower up-front proceeds from research collaborations during the first nine months of 2013 as compared to the same period in 2012.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the periods presented primarily relates to the purchases and maturities of marketable securities. Purchases of property and equipment were $0.6 million and $0.5 million during the nine months ended September 30, 2013 and 2012, respectively. The property and equipment purchases during the nine months ended September 30, 2013 and 2012 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 $65.3 million during the nine months ended September 30, 2013 primarily related to the IPO of our common stock, which resulted in the sale of 5,520,000 shares of common stock at a price of $13.00 per share, which resulted in cash proceeds of $64.9 million after deducting underwriting discounts and commissions and expenses paid by us as of September 30, 2013. Additionally, we received $0.4 million from employee stock option exercises in 2013.

Net cash provided by financing activities for the nine months ended September 30, 2012, primarily related to the sale of preferred stock. In April 2012, we sold 0.4 million shares of Series A-3 convertible preferred stock to GSK UK for proceeds of $10.0 million, of which $3.1 million was considered to be an implied premium and was allocated to the deliverables under the respiratory diseases collaboration, resulting in $6.8 million being allocated to the Series A-3 convertible preferred stock. Additionally, we received $0.1 million from employee stock option exercises.

Contractual Obligations and Contingent Liabilities

During the three months ended September 30, 2013, 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 the Prospectus.

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 represents the potential loss arising from adverse changes in interest rates and concentration of credit risk. As of September 30, 2013, we had cash and cash equivalents, and marketable securities of $86.6 million consisting of bank deposits, interest-bearing money market accounts 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 would 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 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 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 Securities Exchange Act of 1934, as amended, 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 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

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 year ended December 31, 2012, and the nine months ended September 30, 2013, we reported a net loss of $27.6 million and $21.6 million, respectively. As of September 30, 2013, we had an accumulated deficit of $144.3 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. We believe that our existing cash and cash equivalents, marketable securities, and funding we expect to receive under existing collaboration agreements, will fund our projected operating requirements into the third quarter of 2015. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our lead product candidates other than FP-1039 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, prosecution, defense and enforcement of 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 potential future operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. 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 from any revenue generated from 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

Only two of our product candidates are in clinical development. Preclinical testing of FPA144 may not lead to it advancing into clinical trials. We may not identify additional product candidates to targets we have identified or identify or validate additional drug targets. If we do not successfully complete preclinical testing of FPA144, identify additional product candidates to targets we have identified 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. 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, 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 decision by the FDA, other regulatory authorities, IRBs or the company, 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 contract research organizations, or CROs, and clinical trial sites;
- deviations from the trial protocol by clinical trial sites and investigators, or failing to conduct the trial in accordance with regulatory requirements;
- failure of our 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 are 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 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 indication 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.

GSK is responsible for the manufacturing of FP-1039 for GSK's use in clinical trials. Under our FP-1039 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 bulk drug substance and drug product and labeling and distribution of FPA008 drug product and placebo for our Phase 1 clinical trial of FPA008. We have not yet contracted with a third party for the manufacture of FPA144 bulk drug substance or for the filling, labeling and distribution of FPA144 drug product for clinical trials. We have identified and negotiated with several third-party manufacturers with facilities and capabilities necessary to manufacture FPA144 bulk drug substance.

We have not contracted with alternate suppliers in the event the current organizations we utilize are unable to scale production, or if otherwise we 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.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a 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.

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. 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 agreement 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. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. 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 and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

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, Les Laboratoires Servier/EOS S.p.A.'s E-3810 and Janssen Pharmaceuticals, Inc.'s JNJ-42756493. 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*®, *Remicade*® (infliximab) and *Enbrel*® (etanercept). Further competition could arise from products currently in development, including Daiichi Sankyo Co., Ltd./Plexxikon Inc.'s PLX5622 product and Janssen's JNJ-40346527, which act in the same pathway as FPA008.

If FPA144 were approved for the treatment of gastric cancer, it could face competition from currently approved and marketed products, including 5-fluorouracil, capecitabine, doxorubicin, cisplatin and docetaxel, all of which are available as generics. Further competition could arise 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 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 product candidates 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, 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 of the physicians or other healthcare providers or entities 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 and other events beyond our control, which could harm our business.

Our facility has been subject to electrical blackouts as a result of a shortage of available electrical power. Future blackouts could disrupt the operations of our facility. 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.

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, and 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 are currently estimating 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 six discovery collaborations with Boehringer Ingelheim GmbH, or Boehringer, Centocor Research and Development Inc., or Centocor, GSK US, GSK UK, Pfizer Inc., or Pfizer, and UCB, 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 $105.6 million in non-equity funding through September 30, 2013, and allowed us to be less reliant on equity financing during this period. We currently have ongoing discovery collaborations with GSK US, GSK UK and UCB. As of September 30, 2013, we are eligible to receive up to an additional $13.1 million of research funding and technology access fees through 2016 under these collaborations. While we expect we will receive all of this funding and these fees, if GSK US, GSK UK or UCB terminates any of our discovery collaborations, we may not receive all or any of this $13.1 million, which would adversely affect our business or financial condition. The research obligations under each of our discovery collaborations with Boehringer, Centocor and Pfizer have ended. We have no ongoing performance obligations and do not expect to receive any significant additional payments under these discovery collaborations.

As part of our business strategy, we plan to continue to actively seek out discovery collaboration partners and engage in discussions with pharmaceutical and biotechnology companies regarding potential new discovery collaborations with the goal of entering 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 expect to rely on third parties to conduct our future 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 plan to rely upon third-party CROs to monitor and manage data for our future clinical programs. We will 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, and 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 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, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and 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 are reliant 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 involve 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 third parties, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings 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 June 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 Ownership of Our Common Stock

The market price of our stock may be volatile.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The following factors, in addition to other risk factors described in this section, 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;

- announcement or expectation 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 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 will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2013, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 52.0% of our common stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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 Securities Exchange Act of 1934, as amended, or 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 recently completed IPO; (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.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us 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 our company. 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 will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be 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 Market. Our management and other personnel will need to 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 could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of September 30, 2013, 11,298,008 shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold upon expiration of the lockup period. Moreover, holders of an aggregate of 9,931,463 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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 for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or 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 Delaware General Corporation Law, 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

In September 2013, upon the closing of our IPO, all 9,929,159 shares of our then-outstanding convertible preferred stock automatically converted into 9,929,159 shares of common stock. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act, pursuant to Section 3(a)(9) and Section 4(s) of the Securities Act.

In October 2013, we issued an aggregate of 10,414 shares upon the exercise of stock options issued under our 2002 Equity Incentive Plan. The issuance of such shares was exempt from the registration requirements of the Securities Act pursuant to Section 3(b) and Rule 701 promulgated thereunder, as transactions pursuant to a compensatory benefit plan as provided under Rule 701.

Use of Proceeds

On September 23, 2013, we completed our IPO and issued 4,800,000 shares of our common stock at an initial offering price of $13.00 per share. On September 26, 2013, we sold an additional 720,000 shares of common stock directly to our underwriters when they exercised their over-allotment option in full at the initial offering price of $13.00 per share. We received net proceeds from the IPO of approximately $63.9 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. 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).

We expect to use the proceeds from the IPO to fund a Phase 1 clinical trial of FPA008, a Phase 1 clinical trial of FPA144 and for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from our IPO as described in our prospectus dated September 18, 2013, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

As of September 30, 2013, we have used approximately $0.5 million of the net offering proceeds primarily to fund pre-clinical activities for FPA008 and FPA144.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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 13, 2013

/s/ Lewis T. Williams
Lewis T. Williams
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2013

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

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 23, 2013).
3.2	Amended and Restated Bylaws of the Company (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 of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-190194), as filed with the SEC on September 4, 2013).
4.2	Warrant to purchase Series A Convertible Preferred Stock issued to General Electric Capital Corporation, dated as of January 26, 2004 (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on July 26, 2013).
10.1	2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-8 (File No. 333-191700), as filed with the SEC on October 11, 2013).
10.2	Form of Incentive Stock Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on July 26, 2013).
10.3	Form of Non-Qualified Option Agreement under 2013 Omnibus Incentive Plan (incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on July 26, 2013).
10.4	2013 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-8 (File No. 333-191700), as filed with the SEC on October 11, 2013).
10.5	Form of Indemnification Agreement by and between the company and each of its directors and officers (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A (File No. 333-190194), as filed with the SEC on August 16, 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 Five Prime Therapeutics, Inc. for the quarter ended September 30, 2013, 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.

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

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Lewis T. Williams, hereby certify that:

1. I have reviewed this quarterly report on Form 10-Q of Five Prime Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2013

/s/ Lewis T. Williams
Lewis T. Williams
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Marc L. Belsky, hereby certify that:

1. I have reviewed this quarterly report on Form 10-Q of Five Prime Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weakness in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2013

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Five Prime Therapeutics, Inc. ("Five Prime") for the quarter ended September 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lewis T. Williams, President and Chief Executive Officer of Five Prime, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Five Prime.

Dated: November 13, 2013

/s/ Lewis T. Williams
Lewis T. Williams
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Five Prime Therapeutics, Inc. ("Five Prime") for the quarter ended September 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Marc L. Belsky, Vice President and Chief Financial Officer of Five Prime, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Five Prime.

Dated: November 13, 2013

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