FIVE PRIME THERAPEUTICS INC
Form 10-Q
August 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the quarterly period ended June 30, 2016

or

¨ TRANSITION REPORTS PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the transition period from to

Commission File Number: 001-36070

Five Prime Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

Two Corporate Drive

South San Francisco, California 94080

(415) 365-5600

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
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 x

As of August 1, 2016, the number of outstanding shares of the registrant's common stock was 28,344,086.

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Exhibit Index

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 RIPPAS are our registered trademarks. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- our receipt of future milestone payments and/or royalties, and the timing of such payments;
- our or our partners’ ability to timely advance drug candidates into and through clinical data readouts and successful completion of clinical trials;
- the timing of the initiation, progress and results of preclinical studies and research and development programs;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- the implementation, timing and likelihood of success of our plans to develop companion diagnostics for our product candidates;
- our ability to establish and maintain collaborations and necessary licenses;
- the implementation of our business model and strategic plans for our business, 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;
- the ability to negotiate adequate reimbursement and pricing by third parties and government authorities;
- developments relating to our competitors and our industry; and
- our expectations regarding licensing, acquisitions and strategic operations.

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

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

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

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Condensed Balance Sheets

(In thousands)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$38,154	$ 149,971
Marketable securities	431,072	367,495
Receivables from collaborative partners	3,399	4,054
Income tax receivable	1,504	—
Prepaid and other current assets	6,005	6,761
Total current assets	480,134	528,281
Property and equipment, net	5,634	4,539
Deferred tax asset	11,620	15,071
Other long-term assets	380	394
Total assets	$497,768	$ 548,285
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$654	$ 1,894
Accrued personnel-related expenses	4,015	6,878
Other accrued liabilities	8,240	5,882
Deferred revenue, current portion	15,597	17,509
Deferred rent, current portion	817	768
Income tax payable, current portion	14,808	46,437
Total current liabilities	44,131	79,368
Deferred revenue, long-term portion	24,562	31,268
Deferred rent, long-term portion	433	865
Income tax payable, long-term portion	1,799	3,283
Other long-term liabilities	147	295
Commitments		
Stockholders' equity:		
Common stock	27	26
Additional paid-in capital	391,978	372,605
Accumulated other comprehensive income (loss)	219	(74)
Retained earnings	34,472	60,649
Total stockholders' equity	426,696	433,206
Total liabilities and stockholders' equity	$497,768	$ 548,285

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Operations

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Collaboration revenue	$9,229	$6,315	$15,749	$10,602
Operating expenses:				
Research and development	22,177	13,310	41,033	24,521
General and administrative	8,106	4,596	16,163	8,816
Total operating expenses	30,283	17,906	57,196	33,337
Loss from operations	(21,054)	(11,591)	(41,447)	(22,735)
Interest income	646	117	1,182	225
Loss before income tax	(20,408)	(11,474)	(40,265)	(22,510)
Income tax benefit	7,271	-	14,088	-
Net loss	$(13,137)	$(11,474)	$(26,177)	$(22,510)
Basic and diluted net loss per common share	$(0.49)	$(0.45)	$(0.98)	$(0.89)
Weighted-average shares used to compute basic and diluted net loss per common share	26,924	25,690	26,619	25,383

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 June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(13,137)	$(11,474)	$(26,177)	$(22,510)
Other comprehensive income:				
Net unrealized gain on marketable securities, net of tax	109	41	293	71
Comprehensive loss	$(13,028)	$(11,433)	$(25,884)	$(22,439)

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(In thousands)

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	$(26,177)	$(22,510)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	782	823
Stock-based compensation expense	14,527	2,203
Excess tax benefits from employee equity incentive plans	(2,533)	—
Deferred income taxes	3,451	—
Amortization of premium on marketable securities	2,346	1,042
Loss on disposal of property and equipment	(9)	—
Changes in operating assets and liabilities:		
Receivables from collaborative partners	655	(308)
Income tax receivable	(1,504)	—
Prepaid, other current assets, and other long-term assets	770	(637)
Accounts payable	(1,240)	257
Accrued personnel-related expenses	(2,863)	(1,524)
Deferred revenue	(8,618)	(1,165)
Deferred rent	(383)	(178)
Income tax payable	(30,580)	—
Other accrued liabilities and other long-term liabilities	2,210	1,786
Net cash used in operating activities	(49,166)	(20,211)
Investing activities		
Purchases of marketable securities	(339,880)	(102,994)
Maturities of marketable securities	274,250	47,500
Purchases of property and equipment	(1,868)	(1,416)
Net cash used in investing activities	(67,498)	(56,910)
Financing activities		
Proceeds from public offering of common stock, net	-	78,693
Proceeds from issuance of common stock under equity incentive plans	5,916	—
Repurchase of shares to satisfy tax withholding	(3,602)	0
Excess tax benefits from employee equity incentive plans	2,533	2,257
Net cash provided by financing activities	4,847	80,950
Net increase (decrease) in cash and cash equivalents	(111,817)	3,829
Cash and cash equivalents at beginning of period	149,971	15,267
Cash and cash equivalents at end of period	$38,154	$19,096

Supplemental cash flow information		
Cash paid for income taxes	$14,701	$—

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

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements

June 30, 2016

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 innovative protein therapeutics to improve the lives of patients with serious diseases. 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 June 30, 2016 is unaudited. The Condensed Financial Statements included in this report reflect all 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 adjustments are of a normal recurring nature, except for an adjustment to correct for the classification of stock-based compensation expense in the three months ended March 31, 2016. This adjustment corrected for an overstatement of $0.6 million in general and administrative expense and an understatement of $0.6 million in research and development expense. The correction of the error is reflected in the results of operations for the six-month period ended June 30, 2016 and did not affect the prior amount of total operating expense, loss from operations, or net loss reported in the three months ended March 31, 2016. We prepared the accompanying unaudited condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The results for interim periods are not necessarily indicative of the results for the entire year or any other interim period. The accompanying Condensed Financial Statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2015 filed with the U.S. Securities and Exchange Commission.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Fair Value of Financial Instruments

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

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

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be

corroborated by observable market data for substantially the full term of the assets or liabilities; and

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

We determine the fair value of Level 1 assets using quoted prices in active markets for identical assets. We review trading activity and pricing for Level 2 investments as of each measurement date. Level 2 inputs, obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data.

In certain cases where there is limited activity or less transparency around inputs to valuation, we classify securities as Level 3 within the valuation hierarchy. We do not have any assets or liabilities measured using Level 3 inputs as of June 30, 2016.

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

	June 30, 2016			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$29,752	$29,752	$ —	$ —
U.S. Treasury securities	431,072	431,072	—	—
Total cash equivalents and marketable securities	$460,824	$460,824	$ —	$ —

	December 31, 2015			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$34,821	$34,821	$ —	$ —
U.S. Treasury securities	477,125	477,125	—	—
Total cash equivalents and marketable securities	$511,946	$511,946	$ —	$ —

Net Loss Per Share of Common Stock

We compute basic net loss per common share by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period.

We excluded the following options to purchase shares of common stock and restricted stock awards, or RSAs, from the calculation of diluted net loss per share for all periods presented as the effect would have been antidilutive (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Options to purchase common stock	2,561	2,604	2,739	2,635
RSAs	1,319	—	1,412	—
	3,880	2,604	4,151	2,635

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers: Topic 606, to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for us in our first quarter of fiscal 2018 using either of two methods: (i) retrospective application of ASU 2014-09 to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective application of ASU 2014-09 with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. In March, April, and May 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers: Principal versus Agent Considerations, ASU 2016-10, Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing, and ASU 2016-12, Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients to provide supplemental adoption guidance and clarification to ASU 2014-09. The effective date for these new standards is the same as the effective date and transition requirements for ASU 2014-09. We are evaluating the potential impact that ASU 2014-09 may have on our financial position and results of operations.

In February 2016, FASB issued ASU 2016-02, Leases. ASU 2016-2 is aimed at making leasing activities more transparent and comparable and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for our interim and annual reporting periods during the year ending December 31, 2019 and all annual and interim reporting periods thereafter. Early adoption is permitted. We are evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and related disclosures.

In March 2016, FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This standard makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation and the financial statement presentation of excess tax benefits or deficiencies. ASU 2016-09 also clarifies the statement of cash flows presentation for certain components of share-based awards. The guidance will be effective for annual reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of ASU 2016-09 will have on our consolidated financial statements and related disclosures.

3. Cash Equivalents and Marketable Securities

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

	June 30, 2016			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$29,752	$ —	$ —	$29,752
U.S. Treasury securities	430,735	338	(1)	431,072
	460,487	338	(1)	460,824
Less: cash equivalents	(29,752)	—	—	(29,752)
Total marketable securities	$430,735	$ 338	$ (1)	$431,072

	December 31, 2015			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$34,821	$ —	$ —	$34,821
U.S. Treasury securities	477,239	13	(127)	477,125
	512,060	13	(127)	511,946
Less: cash equivalents	(144,470)	—	19	(144,451)
Total marketable securities	$367,590	$ 13	$ (108)	$367,495

As of June 30, 2016, the amortized cost and estimated fair value of our available-for-sale securities by contractual maturity are shown below (in thousands):

	Amortized Cost	Estimated Fair Value

Debt securities maturing:		
In one year or less	$430,735	$431,072
Total marketable securities	$430,735	$431,072

We determined that the gross unrealized losses on our marketable securities as of June 30, 2016 were temporary in nature. We currently do not intend to sell these securities prior to maturity and do not consider these investments to be other-than-temporarily impaired at June 30, 2016. There were no sales of available-for-sale securities in any of the periods presented.

4. Equity Incentive Plans

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

	Options Outstanding		
	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Term
Balance at December 31, 2015	3,028,714	$ 12.62	
Options granted	404,600	$ 40.53	
Options exercised	(697,157)	$ 7.35	
Options forfeited	(82,793)	$ 14.36	
Options expired	(127)	$ 18.33	
Balance at June 30, 2016	2,653,237	$ 14.36	
Options exercisable	1,166,045	$ 10.27	6.36

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

The following table summarizes RSA activity under our 2013 Omnibus Incentive Plan and related information:

	RSAs Outstanding	
	Number of Shares	Weighted-Average Grant-Date Fair Value
Unvested balance at December 31, 2015	1,574,870	$ 19.71
RSAs granted	107,630	$ 37.44
RSAs vested	(266,926)	$ 19.06
RSAs forfeited	(94,536)	$ 18.73
Unvested balance at June 30, 2016	1,321,038	$ 21.36

As of June 30, 2016, there were 2,582,268 shares of common stock available for future issuance under our 2013 Omnibus Incentive Plan.

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$3,868	$596	$8,143	$1,105
General and administrative	3,258	616	6,384	1,098
Total	$7,126	$1,212	$14,527	$2,203

During the first quarter of 2016, we reclassified $0.6 million of stock-based compensation expense from general and administrative to research and development. This adjustment is reflected in the table for the six months ended June 30, 2016. See Note 1 for further discussion under “Unaudited Interim Financial Information”.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Expected term (years)	5.5-6.3	5.5-6.1	5.5-6.3	5.5-6.1
Expected volatility	72%	71%	72-74%	71-73%
Risk-free interest rate	1.4%	1.4-1.9%	1.4-1.5%	1.4-1.9%
Expected dividend yield	0%	0%	0%	0%

As of June 30, 2016, we had $19.7 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 2.8 years. Additionally, we had $15.1 million of total unrecognized compensation expense related to employee and director RSAs that we expect to recognize over a weighted-average period of 0.9 years.

5. Collaborative Research and Development Agreements

GlaxoSmithKline

Respiratory Diseases Collaboration

In January 2016, we amended our research collaboration and license agreement, referred to as the respiratory diseases collaboration, with GlaxoSmithKline, or GSK, that we originally entered into in April 2012 to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease function. The amendment extended the research term by three months to July 2016 to allow for the conduct of additional activities to validate protein targets we discovered in our screens and increased the research funding that GSK is obligated to pay us under the collaboration by $0.7 million. As of June 30, 2016, we had substantially completed our activities under the respiratory diseases collaboration and we fully recognized the remaining deferred revenue related to this agreement.

FP-1039 License and Collaboration

In March 2016, GSK delivered to us written notice of termination for convenience of our license and collaboration agreement, or the FP-1039 license, with Human Genome Sciences, Inc., which was acquired by GSK in 2012. Pursuant to the terms of the FP-1039 license, termination of the FP-1039 license will become effective on September 5, 2016, which is 180 days after GSK's notice of termination. Pursuant to the terms of the FP-1039 license, in April 2016, we elected to have GSK complete the conduct of the Phase 1b clinical trial of FP-1039 that GSK is currently conducting, at GSK's expense.

6. Acquired Technologies

In December 2011, we entered into an exclusive license with Galaxy Biotech, LLC, or Galaxy, for the development, manufacturing and commercialization of certain anti-FGFR2b (fibroblast growth factor receptor 2) monoclonal antibodies. Under the terms of the agreement, we paid Galaxy an upfront license payment of $3.0 million. We are also required to make additional payments based upon the achievement of certain intellectual property, development, regulatory and commercial milestones, as well as royalties on future net sales of products resulting from development of this licensed technology, if any. In May 2016, we amended the agreement to revise certain development-related milestones. As a result, the aggregate amount of development-related milestone payments that we may pay to Galaxy

was decreased by $0.5 million. The aggregate amount of intellectual property-related milestone payments, regulatory-related milestone payments and commercial-related milestone payments remain unchanged. During the quarter ended June 30, 2016, we made a $0.25 million milestone payment to Galaxy and accrued an additional $2.25 million of milestone payments, which consist of milestones expected to be met by December 31, 2016. We did not make any milestone payments during the quarter ended June 30, 2015.

7. Employee Benefit Plans

We sponsor a 401(k) plan under which eligible employees may elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100% of eligible compensation on a pre-tax basis. We pay the administrative costs for the plan.

Effective January 1, 2015, we elected to match employee contributions to the 401(k) plan, or the company match, as permitted by the plan. We make matching contributions every pay period in an amount equal to 50% of the amount contributed by the employee up to an annual maximum company match per employee equal to $6,000. We have recorded 401(k) plan company match expense of $216,000 and $461,000, respectively, for the three and six months ended June 30, 2016 and $157,000 and $336,000, respectively, for the three and six months ended June 30, 2015.

8. Income Taxes

We realized an income tax benefit of $7.3 million and $14.1 million, respectively, for the three and six months ended June 30, 2016 as compared to no tax expense for the three and six months ended June 30, 2015. The income tax benefit represents our ability to recover taxes accrued in 2015 based on existing tax law that allows us to carryback our 2016 or 2017 tax losses and/or credits to recover prior taxes. The income tax benefit is based on the annual effective tax rate method and considers our forecasted 2016 pre-tax losses reduced by non-deductible stock based compensation expenses and other immaterial non-deductible permanent items. In addition, as a result of the forecasted loss, the income tax benefit was decreased by a valuation allowance recorded against certain deferred tax assets due to the uncertainty surrounding the realization of such assets in the future.

As of the year ended December 31, 2015, we recognized approximately $15.1 million of net deferred tax assets based on our review of the reversal pattern of these deferred tax assets that may result in future recovery of tax paid in 2015. Based on our forecasted loss for 2016, we assessed the recoverability of deferred tax assets based on their reversal patterns. We will periodically review our ability to realize our deferred tax assets and any adjustment to this recoverability will impact our annual effective tax rate.

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, 2015, included in our Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission, or the SEC, on March 11, 2016.

Overview

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

- Cabiralizumab (FPA008) is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are studying in clinical trials as a monotherapy in pigmented villonodular synovitis, or PVNS, and in multiple cancers in combination with Bristol-Myers Squibb Company's PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab). In October 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- FPA144 is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are initially developing to treat patients with gastric (stomach) cancer and is in a Phase 1 clinical trial.
- FP-1039 is a fusion protein that "traps" and neutralizes cancer-promoting fibroblast growth factors, or FGFs, involved in cancer cell proliferation and new blood vessel formation, which is in Phase 1b clinical development to treat patients with malignant pleural mesothelioma.

We have a differentiated target discovery platform and library, which we believe encompasses substantially all of the body's medically important targets for protein therapeutics. We have identified approximately 700 of these proteins, which we refer to as the immunome, that we believe modulate immune cell interactions and may be important in understanding and treating cancer patients using immuno-oncology therapeutics. Our target discovery platform and capabilities uniquely position us to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and the focus of our research activities. We are applying all aspects of our biologics discovery platform, including cell-based screening, in vivo screening, receptor-ligand matching technologies and bioinformatics, in our immuno-oncology research program. We have identified several targets that we believe could be useful in immuno-oncology and are actively validating these and looking for additional targets. We generate and preclinically test protein therapeutics, including antibodies and ligand traps, containing or directed to the targets we identify. We plan to advance selected therapeutic candidates into clinical development, with a goal of filing at least one Investigational New Drug, or IND, application for a new molecule per year for the foreseeable future, beginning in 2017.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations and we expect that our expenses will increase as we advance and expand our clinical development activities, in particular as we advance into later stages of clinical development. We have incurred losses in each period since our inception in 2002, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million upfront

payment we received from BMS from our license and collaboration agreement for cabiralizumab, and the fiscal year ended December 31, 2011, due primarily to the $50.0 million upfront payment we received from Human Genome Sciences, Inc. from our license and collaboration agreement for FP-1039. For the six-month periods ended June 30, 2016 and 2015, we reported a net loss of $26.2 million and $22.5 million, respectively.

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

Second Quarter 2016 and Other Recent Highlights

Cabiralizumab

In May 2016, we began dosing patients in the Phase 2 portion of our Phase 1/2 clinical trial to evaluate cabiralizumab as a potential treatment for PVNS.

FPA144

In April 2016, we presented preclinical data at the 2016 American Association for Cancer Research (AACR) Annual Meeting from our evaluation of the immune cell recruitment and anti-tumor effects of FPA144 in the orthotopic 4T1 model of breast cancer in mice.

In June 2016, we presented updated safety and tolerability data from 27 patients and pharmacokinetics, or PK, data from 23 patients from Part 1 of our Phase 1 trial at the American Society of Clinical Oncology's (ASCO) 2016 Annual Meeting, or the ASCO Annual Meeting.

In July 2016, the U.S. Food and Drug Administration, or the FDA, granted Orphan Drug Designation to FPA144 for the treatment of gastric cancer, including cancer of the gastroesophageal junction in patients whose tumors overexpress FGFR2b. Orphan Drug Designation is granted by the FDA Office of Orphan Drug Products to products that treat rare diseases. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States. Orphan Drug Designation provides certain benefits and incentives, including a period of marketing exclusivity for the first marketing application if regulatory approval is received for the designated indication, potential tax credits for certain activities and waiver of certain administrative fees.

FP-1039

GlaxoSmithKline, or GSK, is currently conducting a Phase 1b clinical trial of FP-1039 to evaluate the safety, tolerability, dosage, response rate and duration of response of FP-1039 in combination with chemotherapy in patients with malignant pleural mesothelioma. In June 2016, GSK halted new enrollment into the Phase1b clinical trial because some lots of the FP-1039/GSK3052230 clinical material were trending out of specification, which may limit the supply available for patients. The issue was due to the vials GSK used for filled drug product and was identified by GSK through its standard quality control practices. GSK conducted testing of the lots of FP-1039/GSK3052230 drug product that were trending out of specification to assess the feasibility and safety of use of this material in the Phase 1b clinical trial. GSK’s analyses demonstrated that the filtered drug product has quality attributes within acceptable limits, including drug potency. GSK plans to discuss these findings with regulatory authorities and propose to use the filtered drug product in the Phase 1b clinical trial. GSK continues to dose already-enrolled malignant pleural mesothelioma patients with FP-1039/GSK3052230 in the Phase 1b clinical trial, but GSK has determined not to recruit new malignant pleural mesothelioma patients into the trial beyond the 25 patients that have been enrolled at the 15 mg/kg dose level.

In June 2016, updated data from mesothelioma patients from the ongoing Phase 1b clinical trial were presented at the ASCO Annual Meeting.

GSK Respiratory Diseases Collaboration

In April 2012, we entered into a research collaboration and license agreement, or the respiratory diseases collaboration, with GSK to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease with a particular focus on identifying novel protein therapeutics and antibody targets. The research term for the respiratory diseases collaboration ended in July 2016. In June 2016, GSK exercised its option under the respiratory diseases collaboration to take an exclusive license to the intellectual property related to an undisclosed

respiratory disease target we identified using our proprietary target discovery platform, triggering a $1.5 million license payment to us. GSK continues to evaluate additional respiratory disease targets we identified during the research term of the respiratory diseases collaboration. GSK has a time-limited right to exclusively license intellectual property related to these targets under the respiratory diseases collaboration.

Galaxy License Agreement

In May 2016, we amended our exclusive license agreement with Galaxy Biotech, LLC, or Galaxy, that we entered into in December 2011 and pursuant to which Galaxy granted us an exclusive worldwide license to develop and commercialize FGFR2 antibodies, including FPA144. Pursuant to the amendment, we and Galaxy revised certain milestone definitions, reduced certain milestone payments and added certain development-related milestone payments that will be triggered by dosing of certain patients in the current Phase 1 clinical trial of FPA144, or the Phase 1 milestones. Any Phase 1 milestone that we do not achieve by December 31, 2016 will be deemed achieved as of December 31, 2016. We made a $0.25 million milestone payment following our entry into the amendment and expect to make an aggregate of $2.25 million in milestone payments by December 31, 2016 for milestones we expect to achieve on or prior to December 31, 2016, including the Phase 1 milestones. As a result of the amendment, the aggregate amount of development-related milestone payments that we will be obligated to pay to Galaxy under the license agreement was decreased by $0.5 million. The aggregate amount of intellectual property-related milestone payments, regulatory-related milestone payments and commercial-related milestone payments remain unchanged as a result of the amendment.

Clinical Pipeline

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

Cabiralizumab (FPA008)

Cabiralizumab in Immuno-Oncology

We are conducting a Phase 1a/1b clinical trial with BMS to evaluate the safety, tolerability and preliminary efficacy of combining cabiralizumab with Opdivo® (nivolumab) as a potential treatment for a variety of cancers. The trial is currently expected to enroll approximately 280 patients. We amended the trial protocol to add more patients to the current Phase 1a portion of the trial to enable us to study the highest dose of cabiralizumab as monotherapy and as combination therapy with Opdivo® in patients with certain tumor types beyond those addressed in the Phase 1b cohorts, including in patients whose tumors are refractory to PD-1 checkpoint inhibitors. We will conduct these additional Phase 1a activities in parallel with our commencement of the Phase 1b portion of the trial, which we expect to begin in the second half of 2016. In the Phase 1b portion, we plan to evaluate the safety, tolerability and preliminary efficacy of the selected dose of cabiralizumab in combination with Opdivo® in the following tumor settings:

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

Cabiralizumab in PVNS

In January 2016, the FDA granted cabiralizumab Orphan Drug Designation for the treatment of PVNS.

We are conducting a Phase 1/2 clinical trial of cabiralizumab as a potential treatment for PVNS. We advanced into the Phase 2 portion of this trial in May 2016. During the Phase 2 expansion portion of the trial, we will evaluate tumor response rate and duration and measures of pain and joint function.

FPA144

We are conducting a two-part Phase 1 clinical trial of FPA144 as a treatment for gastric cancer. We are currently enrolling patients in Part 2 of the trial in which we are evaluating the safety, PK and efficacy of FPA144 in metastatic gastric cancer patients, with the aim of exploring the correlation between efficacy and FGFR2b overexpression. We are conducting tumor testing for FGFR2b overexpression centrally using a proprietary immunohistochemistry, or IHC, assay to identify gastric cancer patients that have tumors that overexpress FGFR2b protein. Part 2 of the trial is designed to enroll gastric cancer patients whose tumor samples have protein overexpression in four separate cohorts as follows:

- up to 30 patients whose tumor samples have strong (3+) FGFR2b protein overexpression on at least 10% of their tumor membrane;
- up to 30 patients whose tumor samples have moderate (2+) FGFR2b protein overexpression on at least 10% of their tumor membrane or strong (3+) FGFR2b protein overexpression on less than 10% of their tumor membrane;
- up to 30 patients whose tumor samples have low (1+) FGFR2b protein overexpression on at least 10% of their tumor membrane or moderate (2+) FGFR2b protein overexpression on less than 10% of their tumor membrane; and
- up to 30 patients with gastric cancer without FGFR2b protein overexpression.

Enrollment in the first and fourth cohorts began in November 2015. We expect to soon begin enrolling patients in the second and third cohorts described above. We also are in the process of adding a cohort of bladder cancer patients whose tumors overexpress the FGFR2b protein. Initial enrollment of patients in this bladder cancer cohort is contingent in part on our validation and finalization of the design of a laboratory IHC assay for bladder cancer, which we expect to occur in the fourth quarter of 2016.

In April 2016, we presented preclinical data at the 2016 AACR Annual Meeting from our evaluation of the immune cell recruitment and anti-tumor effects of FPA144 in the orthotopic 4T1 model of breast cancer in mice.

In June 2016, we presented updated data from 27 patients and PK data from 23 patients from Part 1 of our Phase 1 clinical trial at the ASCO Annual Meeting.

FP-1039

GSK is currently conducting a Phase 1b clinical trial of FP-1039 to evaluate the safety, tolerability, dosage, response rate and duration of response of FP-1039 in combination with chemotherapy in patients with malignant pleural mesothelioma pursuant to a license and collaboration agreement, or the FP-1039 license, that we entered into with Human Genome Sciences in March 2011.

In March 2016, GSK delivered to us written notice of termination of the FP-1039 license for convenience. Pursuant to the terms of the FP-1039 license, termination of the FP-1039 license will become effective on September 5, 2016, which is 180 days after GSK's notice of termination. Pursuant to the terms of the FP-1039 license, in April 2016, we elected to have GSK complete the conduct of the Phase 1b clinical trial of FP-1039 that GSK is currently conducting, at GSK's expense.

In June 2016, GSK halted new enrollment into the Phase1b clinical trial because some lots of the FP-1039/GSK3052230 clinical material were trending out of specification, which may limit the supply available for patients. The issue was due to the vials GSK used for filled drug product and was identified by GSK through its standard quality control practices. GSK conducted testing of the lots of FP-1039/GSK3052230 drug product that were trending out of specification to assess the feasibility and safety of use of this material in the Phase 1b clinical trial. GSK's analyses demonstrated that the filtered drug product has quality attributes within acceptable limits, including drug potency. GSK plans to discuss these findings with regulatory authorities and propose to use the filtered drug product in the Phase 1b clinical trial. GSK continues to dose already-enrolled malignant pleural mesothelioma patients with FP-1039/GSK3052230 in the Phase 1b clinical trial, but GSK has determined not to

recruit new malignant pleural mesothelioma patients into the trial beyond the 25 patients that have been enrolled at the 15 mg/kg dose level.

In June 2016, updated data from mesothelioma patients from the ongoing Phase 1b clinical trial was presented at the ASCO Annual Meeting.

We will base decisions on any future development of FP-1039 in mesothelioma on overall safety as well as the quantity and durability of responses in the ongoing Phase 1b clinical trial and other business considerations, such as drug supply and manufacturing.

Immuno-Oncology Drug Discovery and Preclinical Programs

We are currently focusing our internal research efforts in the area of immuno-oncology. Cancers grow and spread because tumor cells have developed ways to evade elimination by the immune system. For example, cancer cells make proteins which apply the “brakes” to immune cells and prevent the immune cells from killing the tumor cells. One of the most exciting recent discoveries in cancer therapy has been the identification of ways to release these “brakes” and allow the immune cells to once again kill tumor cells. This new approach has the potential of not only reducing tumor growth like traditional therapies, but potentially eliminating the cancer entirely in some patients.

We are applying all aspects of our biologics discovery platform to discover and validate targets that we believe could be useful in immuno-oncology and to generate therapeutic proteins, including antibodies and ligand traps, directed to these targets. We have identified antibody targets and ligand traps for use in immuno-oncology and are actively screening for and validating additional targets. We generate and pre-clinically test protein therapeutics, including antibodies and ligand traps, directed to the targets we identify. We plan to advance selected therapeutics candidates into clinical development, with a goal of filing at least one IND application for a new molecule per year for the foreseeable future, beginning in 2017.

Financial Overview

Collaboration and License Revenue

We have not generated any revenue from product sales. We have derived our revenue to date from upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaboration partners and licensees. We currently have an active immuno-oncology research collaboration and cabiralizumab license and collaboration agreement with BMS and an FP-1039 product collaboration and license agreement with GSK. We completed the research term of our research collaboration in respiratory diseases with GSK and our fibrosis and CNS research collaboration with UCB Pharma S.A., or UCB, in July 2016 and March 2016, respectively.

Summary Revenue by Collaboration and License Agreements

The following is a comparison of collaboration and license revenue for the three and six months ended June 30, 2016 and 2015:

(in millions)	Three Months Ended June 30, 2016	2015	Six Months Ended June 30, 2016	2015
R&D Funding				
Respiratory Diseases Collaboration - GSK	$1.4	$1.2	$2.3	$2.1
Fibrosis and CNS Collaboration - UCB	—	0.3	0.1	0.4
Immuno-oncology Research Collaboration - BMS	0.8	0.7	1.4	1.4
Cabiralizumab Collaboration - BMS	1.7	0.2	2.8	0.2
Ratable Revenue Recognition				
Respiratory Diseases Collaboration - GSK	0.4	0.6	0.7	1.3
Fibrosis and CNS Collaboration - UCB	0.7	0.7	1.5	1.5
Immuno-oncology Research Collaboration - BMS	1.1	1.1	2.2	2.2
Cabiralizumab Collaboration - BMS	1.5	—	2.9	—
Milestone and Contingent Payments				
Respiratory Diseases Collaboration - GSK	1.5	—	1.5	—
Fibrosis and CNS Collaboration - UCB	—	—	0.2	—
Other License Revenue				
bluebird bio License Agreement	0.1	1.5	0.1	1.5
Total	$9.2	$6.3	$15.7	$10.6

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

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 disease targets and products.

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

The following is a comparison of research and development expenses for the three and six months ended June 30, 2016 and 2015:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	2016	2015	2016	2015
Development programs:				
Cabiralizumab	$3.9	$4.3	$7.4	$7.4
FPA144	5.6	1.3	9.0	2.5
FP-1039	0.1	0.1	0.1	0.1
Subtotal development programs	9.6	5.7	16.5	10.0
Preclinical programs	4.9	1.3	7.2	1.3
Discovery collaborations	1.7	3.7	5.7	7.6
Early research and discovery	6.0	2.6	11.6	5.6
Total research and development expenses	$22.2	$13.3	$41.0	$24.5

We expect that most of the research and development expenses we incur will continue to relate to activities to support our cabiralizumab and FPA144 development programs and our immuno-oncology preclinical, research and discovery efforts. We expect our research and development expenses to increase as we advance our development programs further and advance additional drug candidates into clinical development, in particular as we increase the number and size of our clinical trials and as we expand our internal immuno-oncology discovery and research efforts. We expect that our cabiralizumab and FPA144 development-related expenses will increase at a faster rate than our other internal program research and development expenses as we advance cabiralizumab through the Phase 2 clinical trial in PVNS and the Phase 1b clinical trial in multiple cancers, and as we advance FPA144 into additional cohorts in part 2 of the Phase 1 trial. We expect our preclinical program expenses to continue to increase as we initiate additional therapeutic molecule campaigns and advance our preclinical programs toward and into IND enabling studies. We expect our discovery collaboration expenses to decline in 2016 as we completed the research terms under our respiratory diseases collaboration with GSK and our fibrosis and CNS collaboration with UCB in July 2016 and March 2016, respectively.

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

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

General and Administrative

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

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

Interest Income

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

Critical Accounting Policies and Estimates

We based our management's discussion and analysis of financial condition and results of operations upon our unaudited condensed financial statements, which we prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our critical accounting policies and estimates on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed financial statements and in Note 1 to our audited financial statements contained in our Annual Report on Form 10-K, or our Annual Report, as filed with the Securities and Exchange Commission, or SEC, on March 11, 2016. There have been no significant or material changes in our critical accounting policies during the six months ended June 30, 2016 as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Use of Estimates" in our Annual Report.

Results of Operations

Comparison for the Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,	
(in millions)	2016	2015
Collaboration and license revenue	$9.2	$6.3
Operating expenses:		
Research and development	22.2	13.3
General and administrative	8.1	4.6
Total operating expenses	30.3	17.9
Interest income	0.6	0.1
Loss before income tax	(20.5)	(11.5)
Income tax benefit	7.3	—
Net loss	$(13.1)	$(11.5)

Collaboration and License Revenue

Collaboration and license revenue increased by $2.9 million, or 46.0%, to $9.2 million for the three months ended June 30, 2016 from $6.3 million for the three months ended June 30, 2015. This increase was primarily due to an

increase of $3.0 million of revenue from our cabiralizumab collaboration agreement with BMS that we entered into in October 2015 and $1.5 million of revenue recognized from milestone payments received from GSK under the respiratory diseases collaboration, which was offset by a decrease of $1.4 million in revenue recognized under our license agreement with bluebird bio, Inc., or bluebird. During the three months ended June 30, 2015, we recognized $1.5 million of revenue from the upfront fee received from bluebird under the license agreement that we entered into in May 2015.

Research and Development

Our research and development expenses increased by $8.9 million, or 66.9%, to $22.2 million for the three months ended June 30, 2016 from $13.3 million for the three months ended June 30, 2015. This increase was primarily due to an increase of $4.3 million related to advancing our FPA144 Phase 1 clinical trial, a $3.6 million increase in preclinical program expenses related to advancing our preclinical programs, and a $3.4 million increase in early research and discovery related to expanding our immuno-oncology efforts, which was offset by a $2.0 million decrease in discovery collaboration expenses.

General and Administrative

Our general and administrative expenses increased by $3.5 million, or 76.1%, to $8.1 million for the three months ended June 30, 2016 from $4.6 million for the three months ended June 30, 2015, primarily due to a $3.7 million increase in cash and stock-based compensation costs.

Income Tax Benefit

We realized an income tax benefit of $7.3 million for the three months ended June 30, 2016 as compared to no tax expense for the three months ended June 30, 2015. The income tax benefit represents our ability to recover taxes accrued in 2015 based on existing tax law that allows us to carryback our 2016 or 2017 tax losses and or credits to recover prior taxes. The income tax benefit is based on the annual effective tax rate method and considers our forecasted 2016 pre-tax losses reduced by non-deductible stock-based compensation expenses and other immaterial non-deductible permanent items. In addition, as a result of the forecasted loss, the income tax benefit was decreased by a valuation allowance recorded against certain deferred tax assets due to the uncertainty surrounding the realization of such assets in the future.

At the end of December 2015, we recognized approximately $15.1 million of net deferred tax assets based on our review of the reversal pattern of these deferred tax assets that may result in future recovery of tax paid in 2015. Based on our forecasted loss for 2016, we assessed the recoverability of deferred tax assets based on their reversal patterns. We will periodically review our ability to realize our deferred tax assets and any adjustment to this recoverability will impact our annual effective tax rate.

Comparison for the Six Months Ended June 30, 2016 and 2015

	Six Months Ended June 30,	
(in millions)	2016	2015
Collaboration and license revenue	$15.7	$10.6
Operating expenses:		
Research and development	41.0	24.5
General and administrative	16.2	8.8
Total operating expenses	57.2	33.3
Interest income and other expense, net	1.2	0.2
Loss before income tax	(40.3)	(22.5)
Income tax benefit	14.1	—
Net loss	$(26.2)	$(22.5)

Collaboration and License Revenue

Collaboration and license revenue increased by $5.1 million, or 48.1%, to $15.7 million for the six months ended June 30, 2016 from $10.6 million for the six months ended June 30, 2015. This increase was primarily due to an increase of $5.5 million of revenue from our cabiralizumab collaboration agreement with BMS that we entered into in October 2015, and $1.5 million of revenue recognized from milestone payments received from GSK under the respiratory diseases collaboration, which was offset by a decrease of $1.4 million in revenue recognized under our license agreement with bluebird and $0.6 million in ratable revenue recognition from our respiratory diseases collaboration with GSK. During the six months ended June 30, 2015, we recognized $1.5 million of revenue from the upfront fee we received from bluebird under the license agreement that we entered into in May 2015.

Research and Development

Our research and development expenses increased by $16.5 million, or 67.3%, to $41.0 million for the six months ended June 30, 2016 from $24.5 million for the six months ended June 30, 2015. This increase was primarily due to an increase of $6.5 million related to advancing our FPA144 Phase 1 clinical trial, a $5.9 million increase in preclinical program expenses related to advancing our preclinical programs, and a $6.0 million increase in early research and discovery related to expanding our immuno-oncology efforts, which was offset by a $1.9 million decrease in discovery collaboration expenses.

General and Administrative

Our general and administrative expenses increased by $7.4 million, or 84.1%, to $16.2 million for the six months ended June 30, 2016 from $8.8 million for the six months ended June 30, 2015. This increase was primarily due to a $7.5 million increase in cash and stock-based compensation costs.

Income Tax Benefit

We realized an income tax benefit of $14.1 million for the six months ended June 30, 2016 as compared to no tax expense for the six months ended June 30, 2015. The income tax benefit represents our ability to recover taxes accrued in 2015 based on existing tax law that allows us to carryback our 2016 or 2017 tax losses and or credits to recover prior taxes. The income tax benefit is based on the annual effective tax rate method and considers our forecasted 2016 pre-tax losses reduced by non-deductible stock-based compensation expenses and other immaterial non-deductible permanent items. In addition, as a result of the forecasted loss, the income tax benefit was decreased by a valuation allowance recorded against certain deferred tax assets due to the uncertainty surrounding the realization of such assets in the future.

At the end of December 2015, we recognized approximately $15.1 million of net deferred tax assets based on our review of the reversal pattern of these deferred tax assets that may result in future recovery of tax paid in 2015. Based on our forecasted loss for 2016, we assessed the recoverability of deferred tax assets based on their reversal patterns. We will periodically review our ability to realize our deferred tax assets and any adjustment to this recoverability will impact our annual effective tax rate.

Liquidity and Capital Resources

As of June 30, 2016, we had $469.2 million in cash and cash equivalents and marketable securities invested in a U.S. Treasury money market fund and U.S. Treasury securities with maturities of 12 months or less.

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

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third party clinical and preclinical research and development services, including clinical trial, manufacturing, laboratory and related supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and 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 sources of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration 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 June 30, 2016 will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Cash Flows

The following is a summary of cash flows for the six months ended June 30, 2016 and 2015:

	Six Months Ended June 30,	
(in millions)	2016	2015
Net cash used in operating activities	$(49.2)	$(20.2)
Net cash used in investing activities	(67.5)	(56.9)
Net cash provided by financing activities	4.8	81.0

Net Cash Used in Operating Activities

Net cash used in operating activities was $49.2 million during the six months ended June 30, 2016 and consisted of net loss of $26.2 million offset by $18.6 million in net non-cash charges, and $41.6 million from changes in operating assets and liabilities. Net non-cash charges included $0.8 million of depreciation and amortization expenses, $14.5 million for stock-based compensation expense, and $2.3 million for amortization of premium on marketable securities. The change in operating assets and liabilities was primarily due to a $30.6 million reduction in income tax payable due to a $14.7 million income tax payment during the period and tax benefits from the carryback of the first half of 2016 net operating loss, and an $8.6 million reduction in deferred revenue from the recognition of revenue in the current period for cash received from collaboration partners in prior periods.

Net cash used in operating activities was $20.2 million during the six months ended June 30, 2015. The net loss of $22.5 million was offset by non-cash charges of $0.8 million for depreciation and amortization, $2.2 million for stock-based compensation expense, and $1.0 million for amortization of premium on marketable securities. The net change in operating assets and liabilities was $1.8 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $67.5 million and $56.9 million during the six months ended June 30, 2016 and 2015, respectively. Net cash used in investing activities for the periods presented primarily relates to the purchases and maturities of marketable securities. Purchases of property and equipment were $1.9 million and $1.4 million during the six months ended June 30, 2016 and 2015, respectively. The property and equipment purchases consisted primarily of purchases of laboratory equipment to support our research and development activities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $4.8 million during the six months ended June 30, 2016, primarily related to $5.9 million received from employee stock option exercises and $2.5 million from excess tax benefits from employee equity incentive plans offset by $3.6 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards.

Net cash provided by financing activities was $81.0 million during the six months ended June 30, 2015, primarily related to the net proceeds of $78.7 million from our 2015 underwritten public offering. Additionally, we received $2.3 million from employee stock option exercises for the six months ended June 30, 2015.

Contractual Obligations and Contingent Liabilities

During the three months ended June 30, 2016, there were no material changes to our contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position reflects the potential losses arising from adverse changes in interest rates and concentration of credit risk. As of June 30, 2016, we had cash and cash equivalents and marketable securities of $469.2 million, consisting of bank deposits, interest-bearing money market accounts and U.S. Treasury 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. Our cash equivalents and marketable securities have an average maturity of approximately six months and the longest maturity is twelve months. Due to the short-term maturities of our cash equivalents and marketable securities and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

Item 4. Controls and Procedures

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

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Capital Needs

We expect to incur net losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2001, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million upfront payment we received from Bristol-Myers Squibb Company, or BMS, from our license and collaboration agreement for cabiralizumab (FPA008), and the fiscal year ended December 31, 2011, due primarily to the $50.0 million upfront payment we received from GSK from our license and collaboration agreement for FP-1039. For the six months ended June 30, 2016, we reported a net loss of $26.2 million.

Although we may from time to time report profitable results, such as during the fiscal years ended December 31, 2015 and December 31, 2011, we generally expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We expect our operating expenses to increase as we 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 consistently profitable.

To date, we have not generated any revenue from commercialization of our product candidates. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or with our partners, to successfully commercialize products, including any of our current product candidates or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. Our ability to generate future product revenue from our current or future product candidates also depends on 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;
- successfully develop and validate companion diagnostics on a timely basis;
- 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 revenue from the sale of any of our products that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

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

As a research and development company, our operations have consumed substantial amounts of cash since inception. Although we have sufficient cash and cash equivalents to fund our projected operating expenses and capital expenditure requirements for at least the next 12 months, we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates further into clinical development, advance additional product candidates into clinical trials and as we increase the number and size of our clinical trials. In addition, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our product candidates through preclinical studies and into clinical development, we may have adverse results 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 could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. Our future funding requirements, both short and long-term, will depend on many factors, including:

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

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

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

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

Risks Related to Our Business and Industry

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

We have invested a significant portion of our efforts and financial resources in the identification and validation of new targets for protein therapeutics and the identification and preclinical development of product candidates to these targets. To date, we have three product candidates, cabiralizumab, FPA144 and FP-1039, in clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to identify and validate new targets and identify and advance preclinical product candidates into and through 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 meaningfully positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

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

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

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

Any inability of us or our partners to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization or sales milestone

payments and royalties on product sales.

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

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

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

For example, we are conducting a Phase 1/2 clinical trial of cabiralizumab in patients with PVNS, which is a rare, locally aggressive CSF1-driven tumor of synovium for which there are no currently approved therapies. Very little data regarding the incidence and prevalence of PVNS exists and the data that has been published suggest that the incidence of PVNS may be as low as 1.8 per 1,000,000. We expect that the limited size of the PVNS patient population will limit patient enrollment rates. Also, we know that Plexxikon Inc. has begun a Phase 3 clinical trial of its PLX3397 candidate in PVNS and Roche has clinically tested its RG7155 antibody in PVNS patients. If Plexxikon or Roche continue the clinical development of their products in PVNS, we would potentially compete with them for the enrollment in this rare patient population, which may adversely impact the rate of patient enrollment in and the timely completion of our Phase 1/2 clinical trial of cabiralizumab in PVNS. Also, although we believe selecting patients using companion diagnostics should increase the probability of success in our clinical trial of FPA144 in gastric cancer, this will limit the number of patients eligible for enrollment.

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

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

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

- our research methodology, including our screening technology, may not successfully identify medically relevant protein therapeutic targets or potential product candidates;
- we tend to identify and select from our discovery platform novel, untested targets in the particular disease indications we are pursuing, which may be challenging to validate because of the novelty of the target or that 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 following:

- 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.
- 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, or because we must undertake costly remediation efforts or seek more costly manufacturing alternatives.

Certain raw materials necessary for the manufacture of our products, 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. In the past we have and we may in the future engage third parties for the manufacture of bulk drug substance and drug product for our products for our clinical trials.

For example, BMS has the exclusive right to manufacture cabiralizumab. Under our cabiralizumab collaboration agreement with BMS, BMS will supply us with cabiralizumab, at its cost and expense, for our use in our conduct of the current combination trial and our Phase 1/2 clinical trial of cabiralizumab in patients with PVNS and will supply us with cabiralizumab for our conduct of our independent development activities with respect to cabiralizumab in exchange for a service fee.

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

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

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

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

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

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;

- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologic License Application or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information to support approval, including additional preclinical or clinical data, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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

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

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product candidate, 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 a risk evaluation and mitigation strategy, or 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 such product candidate, if approved, and could significantly harm our business, results of operations and prospects.

If we are unable to successfully develop a companion diagnostic for our FPA144 therapeutic product candidate, or experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of FPA144.

We plan to develop a companion diagnostic for our FPA144 therapeutic product candidate. We expect that the FDA and comparable foreign regulatory authorities may require the development and regulatory approval of a companion diagnostic as a condition to approving FPA144 for use in patients that overexpress FGFR2b protein. We are initially seeking to develop FPA144 to treat a subset of gastric (stomach) cancer patients whose tumors overexpress the FGFR2b protein, as determined by an IHC diagnostic test. We plan to develop a companion diagnostic with a third party collaborator to help us to more accurately identify these gastric cancer patients, both during our clinical trials and in connection with the commercialization of FPA144.

We do not have experience or capabilities in developing or commercializing diagnostics and will be dependent in large part on the sustained cooperation and effort of a third party to perform these functions. We do not currently have any agreements in place with any third party to develop or commercialize a companion diagnostic for FPA144.

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 any third party that we engage to assist us are unable to successfully develop a companion diagnostic for FPA144, or experience delays in doing so:

- the development of FPA144 may be adversely affected because we may be unable to appropriately select patients for enrollment in our clinical trials;
- FPA144 may not receive marketing approval if its safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of FPA144 if, among other reasons, we are unable to appropriately identify patients with FGFR2b protein overexpression.

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 other court actions to impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

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

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

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

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

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

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain foreign regulatory approvals on a timely basis, if at all. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country or by one regulatory authority outside the United States does not ensure approval by regulatory authorities in any other country or jurisdiction or by the FDA, while a failure or delay in obtaining regulatory approval for any of our product candidates in one country may have a negative effect on the regulatory approval process in others and may significantly diminish the commercial prospects of that product candidate, and our business prospects could decline. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources.

Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

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

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

If cabiralizumab were approved for the treatment of cancer or PVNS, it could face competition from products currently in development as single agents and/or in combination with anti-PD1/PD-L1 agents, including Roche's emactuzumab (RO5509554, RG7155) anti-CSF1R antibody, Lilly's IMC-CS4/LY3022855 anti-CSF1R antibody, Amgen's AMG 820 anti-CSF1R antibody, Syndax Pharmaceuticals Inc.'s UCB6352 anti-CSF1R monoclonal antibody, Novartis' BLZ945 CSF1R-directed small molecule, or Daiichi Sankyo Co., Ltd./Plexxikon Inc.'s PLX3397 and PLX7486 small molecule tyrosine kinase inhibitors, with respect to immuno-oncology, and Daiichi Sankyo Co., Ltd./Plexxikon Inc.'s PLX3397 and PLX7486 small molecule tyrosine kinase inhibitor or Novartis AG's MCS110 CSF1 monoclonal antibody, with respect to PVNS, each of which act in the same pathway as cabiralizumab.

If FPA144 were approved for the treatment of gastric cancer, it could face competition from currently approved and marketed products, including 5-fluorouracil, S-1, capecitabine, doxorubicin, cisplatin, oxaliplatin, carboplatin, paclitaxel and docetaxel or Cyramza™ (ramucirumab), and from products currently in early development, including AstraZeneca plc's AZD-4547 and JNJ-42756493 pan-FGFR small molecules, and Bayer's BAY1187982 FGFR2 non-isoform specific antibody-drug conjugate (ADC), as well as antibodies that bind to PD-1/PD-L1, including BMS's nivolumab (Opdivo®), Merck's pembrolizumab (Keytruda®), Merck Serono/Pfizer's avelumab, and AstraZeneca/MedImmune's tremelimumab anti-CTLA4 antibody and durvalumab (MEDI4736) anti-PD-L1 antibody.

If FP-1039 were approved for the treatment of mesothelioma, it could face competition from currently approved and marketed products, such as cisplatin and pemetrexed, or products in development, such as Boehringer Ingelheim's FGF/PDGF/VEGF receptor kinase inhibitor nintedanib (BIBF 1120), Genentech/Roche's Avastin®, AstraZeneca/MedImmune's tremelimumab anti-CTLA4 antibody or durvalumab (MEDI4736) anti-PD-L1 antibody, or Merck's pembrolizumab (Keytruda®) anti-PD1 antibody.

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

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

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

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

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

- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

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

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

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

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

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

approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the beneficiaries 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 and revising the definition of "average manufacturer price," or AMP, for reporting purposes. The legislation also expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well 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. Federal law requires that any company that participates in the Medicaid rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing. 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 Affordable Care Act 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. On February 1, 2016, the Centers for Medicare and Medicaid Services, the federal agency that administers the Medicaid Drug Rebate Program, issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations become effective on April 1, 2016. The Affordable Care Act 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 if we commercially sell any products that we may develop.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025.

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, of 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 civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, or HIPAA, imposes

criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- HIPAA also imposes obligations on certain covered entity health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

We must attract and retain highly skilled employees in order to succeed.

We are experiencing significant growth in our operations as we expand the scope of our research and clinical activities, including our conduct of a Phase 1/2 clinical trial of cabiralizumab in PVNS, a Phase 1a/1b clinical trial of cabiralizumab in combination with Opdivo® in multiple cancers, a Phase 1 clinical trial of FPA144 in gastric cancer and our preclinical development and immuno-oncology research activities. Our success will depend in part on our ability to manage our growth, including increases to our headcount, effectively. To succeed, we must continue to recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and, as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

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

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

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

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

Risks Related to Our Dependence on Third Parties

Under the terms of our collaboration and license agreement with BMS, BMS has exclusive global rights for the development and commercialization of cabiralizumab. BMS’s failure to timely develop and/or commercialize cabiralizumab would result in a material adverse effect on our business and operating results.

We granted BMS an exclusive global license to develop, subject to certain rights retained by us, and commercialize cabiralizumab. Our development collaboration with BMS on cabiralizumab may not be scientifically, medically or commercially successful due to a number of important factors, including the following:

- cabiralizumab may fail to demonstrate sufficient safety or efficacy in clinical trials to support regulatory approval;
- BMS may be unable to manufacture sufficient quantities of cabiralizumab in a timely or cost-effective manner;
- BMS may be unable to obtain regulatory approval to commercialize cabiralizumab even if clinical and preclinical testing is successful;
    - BMS may not be successful in obtaining sufficient reimbursement for cabiralizumab; and
- existing or future products or technologies developed by competitors may be safer, more effective or more conveniently delivered than cabiralizumab.

In addition, we could be adversely affected by:

- BMS’s failure to timely perform its obligations under our collaboration agreement;
- BMS’s failure to timely or fully develop or effectively commercialize cabiralizumab; or
- a material contractual dispute between us and BMS.

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.

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

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

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

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

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

We rely on third-party CROs to conduct our clinical trials.

We rely on third-party CROs to perform most of the activities related to the conduct of our clinical trials, including site identification, screening, preparation, training, initiation and monitoring, document preparation and coordination, program management and data management. However, we do not directly control the conduct of these activities, including the timing, conduct, expense and quality of the performance of these activities. The performance of our CROs will impact the quality and validity of the results of our clinical trials, which we rely on for business planning purposes and include in submissions to regulatory authorities. We remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal and regulatory requirements even though we contract with CROs to conduct most clinical trial related activities. Our reliance on CROs does not relieve us of our legal and 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 GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, we must conduct our clinical trials with product produced under cGMP requirements. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and

preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Risks Related to Intellectual Property

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

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

The patent prosecution process is expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain the patents covering technology that we license from or license to third parties and may have to rely on our licensors, licensees or collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

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

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

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

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

collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' or collaborators' patents, requiring us or our licensors or collaborators to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors or collaborators may have limited remedies if patents are infringed or if we or our licensors or collaborators are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' or collaborators' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have a material adverse effect on our business and financial condition.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee

or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

Third-party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent.

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

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

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to discover and validate protein therapeutic targets and identify, test, develop, manufacture, market and sell product candidates and use our and our licensors' or collaborators' proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property rights, 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, an exclusive license with INBRX 110 LP to antibodies to glucocorticoid-induced tumor necrosis factor receptor, which we intend to clinically develop for therapeutic and diagnostic uses, and non-exclusive licenses with each of the National Research Council of Canada and the Board of Trustees of the Leland Stanford Junior University to use materials and technologies that we use in the production of our protein library. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

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

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

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

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

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. For example, in January 2016, GSK informed us that the U.S. Attorney's Office had arrested and charged certain individuals, including two former GSK employees, with theft of trade secrets from GSK, which theft included information related to FP-1039. We are investigating this matter to obtain additional information regarding this matter and its impact on FP-1039. However, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to the Ownership of Our Common Stock

The market price of our stock may be volatile.

The trading price of our common stock has been and is likely to continue to be volatile. Since shares of our common stock were sold in our IPO in September 2013, our closing stock price as reported on The NASDAQ Global Market and The NASDAQ Global Select Market has ranged from $8.49 to $51.68 through August 4, 2016. The following factors, in addition to other risk factors described in this section and elsewhere in this report, may have a significant impact on the market price of our common stock:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our or our partners' growth rates relative to our competitors;
- announcements by us, our partners 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;
- failure of our partners' to effectively execute or changes in our partners' strategies with respect to our products or collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- our dependence on third parties, including contract manufacturers, CROs, and any partners we may engage to develop and provide us with companion diagnostic products;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

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

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

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

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

As of June 30, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 39% of our common stock. This concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, acting together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders.

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

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and The NASDAQ Global Select Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

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

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

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of

some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

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

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

Item 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: August 5, 2016	/s/ Lewis T. Williams Lewis T. Williams President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)
Date: August 5, 2016	/s/ Marc L. Belsky Marc L. Belsky Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-36070), as filed with the SEC on September 23, 2013).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on July 26, 2013).
4.1	Specimen Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on September 4, 2013).
10.1†	Amendment to the Exclusive License Agreement, effective as of May 16, 2016, by and between the company and Galaxy Biotech, LLC.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2016, formatted in XBRL (extensible Business Reporting Language): (i) the Condensed Balance Sheets; (ii) the Condensed Statements of Operations; (iii) the Condensed Statements of Comprehensive Loss; (iv) the Condensed Statements of Cash Flows; and (v) Notes to Condensed Financial Statements.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

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