UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2019

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.)**

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	FPRX	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of August 1, 2019, the number of outstanding shares of the registrant's common stock was 36,781,385.

TABLE OF CONTENTS

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

These forward-looking 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 such statements. We discuss many of these risks 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 in this report, 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 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 the information in each of these publications, surveys and studies is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal estimates and research are reliable and the market definitions we use are appropriate, such estimates, research and definitions have not been verified by any independent source.

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2019 (Unaudited)	December 31, 2018 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 38,306	$ 43,953
Marketable securities	175,825	226,185
Receivables from collaborative partners	2,602	5,096
Prepaid and other current assets	13,282	13,334
Total current assets	230,015	288,568
Restricted cash	1,543	1,543
Property and equipment, net	27,031	28,718
Operating lease, right-of-use assets	32,142	—
Other long-term assets	2,180	2,705
Total assets	$ 292,911	$ 321,534
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,515	$ 1,972
Accrued personnel-related expenses	3,587	7,383
Other accrued liabilities	19,651	15,348
Operating lease obligations, current portion	3,835	—
Deferred revenue, current portion	2,914	1,428
Deferred rent, current portion	—	1,356
Total current liabilities	33,502	27,487
Deferred revenue, long-term portion	5,200	10,465
Operating lease obligations, long-term portion	47,597	—
Deferred rent, long-term portion	—	18,443
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 36,794,890 issued and 34,964,313 outstanding at June 30, 2019; 35,625,751 issued and 34,745,721 outstanding at December 31, 2018.	34	34
Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Additional paid-in capital	570,893	559,892
Accumulated other comprehensive income (loss)	142	(106)
Accumulated deficit	(364,457)	(294,681)
Total stockholders' equity	206,612	265,139
Total liabilities and stockholders' equity	$ 292,911	$ 321,534

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

FIVE PRIME THERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 3,333	$ 7,580	$ 8,680	$ 40,066
Operating expenses:				
Research and development	29,425	33,380	61,178	76,932
General and administrative	9,661	9,782	20,171	20,260
Total operating expenses	39,086	43,162	81,349	97,192
Loss from operations	(35,753)	(35,582)	(72,669)	(57,126)
Interest income	1,363	1,522	2,896	2,681
Other expense, net	(1)	—	(3)	(5)
Loss before income tax	(34,391)	(34,060)	(69,776)	(54,450)
Income tax provision	—	—	—	—
Net loss	$ (34,391)	$ (34,060)	$ (69,776)	$ (54,450)
Basic and diluted net loss per common share	$ (0.99)	$ (0.99)	$ (2.00)	$ (1.63)
Weighted-average shares used to compute basic and diluted net loss per common share	34,909	34,401	34,852	33,363

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (34,391)	$ (34,060)	$ (69,776)	$ (54,450)
Other comprehensive gain:				
Unrealized gain on marketable securities	100	208	248	98
Comprehensive loss	$ (34,291)	$ (33,852)	$ (69,528)	$ (54,352)

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

FIVE PRIME THERAPEUTICS, INC.

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2017	28,178,639	$ 28	$ 421,257	$ (476)	$ (155,607)	$ 265,202
Issuance of common stock upon follow-on public offering, net of issuance costs	5,897,435	6	114,994	—	—	115,000
Issuance costs related to the follow-on public offering	—	—	(7,387)	—	—	(7,387)
Issuance of common stock under equity incentive plans	311,179	—	1,704	—	—	1,704
Repurchase of shares to satisfy tax withholding obligations	(52,608)	—	(997)	—	—	(997)
Effect of adoption of ASU 2014-09	—	—	—	—	1,374	1,374
Stock-based compensation expense	—	—	7,820	—	—	7,820
Other comprehensive loss	—	—	—	(110)	—	(110)
Net loss	—	—	—	—	(20,390)	(20,390)
Balances at March 31, 2018	34,334,645	34	537,391	(586)	(174,623)	362,216
Issuance of common stock under equity incentive plans	122,278	—	1,160	—	—	1,160
Repurchase of shares to satisfy tax withholding obligations	(5,766)	—	(101)	—	—	(101)
Stock-based compensation expense	—	—	7,435	—	—	7,435
In transit: issuance of common stock under equity incentive plans	3,661	—	—	—	—	—
In transit: repurchase of shares to satisfy tax withholding	(4,365)	—	—	—	—	—
Other comprehensive gain	—	—	—	208	—	208
Net loss	—	—	—	—	(34,060)	(34,060)
Balances at June 30, 2018	34,450,453	34	545,885	(378)	(208,683)	336,858

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	34,745,721	$ 34	$ 559,892	$ (106)	$ (294,681)	$ 265,139
Issuance of common stock under equity incentive plans	150,666	—	222	—	—	222
Repurchase of shares to satisfy tax withholding obligations	(57,703)	—	(670)	—	—	(670)
Stock-based compensation expense	—	—	4,872	—	—	4,872
Other comprehensive gain	—	—	—	148	—	148
Net loss	—	—	—	—	(35,385)	(35,385)
Balances at March 31, 2019	34,838,684	34	564,316	42	(330,066)	234,326
Issuance of common stock under equity incentive plans	131,586	—	772	—	—	772
Repurchase of shares to satisfy tax withholding obligations	(5,957)	—	(58)	—	—	(58)
Stock-based compensation expense	—	—	5,863	—	—	5,863
Other comprehensive gain	—	—	—	100	—	100
Net loss	—	—	—	—	(34,391)	(34,391)
Balances at June 30, 2019	34,964,313	34	570,893	142	(364,457)	206,612

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

FIVE PRIME THERAPEUTICS, INC.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (69,776)	$ (54,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,664	2,456
Stock-based compensation expense	10,735	15,255
Amortization of discounts and premiums on marketable securities	(1,446)	(336)
Non-cash operating lease expense	1,143	—
Loss on disposal of property and equipment	—	5
Changes in operating assets and liabilities:		
Receivables from collaborative partners	2,494	10,422
Prepaid, other current assets and other long-term assets	(8)	(3,813)
Accounts payable	2,259	229
Accrued personnel-related expenses	(3,796)	(2,037)
Deferred revenue	(3,779)	(7,406)
Deferred rent	—	1,250
Other accrued liabilities, and other long-term liabilities	4,264	(578)
Operating lease liabilities	(1,084)	—
Net cash used in operating activities	(56,330)	(39,003)
Investing activities		
Purchases of marketable securities	(125,088)	(212,147)
Maturities of marketable securities	177,142	145,500
Purchases of property and equipment	(1,636)	(10,733)
Net cash provided by (used in) investing activities	50,418	(77,380)
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	—	107,613
Proceeds from issuance of common stock under equity incentive plans	993	2,863
Repurchase of shares to satisfy tax withholding obligations	(728)	(1,098)
Net cash provided by financing activities	265	109,378
Net decrease in cash and cash equivalents and restricted cash	(5,647)	(7,005)
Cash, cash equivalents and restricted cash at beginning of period	45,496	61,333
Cash, cash equivalents and restricted cash at end of period	$ 39,849	$ 54,328
Supplemental disclosure		
Property and equipment purchases included in accrued liabilities	$ 57	$ 24
Supplemental cash flow information		
Cash and cash equivalents at beginning of period	$ 43,953	$ 59,790
Restricted cash at beginning of period	1,543	1,543
Cash, cash equivalents and restricted cash at beginning of period	$ 45,496	$ 61,333
Cash and cash equivalents at end of period	$ 38,306	$ 52,785
Restricted cash at end of period	1,543	1,543
Cash, cash equivalents and restricted cash at end of period	$ 39,849	$ 54,328

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

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. 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, 2019 is unaudited. The financial statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that our management considers necessary for the fair statement of the results of operations for the interim periods covered and of our financial condition at the date of the interim balance sheet. The accompanying unaudited consolidated financial statements have been prepared 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 financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission, or the SEC, on February 26, 2019, or our Annual Report.

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 that affect the amounts reported in the financial statements and accompanying notes as of the date of the financial statements. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable. Actual results could differ materially from those estimates.

Restricted Cash

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

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, which are obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data. There were no transfers between Level 1 and Level 2 securities in the periods presented.

In certain cases where there is limited activity or less transparency around inputs to valuation, 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, 2019.

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

	June 30, 2019			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 21,141	$ 21,141	$ —	$ —
U.S. Treasury securities	20,972	20,972	—	—
Agency bonds	105,458	105,458	—	—
Corporate bonds	12,440	—	12,440	—
Commercial paper	36,954	—	36,954	—
Certificate of deposit	1,543	—	1,543	—
Total	$ 198,508	$ 147,571	$ 50,937	$ —

	December 31, 2018			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 40,849	$ 40,849	$ —	$ —
U.S. Treasury securities	104,140	104,140	—	—
Agency bonds	53,999	53,999	—	—
Corporate bonds	11,893	—	11,893	—
Commercial paper	56,152	—	56,152	—
Certificate of deposit	1,543	—	1,543	—
Total	$ 268,576	$ 198,988	$ 69,588	$ —

Revenue Recognition

Effective January 1, 2018, we adopted Financial Accounting Standards Board, or FASB, Accounting Standard Update, or ASU 2014-09*, Revenue from Contracts with Customers (Topic 606)*, or Topic 606, using the modified retrospective transition method. We applied the standard to contracts that were not completed at the date of initial application. Topic 606 provides a unified model to determine how revenue is recognized. We determine revenue recognition for arrangements within the scope of Topic 606 by performing the following five steps: (i) identifying the contract; (ii) identifying the performance obligations in the contract; (iii) determining the transaction price; (iv) allocating the transaction price to the performance obligations in the contract; and (v) recognizing revenue when, or as, the company satisfies a performance obligation.

The terms of our collaborative research and development agreements include upfront and license fees, research, development and other funding or reimbursements, milestone and other contingent payments for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of commercialized products. Arrangements that include upfront payments may require deferral of revenue recognition to a future period until we perform obligations under these arrangements. We record research and development funding payable to us as accounts receivable when our right to consideration is unconditional. The event-based milestone and other contingent payments represent variable consideration, and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainty around occurrence of these events, we determine the milestone and other contingent amounts to be fully constrained until the uncertainty associated with these payments is resolved. We will recognize revenue from sales-based royalty payments when or as the sales occur. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting in Topic 606. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the applicable performance obligation is satisfied. Under Topic 606, we elected to use the practical expedient permitted related to adoption, which does not require us to disclose certain information regarding our remaining performance obligations as of the end of the reporting period prior to the initial date of adoption. Additionally, we elected the practical expedient for certain research and development funding which allows us to recognize revenue in the amount for which we have a right to invoice if our right to consideration is an amount that corresponds directly to the value of our performance completed to date. As a result, we effectively bypass the steps of determining the transaction price and allocating that transaction price to the performance obligation.

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. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since the effect of potentially dilutive securities is antidilutive.

We excluded the following securities from the calculation of basic net loss per share (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Options to purchase common stock	4,019	3,904	3,944	3,967
Restricted stock awards (RSAs)	1,227	1,015	1,102	923
	5,246	4,919	5,046	4,890

Accounting Pronouncements Adopted in 2019

In February 2016, FASB issued *ASU 2016-02, Leases (Topic 842)*, or ASU 2016-02, which amends existing guidance to require substantially all leases to be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases.

We adopted the standard, effective January 1, 2019, using the updated modified retrospective transition method, in which the new standard is applied as of the date of initial adoption. We recognized and measured agreements executed prior to the date of initial adoption that were considered leases on January 1, 2019. No cumulative effect adjustment of initially applying the standard to the opening balance of retained earnings was made upon adoption. We elected the package of practical expedients permitted under the transition guidance that will retain the lease classification and initial direct costs for any leases that exist prior to adoption of the standard. We have not reassessed whether any contracts entered into prior to adoption are leases. In addition, we elected the accounting policy to not record short-term leases with a lease term at the commencement date of twelve months or less on the balance sheet as permitted by the new standard.

Upon adoption, we derecognized $19.8 million in deferred rent and recognized $52.5 million in lease liabilities and $33.3 million in right-of-use assets on our balance sheet. The financial statements for the three and six months ended June 30, 2019 are presented under the new standard, while comparative years presented are not adjusted and continue to be reported in accordance with our historical accounting policy.

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, Disclosure Update and Simplification. These amendments eliminate, modify, or integrate into other SEC requirements certain disclosure rules. Among the amendments is the requirement to present an analysis of changes in stockholders' equity in the interim financial statements included in quarterly reports on Form 10-Q. The analysis, which can be presented as a footnote or separate statement, is required for the current and comparative quarters and year-to-date interim periods. The amendments are effective for all filings made on or after November 5, 2018. In light of the anticipated timing of effectiveness of the amendments and expected proximity of effectiveness to the filing date for most filers' quarterly reports, the SEC's Division of Corporate Finance issued a Compliance and Disclosure Interpretation related to Exchange Act Forms, or CDI – Question 105.09, that provides transition guidance related to this disclosure requirement. CDI – Question 105.09 states that the SEC would not object if the filer's first presentation of the changes in shareholders' equity is included in its quarterly report on Form 10-Q for the quarter that begins after the effective date of the amendments. As such, we adopted these SEC amendments on November 5, 2018 and presented the analysis of changes in stockholders' equity beginning the first quarter of 2019. No adjustment was required as a result of this adoption.

Accounting Pronouncements Not Yet Adopted

In November 2018, FASB issued *ASU No. 2018-18, Collaborative Arrangements (Topic 808)*, or ASU 2018-18, which clarifies when certain transactions between collaborative arrangement participants should be accounted for under Topic 606 and incorporates unit-of-account guidance consistent with Topic 606 to aid in this determination. ASU 2018-18 will become effective January 1, 2020 and will apply to all annual and interim reporting periods thereafter. Early adoption is permitted. ASU 2018-18 should generally be applied retrospectively to the date of initial application of Topic 606. We do not anticipate that the adoption of this standard will have a material effect on our financial statements.

In August 2018, FASB issued *ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820)*, or ASU 2018-13. The updated guidance improves the disclosure requirements on fair value measurements. The update will become effective for us beginning in the first quarter of 2020. Early adoption is permitted for any removed or modified disclosures. We are currently assessing the timing and impact of adopting the updated provisions.

In June 2016, FASB issued *ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)*, or ASU 2016-13. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for us beginning in the first quarter of 2020 and must be adopted using a modified retrospective approach, with certain exceptions. We are currently assessing the impact of adopting the updated provisions and do not anticipate that the adoption of this standard will have a material effect on our financial statements.

In April 2015, FASB issued *ASU 2018-15, Intangibles – Goodwill and Other – Internal-Use Software (Topic 350)*, or ASU 2018-15. ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal use software guidance to determine which implementation costs to defer and recognize as an asset. This guidance will become effective for us beginning in the first quarter of 2020 and can be adopted prospectively to all implementation costs incurred after the date of adoption or retrospectively. We are currently assessing the timing and impact of adopting the updated provisions.

3. Cash Equivalents and Marketable Securities

The following table summarizes our cash equivalents and marketable securities (in thousands):

	June 30, 2019			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$ 21,141	$ —	$ —	$ 21,141
U.S. Treasury securities	20,959	13	—	20,972
Agency bonds	105,364	94	—	105,458
Corporate bonds	12,432	8	—	12,440
Commercial paper	36,928	27	—	36,955
Total cash equivalents and marketable securities	196,824	142	—	196,966
Less: cash equivalents	(21,141)	—	—	(21,141)
Total marketable securities	$ 175,683	$ 142	$ —	$ 175,825

	December 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$ 40,849	$ —	$ —	$ 40,849
U.S. Treasury securities	104,218	—	(78)	104,140
Agency bonds	54,005	9	(15)	53,999
Corporate bonds	11,897	—	(4)	11,893
Commercial paper	56,171	—	(19)	56,152
Total cash equivalents and marketable securities	267,140	9	(115)	267,034
Less: cash equivalents	(40,849)	—	—	(40,849)
Total marketable securities	$ 226,291	$ 9	$ (115)	$ 226,185

As of June 30, 2019, 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	$ 175,683	$ 175,825
Total marketable securities	$ 175,683	$ 175,825

We determined that the gross unrealized losses on our marketable securities as of June 30, 2019 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, 2019. 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 Contractual Term (years)
Balance at December 31, 2018	3,710,181	$ 28.37	
Options granted	839,850	11.05	
Options exercised	(41,161)	8.14	
Options forfeited	(404,916)	25.30	
Options expired	(201,285)	30.76	
Balance at June 30, 2019	3,902,669	25.05	6.79
Options exercisable at June 30, 2019	2,332,191	27.28	5.45

We have granted restricted stock awards, or RSAs, some of which are subject to performance conditions and/ or market conditions. RSAs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting and are not forfeitable once fully vested. We base the fair value of RSAs on the closing sale price of our common stock on the grant date. For RSAs subject to market conditions, we based the fair value of the awards on a Monte Carlo simulation model. For RSAs subject to performance conditions, we recognize stock-based compensation expense using the accelerated attribution recognition method when it is probable that the performance condition will be achieved and, for RSAs subject to market conditions, we recognize stock-based compensation expense commencing at the grant date over the derived service period.

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, 2018	880,030	$ 26.36
RSAs granted	1,451,050	8.14
RSAs vested	(156,450)	30.32
RSAs forfeited	(344,053)	22.09
Unvested balance at June 30, 2019	1,830,577	12.38

As of June 30, 2019, there were 1,968,771 shares of common stock available for future issuance under our 2013 Omnibus Incentive Plan.

Stock-Based Compensation

Total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 2,621	$ 4,055	$ 4,383	$ 7,988
General and administrative	3,243	3,380	6,352	7,267
Total	$ 5,864	$ 7,435	$ 10,735	$ 15,255

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Expected term (years)	5.5-6.3	6.0-6.3	5.5-6.3	6.0-6.3
Expected volatility	67.7%	69.1%	67.7%	69.1-69.8%
Risk-free interest rate	2.2%	2.8%	2.2-2.5%	2.6-2.8%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

As of June 30, 2019, we had $20.4 million of total unrecognized compensation expense related to unvested stock options that we expect to recognize over a weighted-average period of 2.7 years. Additionally, we had $12.8 million of total unrecognized compensation expense related to employee and director RSAs that we expect to recognize over a weighted-average period of 2.2 years.

Stock Option Exchange Program

On July 1, 2019, we commenced a tender offer to our employees, excluding executive officers, to exchange eligible stock options for replacement stock options with modified terms, or our exchange offer. Pursuant to the exchange offer, we offered employees who held outstanding stock options granted on or before June 6, 2018 with an exercise price equal to or greater than $18.00 per share, or eligible options, the opportunity to tender each eligible option in exchange for a new stock option with modified terms, or new options. Pursuant to the exchange offer, each new option would:

- have an exercise price equal to the closing price of our common stock reported on The Nasdaq Global Select Market, or Nasdaq, on the date that the new option is granted, or the grant date;
- vest in equal monthly amounts over either one or three years, depending on whether the tendered eligible option was vested as of July 29, 2019;
- have a maximum term of seven years;
- be granted as a nonqualified stock option;
- be granted under our 2013 Omnibus Incentive Plan; and
- be exercisable for a reduced number of shares using an exchange ratio based on the exercise price of the tendered eligible option.

The exchange offer expired at 6:00 p.m., Pacific time, on July 29, 2019. Pursuant to the exchange offer, 55 employees elected to exchange outstanding stock options, and we accepted for cancellation stock options to purchase an aggregate of 436,648 shares of common stock, representing approximately 85% of the total shares of common stock underlying the eligible options. On July 29, 2019, immediately following the expiration of the exchange offer, we granted new options to purchase 235,419 shares of common stock, each with an exercise price of $5.06 per share, which was the closing price per share of our common stock on Nasdaq on the grant date. As a result, 201,229 shares of common stock returned to the 2013 Omnibus Incentive Plan and became available for future issuance.

The exchange of stock options was treated as a modification for accounting purposes. The incremental expense for vested stock options calculated using the Black-Scholes option pricing model will be recorded in our financial statements for the quarter ending September 30, 2019. The incremental expense, together with the unamortized expense remaining on the unvested options, will be amortized over the vesting period of the new options beginning on July 29, 2019.

5. License and Collaboration Arrangements

See Note 8 to the audited consolidated financial statements included in Part IV, Item 15 of our Annual Report for information on our license and collaboration agreements.

The following table presents changes during the six months ended June 30, 2019 in the balances of our contract assets, including receivables from collaboration partners, and contract liabilities, including deferred revenue, as compared to what we disclosed in our Annual Report.

(in thousands)	Contract Assets
Balance at December 31, 2018	$ 5,096
Additions	4,900
Deductions	(7,394)
Balance at June 30, 2019	$ 2,602

(in thousands)	Contract Liabilities
Balance at December 31, 2018	$ 11,893
Additions for advance billings	1,085
Deductions for performance obligations satisfied in current period	(3,190)
Deductions for performance obligations satisfied in the prior periods in connection with updates to the measure of progress	(1,674)
Balance at June 30, 2019	$ 8,114

Bristol-Myers Squibb Company

Immuno-Oncology Research Collaboration

In March 2014, we entered into a research collaboration and license agreement, or the immuno-oncology research collaboration, with Bristol-Myers Squibb Company, or BMS.

We identified one performance obligation under the immuno-oncology research collaboration for the research license to access our technology, the exclusive commercial license and research activities. BMS's option to select additional collaboration targets is not priced at a discount and therefore does not represent one or more performance obligations for which the transaction price would be allocated. The transaction price of $36.1 million includes the $20.0 million non-refundable upfront fee, $13.7 million of research funding and $2.4 million of equity premium. We concluded that the transaction price should not include the variable consideration related to maintenance fees and unachieved clinical and regulatory development milestones as this consideration was considered to be constrained since it is probable that the inclusion of such variable consideration could result in a significant reversal in revenue in the future. For the three and six months ended June 30, 2019, no milestone payments were triggered under the immuno-oncology research collaboration. We will recognize any consideration related to sales-based payments (including milestones and royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation or the occurrence of the related sales. We will re-evaluate the transaction price at each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

Under the input method, we recognize revenue on the basis of our efforts or inputs applicable to the satisfaction of a performance obligation (e.g., resources consumed, labor hours expended, costs incurred, or time elapsed) relative to the total expected inputs applicable to the satisfaction of that performance obligation. We concluded that we will recognize revenue based on actual costs incurred as a percentage of total budgeted costs as we complete our performance obligation. As the performance obligation was fully satisfied through March 31, 2019, the transaction price of $36.1 million was fully recognized as collaboration revenue. Revenue recognized from the performance obligation was $0 and $1.4 million for the three and six months ended June 30, 2019, respectively.

License and Collaboration Agreement

On October 14, 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with BMS. The cabiralizumab collaboration agreement supersedes the clinical trial collaboration agreement we entered into with BMS in November 2014, or the original collaboration agreement. We assessed the two agreements separately as standalone agreements under Topic 606.

Under the original collaboration agreement, we identified one performance obligation for the execution of a Phase 1a/1b clinical trial of cabiralizumab in combination with *Opdivo*®. The transaction price consists of the $30.0 million non-refundable upfront fee under the original collaboration agreement. We will re-evaluate the transaction price at each reporting period. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

We used the input method to measure progress toward completion of the performance obligation and concluded that we will recognize revenue based on actual costs incurred by our clinical research organization, or CRO, as a percentage of total budgeted costs as we complete our performance obligation. We will recognize revenue from reimbursements when we have the right to invoice BMS. We recognized $0.9 million and $2.9 million of the transaction price as revenue for the three and six months ended June 30, 2019, respectively. Total revenue recognized for reimbursements for the three and six months ended June 30, 2019 was $1.0 million and $2.4 million, respectively. Through June 30, 2019, we recognized $27.6 million of the transaction price as collaboration revenue under the original collaboration agreement. The remaining transaction price of $2.4 million is recorded as deferred revenue as of June 30, 2019 and will be recognized as revenue under the input method over the estimated performance period.

Under the cabiralizumab collaboration agreement, we identified the following performance obligations: (1) the license grant to BMS and (2) the transfer of licensed know-how to BMS. The transaction price consisted of the $350.0 million non-refundable up-front fee. As the performance obligations were fully satisfied in 2015, the transaction price of $350.0 million was fully recognized as revenue concurrent with the transfer of the license and know-how in prior years. We concluded that the transaction price should not yet include milestone payments that may become due, as they are fully constrained. For the three and six months ended June 30, 2019, no milestone payments were triggered under the cabiralizumab collaboration agreement. We will recognize any consideration related to royalties when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized upon the occurrence of the related sales. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

Zai Lab China License and Collaboration Agreement

In December 2017, we entered into a license and collaboration agreement, or the China collaboration agreement, with Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan.

We identified the following performance obligations: (1) the license grant to Zai Lab together with the transfer of licensed know-how, development drug supply and global development activities, or the license grant, and (2) the development of companion diagnostics. Zai Lab has the option to purchase commercial drug supply from us pursuant to a separate commercial supply agreement to be negotiated in the future. The commercial drug supply will be accounted for as a separate contract when Zai Lab exercises this option. The transaction price of $14.7 million consists of the $8.8 million of expected reimbursement from Zai Lab for global development activities, $4.2 million non-refundable upfront fee and $1.7 million clinical development milestone payment. We estimated the $8.8 million of expected reimbursements from Zai Lab based on the probability-weighted amounts of a range of possible consideration amounts. We have not included the regulatory milestone payments in the transaction price, as all such milestone amounts are fully constrained. For the three and six months ended June 30, 2019, no milestone payments were triggered under the China collaboration agreement. We will recognize any consideration related to royalties when the related sales occur, as we determined that these amounts relate predominantly to the license granted and therefore will be recognized upon the occurrence of the related sales. We concluded that the reimbursement of costs incurred for the development of companion diagnostics qualifies for the practical expedient under Topic 606, which allows us to recognize revenue in the amount for which we have a right to invoice if our right to consideration is an amount that corresponds directly to the value to Zai Lab of our performance completed to date. We therefore effectively bypass the steps of determining the transaction price and allocating that transaction price to the performance obligation. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

We use the input method to measure progress toward completion of the performance obligation for the license. We concluded that revenue will be recognized based on actual costs incurred by our CRO as a percentage of total budgeted costs as we complete our performance obligation. We will recognize revenue from reimbursements for the development of companion diagnostics when we have the right to invoice Zai Lab.

For the three and six months ended June 30, 2019, revenue recognized for the license grant performance obligation was $0.4 million and $0.6 million, respectively. Total revenue recognized for the companion diagnostics development performance obligation was $1.0 million and $1.4 million for the three and six months ended June 30, 2019, respectively. Of the remaining transaction price of $12.4 million, we recorded $5.2 million in deferred revenue, which we will recognize over the estimated performance period for satisfaction of the performance obligations. The remaining $7.2 million of the transaction price will be recorded in deferred revenue when invoiced as we complete global development activities.

GlaxoSmithKline LLC

In April 2012, we entered into a research collaboration and license agreement, or the respiratory diseases collaboration, with Glaxo Group Limited, or GSK, to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease, or COPD, with a particular focus on identifying novel protein therapeutics and antibody targets. In January 2016, we amended our respiratory diseases collaboration to extend the research term by three months to July 2016 to allow additional validation of the protein targets we discovered and to increase the research funding.

Under the respiratory diseases collaboration, we identified one performance obligation for the research license and research activities. The non-refundable upfront fee, the equity premium and the variable consideration for research activities were included as part of the transaction price. As the performance obligation under the respiratory diseases collaboration was fully satisfied in 2016, the transaction price was fully recognized in prior years. The clinical and regulatory development milestone payments have not been included in the transaction price, as all such milestone amounts are fully constrained. For the three and six months ended June 30, 2019, no milestone payments were triggered under the respiratory diseases collaboration. We will recognize any consideration related to sales-based payments (including milestones royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation or the occurrence of the related sales. Under the respiratory diseases collaboration, additional research funding that GSK had the option to add was also not included in the transaction price. We will re-evaluate the transaction price for the respiratory diseases collaboration in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

UCB Fibrosis and CNS Collaboration

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

Under the fibrosis and CNS collaboration, we identified research activities as our only performance obligation. UCB's options to select additional collaboration targets and to license exclusive rights to selected targets are not priced at a discount and therefore do not represent performance obligations for which the transaction price would be allocated. The transaction price of $15.6 million included the $6.0 million non-refundable upfront fee, the $6.6 million technology access fee, the $1.0 million reimbursement for reagent costs and the $2.0 million of research funding. As the performance obligation under the fibrosis and CNS collaboration was fully satisfied in 2018, the transaction price of $15.6 million was fully recognized in 2018. We have not included the clinical and regulatory development milestone payments in the transaction price as all such milestone amounts are fully constrained. For the three and six months ended June 30, 2019, no milestone payments were triggered under the fibrosis and CNS collaboration. We will recognize any consideration related to sales-based payments (including milestones and royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation or the occurrence of the related sales. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and six months ended June 30, 2019, no adjustments were made to the transaction price.

6. **Leases**

We adopted ASU 2016-02, effective January 1, 2019, using the updated modified retrospective transition method, in which the new standard is applied as of the date of initial adoption. We recognized and measured agreements executed prior to the date of initial adoption that were considered leases on January 1, 2019. No cumulative effect adjustment of initially applying the standard to the opening balance of retained earnings was made upon adoption. We elected the package of practical expedients permitted under the transition guidance that will retain the lease classification and initial direct costs for any leases that exist prior to adoption of the standard. We have not reassessed whether any contracts entered into prior to adoption are leases. In addition, we elected the accounting policy of not recording short-term leases with a lease term at the commencement date of twelve months or less on the balance sheet as permitted by the new standard.
When available, we use the rate implicit in the lease to discount lease payments to present value; however, our leases do not provide a readily determinable implicit rate. Therefore, we must estimate our incremental borrowing rate to discount the lease payments based on information available at lease commencement.

We entered into a lease agreement for our corporate office and laboratory facility in December 2016, which we refer to as the facility lease. We moved into our new corporate office and laboratory facility in December 2017. The facility lease has an initial term of 10 years, beginning on the rent commencement date, with an option to extend the lease for an additional period of five years. We did not have to pay rent until the rent commencement date of January 1, 2018, and rent was reduced by 50% for the first six months. The facility lease contains scheduled rent increases over the lease term. We received lease incentives from our landlord for a portion of the costs of leasehold improvements we made to the premises. In addition, the facility lease required us to deliver an irrevocable standby letter of credit in an amount of $1.5 million to the landlord for the period commencing on the effective date of the facility lease until at least 60 days after the expiration of the lease, subject to 50% reduction on January 1, 2023 if certain conditions are met.

In July 2018, we entered into a lease agreement for the installation, operational qualifications and performance qualifications of four sequencing instruments to support our bemarituzumab program, which we refer to as the instruments lease. The instruments lease has two three-year terms based on delivery dates for the first three instruments in July 2018 and the fourth instrument in February 2019. The instruments lease contains consistent rent payments over the term of the lease.

We have evaluated our leases and determined that, effective upon the adoption of ASU 2016-02, they were all operating leases. The classification of our leases is consistent with our determination under the previous accounting standard. The balance sheet classification of our lease assets and liabilities are presented on our balance sheet. We recognize operating lease cost as a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a straight-line basis. Variable lease payments that are not included in the lease liability are recognized on the statement of operations in the period in which the obligation for those payments is incurred. For the three and six months ended June 30, 2019, we recognized operating lease cost of $1.5 million and $3.1 million, respectively, and variable lease cost of $0.5 million and $0.9 million, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $1.8 million and $3.0 million for the three and six months ended June 30, 2019.

The weighted-average discount rate of our operating leases is 7%, and the weighted-average remaining lease term of our operating leases is eight years as of June 30, 2019.

The table below reconciles the undiscounted cash flows for each of the first five years and the total of the remaining years to the operating lease labilities recorded on the balance sheet.

	Operating Leases
Remainder of 2019	$ 3,730
Years ending December 31,	
2020	7,564
2021	7,705
2022	7,793
2023	8,064
2024 and on	35,166
Total minimum lease payments	$ 70,022
Less: amount of lease payments representing interest	(18,590)
Present value of future minimum lease payments	$ 51,432
Less: operating lease obligations, current portion	(3,835)
Operating lease obligations, long-term portion	$ 47,597

7. **Subsequent Event**

The exchange offer commenced on July 1, 2019 and expired on July 29, 2019. See Note 4 for additional information on our exchange offer.

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 financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or this Quarterly Report, and with our audited financial statements and related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission, or the SEC, on February 26, 2019, or our Annual Report.

Overview

We are a clinical-stage biotechnology company focused on discovering and developing innovative protein therapeutics to improve the lives of patients with serious diseases. Each of our product candidates has an innovative mechanism of action and addresses patient populations for which better therapies are needed. Our primary focus is on researching and developing immuno-oncology and targeted cancer therapies. In addition, we use companion diagnostics where appropriate to allow us to select patients most likely to benefit from treatment with our product candidates. The most advanced product candidates that we or our partners are developing are identified below.

- **Bemarituzumab (FPA144)** is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, and that induces antibody-dependent cellular cytotoxicity that we are studying in a clinical trial in combination with 5-fluorouracil (5-FU), leucovorin and oxaliplatin, a standard-of-care chemotherapy regimen known as mFOLFOX6, as front-line treatment of patients with gastric (stomach) or gastroesophageal junction, or GEJ, cancer that overexpresses FGFR2b. In December 2017, we granted Zai Lab (Shanghai) Co., Ltd., or Zai Lab, an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan.
- **FPA150** is an antibody that targets B7-H4 that we are studying in a clinical trial in ovarian, breast and endometrial cancers that overexpress B7-H4.
- **FPT155** is a soluble CD80 fusion protein that enhances co-stimulation of T cells through CD28 that we are studying in a clinical trial in multiple cancers.
- **Cabiralizumab (FPA008)** is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we and our partner Bristol-Myers Squibb Company, or BMS, are studying in clinical trials in pancreatic and other cancers in combination with BMS's PD-1 immune checkpoint inhibitor, *Opdivo*® (nivolumab). In October 2015, we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- **BMS-986258** is an anti-T cell immunoglobulin and mucin domain-3, or TIM-3, antibody that our partner, BMS, is studying in a clinical trial as a single agent and in combination with *Opdivo* in patients with advanced malignant tumors.

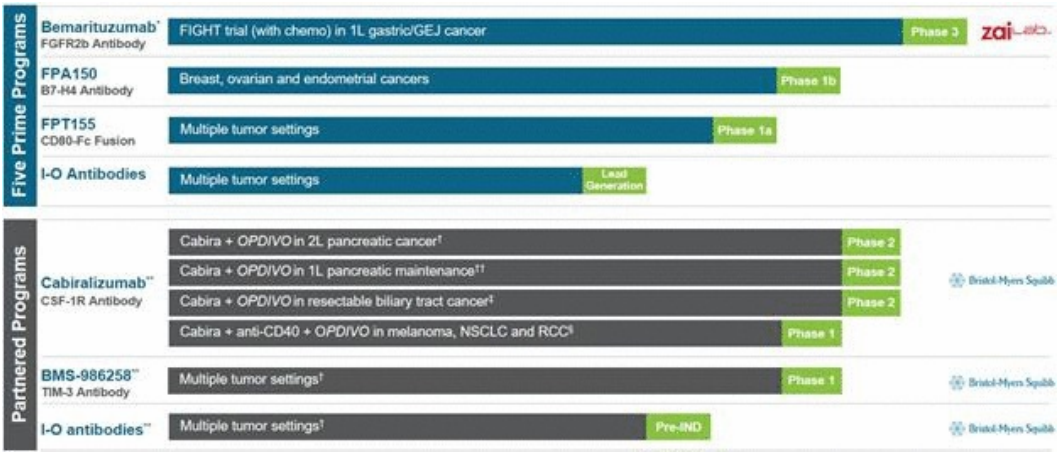
We are focusing our activities on immuno-oncology and targeted cancer therapies, which we believe to have significant therapeutic potential. We leverage our differentiated discovery capabilities and protein therapeutic generation and engineering capabilities to identify and validate targets that we believe could be useful in oncology and generate and preclinically test therapeutic proteins, including antibodies and fusion proteins, directed to or containing the targets we identify and validate. We plan to continue to advance selected therapeutic candidates into clinical development. Our product candidates are typically only-in-class, first-in-class or meaningfully differentiated from other in-class therapeutics. We generally look for single-agent activity or clear activity in, for example, tumor types that are rarely sensitive to checkpoint inhibitors.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. We expect that our expenses will increase as we advance our product candidates into later stages of clinical development and increase the number of product candidates in clinical development. We have incurred losses in each period since inception of operations in 2002, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million up-front payment we received from BMS under 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 a license and collaboration agreement for FP-1039, a product candidate we were developing at the time. For the six months ended June 30, 2019 and 2018, we reported a net loss of $69.8 million and $54.4 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 report which we prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended, or the Exchange Act.

Product Pipeline

The following table shows the stage of development of the most advanced product candidates that we are developing or that have come from our pipeline and are being developed or supported by our collaborators:



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* Partnered with Zai Lab – see "Part I—Item 1. Collaborations" of our Annual Report for a description of our China collaboration agreement with Zai Lab.
** Partnered with BMS – see "Part I—Item 1. Collaborations" of our Annual Report for a description of our collaboration agreements with BMS.
† Clinical development is being conducted exclusively by BMS.
†† Clinical development is being conducted by the University of California, San Diego, the sponsor of the trial, in collaboration with Stand Up To Cancer and BMS.
‡ Clinical development is being conducted by the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, the sponsor of the trial, in collaboration with BMS.
§ Clinical development is being conducted by the Yale Cancer Center, the sponsor of the trial, in collaboration with Apexigen, Inc. and BMS.

Bemarituzumab (FPA144)

We are dosing patients in a global Phase 3 clinical trial of bemarituzumab in combination with mFOLFOX6 as front-line treatment of patients with advanced gastric or GEJ cancer that overexpresses FGFR2b, which we refer to as our FIGHT trial. We are conducting the trial in China in collaboration with Zai Lab.

We are identifying patients for inclusion in the FIGHT trial using both an immunohistochemistry, or IHC, test, which allows us to detect FGFR2b overexpression on the tumor tissue in a biopsy specimen, and a circulating tumor DNA, or ctDNA, blood-based test, which allows us to detect in blood plasma *FGFR2* gene amplification from DNA shed by tumor cells. *FGFR2* gene amplification is a cause of FGFR2b overexpression, and measuring *FGFR2* gene amplification in the blood is an indirect way of identifying tumors that overexpress FGFR2b that we may otherwise not identify using an IHC test. The FIGHT trial is designed to enroll patients that test positive for (a) FGFR2b overexpression, as detected by the IHC test alone, (b) *FGFR2* gene amplification, as detected by the ctDNA test alone, and (c) both FGFR2b overexpression, as detected by the IHC test, and *FGFR2* gene amplification, as detected by the ctDNA test. We believe that patients with tumors that meet the criteria in any of these subgroups may benefit from the addition of bemarituzumab to front-line chemotherapy.

Initially, we expected that approximately 10% of the previously untreated, advanced gastric and GEJ cancer patients that we pre-screened in the FIGHT trial would test positive for FGFR2b overexpression or *FGFR2* gene amplification, as detected by the IHC and ctDNA tests we are using to identify patients eligible for enrollment in the trial. We also expected that the majority of patients that test positive for FGFR2b overexpression by IHC would also test positive for *FGFR2* gene amplification by ctDNA.

As of July 26, 2019, more than 30% of the patients that we have pre-screened for possible enrollment in the FIGHT trial have tested positive for FGFR2b overexpression, as measured by the IHC test alone. This is significantly higher than we expected at the time we started the trial. In addition, contrary to our initial expectations, the vast majority of patients that test positive for FGFR2b overexpression do not test positive for *FGFR2* gene amplification. These results suggest that the FIGHT trial may be enrolling a greater proportion of patients whose tumors overexpress FGFR2b due to a reason other than *FGFR2* gene amplification. We believe all patients being enrolled in the FIGHT trial may benefit from the addition of bemarituzumab to front-line chemotherapy, as bemarituzumab targets FGFR2b that is overexpressed on the cell surface. However, the composition of the patient population in our FIGHT trial differs from the composition of the patient population for which we designed the FIGHT trial. This represents an additional unknown because we have limited clinical data from patients who overexpress FGFR2b in the absence of *FGFR2* gene amplification, and these patients represent a vast majority of the patients we have enrolled. These patients may be less responsive to the combination of bemarituzumab and mFOLFOX6 than the population of patients we originally sought to enroll, which increases the risk that we do not achieve the primary endpoints of the FIGHT trial with statistical significance and increases the risk that the FIGHT trial will not enable registration of bemarituzumab in combination with mFOLFOX6 as front-line treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b.

Accordingly, we plan to conduct an early futility analysis in the first half of 2020 after the occurrence of a pre-specified number of events. The futility analysis will allow us to ensure that the FIGHT trial is adequately powered to detect an overall survival benefit at full enrollment in previously untreated, advanced gastric and GEJ cancer patients whose tumors test positive for FGFR2b overexpression. The outcome of the futility analysis will lead to a recommendation from the independent Data Monitoring Committee in the FIGHT trial to continue the trial as is, stop the trial or amend the trial. Stopping or amending the FIGHT trial as a result of our early futility analysis may further delay our development of bemarituzumab in combination with mFOLFOX6 as a treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b.

We plan to pause enrollment in the FIGHT trial once we have reached approximately 25% of our total planned enrollment. We believe this should be a sufficient number of patients to allow us to conduct the futility analysis as planned. Because the proportion of front-line gastric and GEJ cancer patients who test positive for FGFR2b overexpression is significantly higher than we initially expected, the population of potential patients who may be eligible to enroll in the FIGHT trial is larger than we had anticipated. As a result, the FIGHT trial has been enrolling ahead of our initial projections. Based on the current enrollment rate, we expect to pause enrollment in the fourth quarter of 2019.

FPA150

We are conducting a Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of FPA150 monotherapy as a potential therapy in patients with a variety of cancers. We are dosing patients in the Phase 1b expansion portion of the trial, in which we are evaluating FPA150 monotherapy in HR+/HER2- and triple-negative breast cancers, ovarian cancer and endometrial cancer patients whose tumors overexpress B7-H4.

We are also evaluating FPA150 in combination with *Keytruda*® (pembrolizumab) in this trial. In May 2019, we initiated dosing in a safety lead-in of the combination in patients with advanced ovarian cancer that overexpresses B7-H4 who have not received prior therapy with an anti-PD1 or PD-L1-directed agent. We plan to follow the safety lead-in with a Phase 1b expansion cohort to test this combination in additional patients with advanced ovarian cancer that overexpresses B7-H4 who have not received prior therapy with an anti-PD1 or PD-L1-directed agent.

In June 2019, we presented in a clinical poster at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, or the ASCO presentation, preliminary safety and pharmacokinetic data from 29 patients from the Phase 1a portion of the Phase 1a/1b clinical trial. As of the March 15, 2019 data cut-off date for the ASCO presentation, we had tested FPA150 in patients with advanced solid tumors at doses of up to 20mg/kg given as monotherapy every three weeks, including patients with tumors that overexpress B7-H4. We observed that FPA150 was well tolerated in doses up to 20mg/kg, with no dose-limiting toxicities and no serious adverse events or treatment-related adverse events greater than Grade 4 that were attributable to FPA150. In addition, we believe the observed trough concentration at a dose of 20mg/kg achieves greater than 95% occupancy for both B7-H4 and the FcγRIIIa receptor. Based on the safety and pharmacokinetic data, we selected a dose of 20mg/kg of FPA150 every three weeks for the Phase 1b monotherapy expansion cohorts in our FPA150 trial.

FPT155

We are conducting a Phase 1a/1b clinical trial of FPT155 in patients with solid tumors. We plan to open an exploratory cohort during the Phase 1a dose escalation portion of the trial after we complete a cohort testing a dose that has shown efficacy in preclinical models. In the exploratory cohort, we will investigate FPT155 monotherapy in patients with solid tumors, with the objective of gaining data on safety, pharmacokinetics and potential preliminary single-agent clinical activity of FPT155. In the Phase 1b expansion portion of the trial, we plan to evaluate FPT155 in various disease-specific cohorts of patients.

Cabiralizumab (FPA008)

We are completing a Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining cabiralizumab with *Opdivo* as a potential treatment for a variety of cancers. We have completed enrollment in this trial and continue to treat patients still on study.

BMS is conducting a randomized, controlled multi-arm Phase 2 clinical trial to determine the efficacy of cabiralizumab in combination with *Opdivo*, with and without chemotherapy, as a second-line treatment for patients with pancreatic cancer (NCT03336216). In the trial, BMS will evaluate approximately 160 patients, each of whom has been randomized to one of four study arms based on the patient's prior therapy, across sites in the United States, Canada, Europe, Japan, Korea and Taiwan.

Pursuant to our cabiralizumab collaboration agreement with BMS, we retain the rights to a co-promotion option in the United States, which, if we exercise, will allow us to field a minority percentage of the total United States sales force promotional effort.

BMS-986258

BMS is conducting a Phase 1/2 clinical trial of BMS-986258 as a single agent, in combination with *Opdivo*, and in combination with Halozyme Therapeutics, Inc.'s rHuPH20 in patients with advanced malignant tumors (NCT03446040). In July 2019, the expected size of the trial was increased from 308 to 383 patients.

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 cabiralizumab license and collaboration agreement with BMS and an active collaboration and license agreement with Zai Lab. We completed the research terms of our immuno-oncology research collaboration with BMS in March 2019, our research collaboration in respiratory diseases with GSK in July 2016, and our fibrosis and CNS research collaboration with UCB in March 2016. GSK and UCB have each licensed rights around certain protein targets identified in those discovery collaborations.

Summary Revenue under Collaboration and License Agreements

The following is a comparison of collaboration and license revenue for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2019**	**2018**	**2019**	**2018**
Milestone Payments[1]				
Cabiralizumab Collaboration - BMS	—	—	—	25.0
Fibrosis and CNS Collaboration - UCB	—	—	—	0.3
Other Payments				
China Collaboration - Zai Lab	1.4	1.6	2.0	2.7
Cabiralizumab Collaboration - BMS	1.9	4.4	5.3	8.9
Immuno-oncology Research Collaboration - BMS	—	1.6	1.4	3.2
Total	$ 3.3	$ 7.6	$ 8.7	$ 40.1

[1] Includes milestone payments recognized at a point in time. Other payments may also include milestone payments recognized over time.

We expect that the level of revenue we generate will fluctuate from period to period as a result of the timing and amount of milestone, reimbursable expense and other payments we receive in the course of our existing collaborations and licenses and as a result of the deferred revenue that we recognize, including due to revisions to estimates related to reimbursable activities or to estimates of actual or estimated costs as a percentage of total budgeted costs, or as a result of entry into any new collaborations and license agreements.

Research and Development

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

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

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

The following is a comparison of our research and development expenses for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2019**	**2018**	**2019**	**2018**
Development programs:				
Cabiralizumab	$ 2.4	$ 2.4	$ 5.5	$ 7.9
Bemarituzumab	12.2	11.3	21.6	27.3
FPA150	6.0	3.5	14.1	9.5
FPT155	2.7	—	6.1	0.1
Subtotal development programs	23.3	17.2	47.3	44.8
Preclinical programs	—	6.0	—	12.0
Discovery collaborations	—	0.7	0.5	1.4
Early research and discovery	6.1	9.5	13.4	18.7
Total research and development expenses	$ 29.4	$ 33.4	$ 61.2	$ 76.9

We expect that most of the research and development expenses we incur will continue to relate to activities to support our clinical development programs, preclinical programs and other research efforts. Our research and development expenses may increase as we advance our current product candidates through clinical development and additional product candidates into preclinical and clinical development, and, in particular, as we increase the number and size of our clinical trials and advance our late-stage research programs into preclinical development.

In January 2019, we implemented a corporate restructuring to focus our resources on our clinical development and late-stage research programs. Pursuant to the restructuring, we eliminated 41 employee positions, representing approximately 20% of our then-current headcount, primarily in areas relating to research, pathology and manufacturing. We incurred approximately $1.8 million of pre-tax charges for severance and other costs related to the restructuring during the first quarter of 2019.

The process to obtain marketing approval of a drug candidate, including preclinical and clinical development and the development of manufacturing processes, 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 and clinical results, competition, manufacturing capability and capacity and commercial viability.

The successful development of our drug candidates is highly uncertain and may not result in products that are approved for marketing by the FDA or any comparable foreign regulatory authority. The costs and duration of the processes necessary to achieve marketing approval for each drug candidate can vary significantly and are difficult to predict. Given the uncertainty associated with clinical trial patient enrollment and the risks inherent in the development process, estimating the duration and completion costs of 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 approved drug candidates is difficult and uncertain. 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, preclinical and clinical activities with respect to each drug candidate, as well as ongoing assessments as to each drug candidate's commercial potential. We will need to raise additional capital and may seek to enter into additional collaborations in the future to advance and complete the development and commercialization of our current and future drug candidates.

General and Administrative

General and administrative expenses consist primarily of employee salaries and related benefits, including associated stock-based compensation, related to our executive, finance, legal, business development, human resources and support functions. Other general and administrative expenses include facility costs, consulting costs and professional fees for auditing and tax and legal services, including intellectual property-related legal services.

We do not expect our general and administrative expenses to increase or decrease significantly in the near term. We expect our general and administrative expenses to increase as our research and development activities expand. Also, we expect our intellectual property-related legal expenses, including those related to preparing, filing and prosecuting patent applications and maintaining patents, to increase as our intellectual property portfolio expands.

Interest Income

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

Other (Expense) Income, Net

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

Critical Accounting Policies and Estimates

We based our management's discussion and analysis of financial condition and results of operations upon our unaudited 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 ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results under different assumptions and conditions may differ from these estimates. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited financial statements and in Note 2 of our audited financial statements contained in our Annual Report.

Results of Operations

Comparison for the Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,	
(in millions)	**2019**	**2018**
Collaboration and license revenue	$ 3.3	$ 7.6
Operating expenses:		
Research and development	29.4	33.4
General and administrative	9.7	9.8
Total operating expenses	39.1	43.2
Interest income	1.4	1.5
Loss before income tax	(34.4)	(34.1)
Net loss	$ (34.4)	$ (34.1)

Collaboration and License Revenue

Collaboration and license revenue decreased by $4.3 million, or 57%, to $3.3 million for the three months ended June 30, 2019 from $7.6 million for the three months ended June 30, 2018. This decrease was primarily due to a $3.0 million decrease of revenue recognized for the three months ended June 30, 2019 from progress made towards our performance obligation under our original collaboration agreement with BMS and a $1.6 million decrease as we completed the research terms of our immuno-oncology research collaboration with BMS in March 2019. This decrease was offset by a $0.5 million increase in research and development funding from our original collaboration agreement with BMS as our Phase 1a/1b combination trial of cabiralizumab and nivolumab completed enrollment in 2018.

Research and Development

Our research and development expenses decreased by $4.0 million, or 12%, to $29.4 million for the three months ended June 30, 2019 from $33.4 million for the three months ended June 30, 2018. This decrease was due to a $4.3 million decrease in compensation costs, a $2.1 million decrease in companion diagnostic expense directed towards our bemarituzumab development program, a $1.3 million decrease in manufacturing costs directed towards our FPT155 program, a $1.3 million decrease in costs related to our preclinical programs, a $0.8 million decrease in allocated and other research and development costs and a $0.5 million decrease in expense related to temporary resources. The decreases were offset by a $6.3 million increase in clinical trial expenses primarily to advance our bemarituzumab, FPA150 and FPT155 programs.

General and Administrative

Our general and administrative expenses decreased by $0.1 million, or 1%, to $9.7 million for the three months ended June 30, 2019 from $9.8 million for the three months ended June 30, 2018. This decrease was primarily due to a $0.4 million decrease in expense related to temporary resources, offset by a $0.3 million increase in allocated general and administrative costs due to the corporate restructuring in January 2019.

Income Tax Provision

We did not record an income tax provision as a result of our net operating losses for the three months ended June 30, 2019 and 2018.

Comparison for the Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30,	
(in millions)	**2019**	**2018**
Collaboration and license revenue	$ 8.7	$ 40.1
Operating expenses:		
Research and development	61.2	76.9
General and administrative	20.2	20.3
Total operating expenses	81.4	97.2
Interest income	2.9	2.7
Loss before income tax	(69.8)	(54.5)
Income tax provision	—	—
Net loss	$ (69.8)	$ (54.5)

Collaboration and License Revenue

Collaboration and license revenue decreased by $31.4 million, or 78%, to $8.7 million for the six months ended June 30, 2019 from $40.1 million for the six months ended June 30, 2018. This decrease was primarily due to $25.0 million decrease of revenue recognized for the six months ended June 30, 2018 under our cabiralizumab collaboration agreement with BMS for the achievement of the developmental milestone for the dosing of the first patient in BMS's Phase 2 clinical trial of cabiralizumab in combination with *Opdivo*, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer, a $2.4 million decrease from progress made towards our performance obligation under our original collaboration agreement with BMS, a $1.8 million decrease as we completed the research terms of our immuno-oncology research collaboration with BMS in March 2019, a $1.2 million decrease in research and development funding from our original collaboration agreement with BMS as our Phase 1a/1b combination trial completed enrollment in 2018, a $0.7 million decrease of collaboration and license revenue from our collaboration with Zai Lab and a $0.3 million decrease in target evaluation and selection fees from our fibrosis and CNS collaboration with UCB.

Research and Development

Our research and development expenses decreased by $15.7 million, or 20%, to $61.2 million for the six months ended June 30, 2019 from $76.9 million for the six months ended June 30, 2018. This decrease was due to a $9.4 million decrease in companion diagnostic expense directed towards our bemarituzumab development program, a $6.5 million decrease in compensation costs primarily due to the corporate restructuring in January 2019, a $3.1 million decrease in costs related to our preclinical programs, a $1.2 million decrease primarily due to milestone obligations under our FPA150 program in 2018, a $0.9 million decrease in expense related to temporary resources, a $0.8 million decrease in allocated research and development costs and a $0.5 million decrease in toxicology expense directed towards our FPT155 program. The decreases were offset by a $6.0 million increase in clinical trial expenses primarily to advance our bemarituzumab, FPA150 and FPT155 programs and $0.6 million in other miscellaneous costs.

General and Administrative

Our general and administrative expenses decreased by $0.1 million, or less than 1%, to $20.2 million for the six months ended June 30, 2019 from $20.3 million for the six months ended June 30, 2018. This decrease was primarily due to a $0.9 million decrease in compensation costs, offset by a $0.8 million increase in allocated general and administrative costs due to the corporate restructuring in January 2019.

Income Tax Provision

We did not record an income tax provision as a result of our net operating losses for the six months ended June 30, 2019 and 2018.

Liquidity and Capital Resources

As of June 30, 2019, we had $214.1 million in cash, cash equivalents and marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, agency bonds, corporate bonds and commercial paper with maturities of eleven 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 receiving any such payments is primarily dependent upon the outcome of our collaborators' and licensees' research and development activities and remains uncertain. 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 services and supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and CMOs provides us with flexibility in managing our spending and limits our cost commitments at any point in time.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot predict 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 that we can generate substantial product revenues, if ever, 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, 2019 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, 2019 and 2018:

	Six Months Ended June 30,	
(in millions)	**2019**	**2018**
Net cash used in operating activities	$ (56.3)	$ (39.0)
Net cash provided by (used in) investing activities	50.4	(77.4)
Net cash provided by financing activities	0.3	109.4

Net Cash Used in Operating Activities

Net cash used in operating activities was $56.3 million for the six months ended June 30, 2019 and consisted of net loss of $69.8 million, offset by $13.1 million in net non-cash charges and $0.4 million from changes in operating assets and liabilities. Net non-cash charges included $10.7 million for stock-based compensation expense, $2.7 million of depreciation and amortization expenses and $1.1 million of non-cash operating lease expenses, offset by $1.4 million for amortization of premiums on marketable securities.

Net cash used in operating activities was $39.0 million for the six months ended June 30, 2018 and consisted of net loss of $54.5 million, offset by $17.4 million in net non-cash charges, and $1.9 million from changes in operating assets and liabilities. Net non-cash charges included $2.5 million of depreciation and amortization expenses and $15.3 million for stock-based compensation expense.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $50.4 million for the six months ended June 30, 2019. Net cash provided by investing activities primarily relates to the maturities of marketable securities exceeding the purchase of such marketable securities by $52.1 million. This was offset by payments for the purchases of property and equipment of $1.6 million.

Net cash used in investing activities was $77.4 million for the six months ended June 30, 2018. Net cash used in investing activities primarily relates to the purchase of marketable securities exceeding maturities of such marketable securities by $66.6 million. Payments for the purchases of property and equipment were $10.7 million during the six months ended June 30, 2018.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.3 million for the six months ended June 30, 2019, which consisted primarily of $1.0 million received from employee stock option exercises, offset by $0.7 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards.

Net cash provided by financing activities was $109.4 million for the six months ended June 30, 2018, which consisted primarily of $107.6 million in net proceeds from the public offering of our common stock in January 2018 and $2.9 million received from employee stock option exercises. This was partially offset by $1.1 million paid to satisfy tax withholding obligations from the net share issuance of RSAs.

Contractual Obligations and Contingent Liabilities

During the six months ended June 30, 2019, 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, 2019, we had cash and cash equivalents and marketable securities of $214.1 million, consisting of bank deposits, interest-bearing money market accounts, a U.S. Treasury money market fund, U.S. Treasury securities, agency bonds, corporate bonds and commercial paper. 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 four months and the longest maturity is eight 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 can 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 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 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 Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Changes in internal control over financial reporting. There have been no 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 Business and Industry

If we are unable to advance additional product candidates into clinical development or identify or validate additional drug targets, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

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

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

Before obtaining marketing approval from regulatory authorities to sell our product candidates, we or our partners must conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive and difficult to design and implement, generally takes 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 of their product candidates, notwithstanding promising results in earlier trials. Even though we have already generated results from certain preclinical studies and clinical trials of our product candidates, we do not know whether the clinical trials of our product candidates that we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of these product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials for one or more of our product candidates do not produce favorable results, we or our partners may be unable to obtain regulatory approval for such product candidates.

If the patients we enroll in our FIGHT trial are less responsive to the combination of bemarituzumab and mFOLFOX6 than the population of patients we originally expected to enroll, we may not achieve the primary endpoints of the FIGHT trial with statistical significance and the FIGHT trial may not enable registration of bemarituzumab in combination with mFOLFOX6 as front-line treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b.

We are identifying patients for inclusion in our Phase 3 clinical trial evaluating bemarituzumab in combination with 5-fluorouracil, or 5-FU, leucovorin, and oxaliplatin, a standard of care chemotherapy regimen known as mFOLFOX6, as front-line treatment for patients with gastric or gastroesophageal junction, or GEJ, cancer with tumors that overexpress FGFR2b, or our FIGHT trial, using both an immunohistochemistry, or IHC, test, which allows us to detect FGFR2b overexpression on the tumor tissue in a biopsy specimen, and a circulating tumor DNA, or ctDNA, blood-based test, which allows us to detect in blood plasma *FGFR2* gene amplification from DNA shed by tumor cells. *FGFR2* gene amplification is a cause of FGFR2b overexpression, and measuring *FGFR2* gene amplification in the blood is an indirect way of identifying tumors that overexpress FGFR2b that we may otherwise not identify using an IHC test. The FIGHT trial is designed to enroll patients that test positive for (a) FGFR2b overexpression, as detected by the IHC test alone, (b) *FGFR2* gene amplification, as detected by the ctDNA test alone, and (c) both FGFR2b overexpression, as detected by the IHC test, and *FGFR2* gene amplification, as detected by the ctDNA test. We believe that patients with tumors that meet the criteria in any of these subgroups may benefit from the addition of bemarituzumab to front-line chemotherapy.

Initially, we expected that approximately 10% of the previously untreated, advanced gastric and GEJ cancer patients that we pre-screened in the FIGHT trial would test positive for FGFR2b overexpression or *FGFR2* gene amplification, as detected by the IHC and ctDNA tests we are using to identify patients eligible for enrollment in the trial. We also expected that the majority of patients that test positive for FGFR2b overexpression by IHC would also test positive for *FGFR2* gene amplification by ctDNA.

As of July 26, 2019, more than 30% of the patients that we have pre-screened for possible enrollment in the FIGHT trial have tested positive for FGFR2b overexpression, as measured by the IHC test alone. This is significantly higher than we expected at the time we started the trial. In addition, contrary to our initial expectations, the vast majority of patients that test positive for FGFR2b overexpression do not test positive for *FGFR2* gene amplification. These results suggest that the FIGHT trial may be enrolling a greater proportion of patients whose tumors overexpress FGFR2b due to a reason other than *FGFR2* gene amplification. We believe all patients being enrolled in the FIGHT trial may benefit from the addition of bemarituzumab to front-line chemotherapy, as bemarituzumab targets FGFR2b that is overexpressed on the cell surface. However, the composition of the patient population in our FIGHT trial differs from the composition of the patient population for which we designed the FIGHT trial. This represents an additional unknown because we have limited clinical data from patients who overexpress FGFR2b in the absence of *FGFR2* gene amplification, and these patients represent a vast majority of the patients we have enrolled. These patients may be less responsive to the combination of bemarituzumab and mFOLFOX6 than the population of patients we originally sought to enroll, which increases the risk that we do not achieve the primary endpoints of the FIGHT trial with statistical significance and increases the risk that the FIGHT trial will not enable registration of bemarituzumab in combination with mFOLFOX6 as front-line treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b.

Accordingly, we plan to conduct an early futility analysis in the first half of 2020 after the occurrence of a pre-specified number of events and pause enrollment in the FIGHT trial once we have reached approximately 25% of our total planned enrollment, as we believe this should be a sufficient number of patients to conduct the futility analysis as planned. Based on the current enrollment rate, we expect to pause enrollment in the fourth quarter of 2019. The futility analysis will allow us to ensure that the FIGHT trial is adequately powered to detect an overall survival benefit at full enrollment in previously untreated, advanced gastric and GEJ cancer patients whose tumors test positive for FGFR2b overexpression. The outcome of the futility analysis will lead to a recommendation from the independent Data Monitoring Committee in the FIGHT trial to continue the trial as is, stop the trial or amend the trial. Amending the FIGHT trial as a result of our early futility analysis may increase the costs of conducting the FIGHT trial. Additionally, stopping or amending the FIGHT trial as a result of our early futility analysis may further delay our development of bemarituzumab in combination with mFOLFOX6 as a treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b and may prevent us from obtaining approval for and commercializing bemarituzumab in a timely manner or at all.

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

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

- delays in reaching an agreement with or failure to obtain authorization from the U.S. Food and Drug Administration, or FDA, or other comparable regulatory authorities, and institutional review boards, or IRBs;
- imposition of a clinical hold following an inspection of our manufacturing or clinical trial operations, including clinical trial sites, by the FDA or other comparable regulatory authorities, or a decision by the FDA, other comparable regulatory authorities, IRBs or us, or a recommendation by a data safety monitoring board, to suspend or terminate a clinical trial at any time for safety or other reasons;
- delays in reaching, or the inability to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical trial sites, laboratory service providers, companion diagnostic development partners, contract manufacturing organizations, or CMOs, and other service providers we may engage to support the conduct of our clinical trials or eventual commercialization of our products;
- deviations from the clinical trial protocol by clinical trial sites or investigators or failure to conduct a clinical trial in accordance with regulatory requirements;
- failure of third parties, such as CROs or other service providers, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation and manufacturing of product candidates and the delivery of these product candidates to clinical trial sites;
- in the case of clinical trials testing combination treatment of our product candidates with third-party drug products, delays in procuring such third-party drug products and the delivery of such third-party drug products to clinical trial sites, or the inability to procure such third-party drug products at all;
- for clinical trials in selected patient populations, delays in identifying and auditing central or other laboratories that develop or use assays to identify eligible patients for our clinical trials, delays in the validation of such assays or their transfer to such laboratories, or the failure of the clinical trial, as designed, to enroll the patient population necessary to meet the primary endpoints of such clinical trial;
- with respect to patients in any of our clinical trials, delays in completing their participation in any such clinical trial or returning for post-treatment follow-up;
- the occurrence of side effects, disease progression or other events requiring patients to drop out of one or more of our clinical trials before completion;
- withdrawal of one or more clinical trial sites from our clinical trials, including as a result of any investigator ceasing his or her affiliation with any such site, changes to any applicable standard of care or the ineligibility of any such site to participate in our clinical trials;
- administrative actions or changes in government policies, laws or regulations affecting any aspect of the conduct of our clinical trials; or
- lack of adequate funding to continue our clinical trials.

For example, for the reasons described in the foregoing risk factor in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, we plan to conduct an early futility analysis for our FIGHT trial in the first half of 2020 and pause enrollment in the FIGHT trial once we have reached approximately 25% of our total planned enrollment, as we believe this should be a sufficient number of patients to conduct the futility analysis as planned. Based on the current enrollment rate, we expect to pause enrollment in the fourth quarter of 2019. The outcome of the futility analysis will lead to a recommendation from the independent Data Monitoring Committee in the FIGHT trial to continue the trial as is, stop the trial or amend the trial. Amending the FIGHT trial as a result of our early futility analysis may increase the costs of conducting the FIGHT trial. Additionally, stopping or amending the FIGHT trial as a result of our early futility analysis may further delay our development of bemarituzumab in combination with mFOLFOX6 as a treatment for patients with advanced gastric or GEJ cancer that overexpresses FGFR2b and may prevent us from obtaining approval for and commercializing bemarituzumab in a timely manner or at all.

Moreover, we are conducting the FIGHT trial in China in collaboration with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Zai Lab's ability to conduct the FIGHT trial in China depends on Zai Lab's and our ability to comply with the government policies, laws and regulations applicable to conducting clinical trials in China. The government policies, laws and regulations in China are evolving rapidly and changes to these policies, laws and regulations are difficult to predict. If any such government policies, laws or regulations in China evolve in a way that makes it more difficult or inefficient for us or Zai Lab to conduct our FIGHT trial in China, we may experience delays in initiating or conducting our FIGHT trial at clinical trial sites in China, which would delay our ability to obtain approval for and commercialize bemarituzumab.

In addition, in order to successfully initiate and conduct the FIGHT trial in each country where the trial is taking place, we must obtain sufficient clinical supply of each component of mFOLFOX6 to administer the mFOLFOX6 regimen to patients in each such country. If we have difficulty obtaining or are unable to obtain sufficient supply of any component of the mFOLFOX6 regimen in any country, we may experience delays in initiating or conducting our FIGHT trial at clinical trial sites in such country, which would delay our ability to obtain approval for and commercialize bemarituzumab.

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

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

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

- the size and nature of the patient population;
- the number and location of clinical trial sites;
- competition with other companies for clinical trial sites or patients;
- the eligibility and exclusion criteria for the clinical trial;
- for clinical trials in selected populations, the ability and time required to properly identify for inclusion in the clinical trial the population of patients we seek to enroll;
- the design of the clinical trial;
- the ability to obtain and maintain patient consents;
- the risk that enrolled patients will drop out before completion of the trial; and
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We currently face and will continue to face significant competition in recruiting patients for our and our partners' current and future clinical trials, 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 our current or future product candidates, which may force us to terminate our development efforts for one or more programs.

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

- our research methodology, including our screening technology, may not successfully identify medically relevant protein therapeutic targets or potential product candidates;
- our discovery platform often identifies novel, untested targets that may be challenging to validate because of the novelty of the target or that we may be unable to validate at all after further research;
- product manufacturing difficulties may limit product yield or produce undesirable product characteristics that may increase our costs, cause delays or make our product candidates unmarketable;
- third parties on whom we may rely to generate antibody or other product candidates may fail to produce candidates that we can successfully validate or that have the characteristics necessary to become marketable product candidates;
- we may design one or more of our clinical trials in a way that makes it difficult or impossible to meet the primary endpoints of such trial, which could make further clinical development of the applicable product candidate infeasible, even if that product candidate proves to be efficacious;
- our product candidates may cause adverse effects in patients, even after successful initial toxicology studies or early-stage clinical trials, which may make our product candidates unsuitable for approval or otherwise unmarketable;
- our product candidates may have unacceptable safety profiles or otherwise fail to provide a meaningful benefit to patients; or
- our collaboration partners may change their development profiles or plans for our partnered product candidates or abandon a therapeutic area for or the development of a partnered product candidate.

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

We and our product candidates are subject to a multitude of manufacturing risks, the occurrence of any of which could substantially increase our costs and limit supply of such product candidates.

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

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

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

We have process development and small-scale preclinical manufacturing capabilities. We do not have and we do not have current plans to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. In the past we have engaged, and we expect in the future to engage, CMOs for the manufacture of bulk drug substance and drug product for our clinical trials and additional third parties for our supply chain. In addition, Bristol-Myers Squibb Company, or BMS, has the exclusive right to manufacture cabiralizumab under our cabiralizumab collaboration agreement. Under this agreement, BMS will supply us with cabiralizumab, in exchange for a service fee, for our conduct of independent development activities with respect to cabiralizumab.

We have not contracted with alternate suppliers in the event that our current CMOs or other third parties on whom we rely to provide us with drug product, such as BMS, are unable to scale production or if we otherwise experience any problems with these CMOs or such other third parties. Any problems we experience with our current CMOs or these third parties could delay the manufacturing of our product candidates or the progress of our clinical trials, which could harm our results of operations. In addition, if we are unable to arrange for alternative third-party manufacturing sources, or are unable to do so on commercially reasonable terms or in a timely manner, the development of our product candidates may be delayed.

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

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

The FDA and comparable foreign regulatory authorities extensively and rigorously regulate and evaluate the manufacture, testing, distribution, advertising and marketing of drug products prior to granting marketing approvals with respect to such products. This approval process generally requires, at minimum, testing of any product candidate in preclinical studies and clinical trials to establish its safety and effectiveness, and confirmation by the FDA and comparable foreign regulatory authorities that any such product candidate, and any parties involved in its manufacturing, testing and development, complied with current Good Manufacturing Practices, or GMP, current Good Laboratory Practices, or GLP, and current Good Clinical Practices, or GCP, regulations, standards and guidelines during such manufacturing, testing and development. The time required to obtain approval to market a product candidate from the FDA or any comparable foreign regulatory authority is unpredictable but typically takes many years following the commencement of clinical trials and depends on numerous factors, including the conduct of manufacturing, testing and development activities with respect to such product candidate and the substantial discretion of the applicable regulatory authorities. In addition, approval policies, regulations, or the type or amount of clinical data necessary to obtain approval may change over the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any of our product candidates and it is possible that none of our existing product candidates or potential future product candidates will ever obtain regulatory approval.

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

- the FDA's or such comparable foreign regulatory authority's disagreement with the design or implementation of our clinical trials testing any such product candidate;
- our failure to demonstrate that a product candidate is effective for its proposed indication and has an acceptable safety profile;
- our failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the failure of our clinical trial data for a product candidate to meet the level of statistical significance required for regulatory approval;
- the FDA's or such comparable foreign regulatory authority's disagreement with our interpretation of data from preclinical studies or clinical trials testing a product candidate;
- the insufficiency of our clinical trial data for a product candidate to support the submission and filing of a Biologic License Application or other regulatory submission or to obtain regulatory approval for such product candidate;
- our failure to obtain approval from the FDA or such comparable foreign regulatory authority for the manufacturing or testing processes or facilities of CMOs or CROs with whom we contract for clinical and commercial product supply or preclinical or clinical testing; or
- changes in the applicable standard of care or the FDA's or such comparable foreign regulatory authority's approval policies or regulations that render our preclinical and clinical data for a product candidate insufficient for regulatory approval.

The FDA or a comparable foreign regulatory authority may require additional information, including preclinical or clinical data, to support approval of a product candidate, which may delay or prevent approval and our commercialization plans, or result in our decision to abandon the development program with respect to such product candidate. For example, given the greater potential patient population in Asia, we expect that a substantial number of the patients in our Phase 3 FIGHT trial will come from clinical trial sites in Asia. However, we are currently unable to provide regulatory authorities with data that demonstrate that patients participating in the FIGHT trial at clinical trial sites in Asia are representative of the general patient population and will respond to bemarituzumab in the same way as other patient populations. If we obtain a significant portion of any positive clinical data from clinical trial sites in Asia as compared to data from clinical trial sites located elsewhere in the world, and an analysis of the data from Asian patients suggest that other patient populations may not have similar outcomes, the FDA and comparable foreign regulatory authorities may determine that the positive data we observe in Asian patients are not sufficient to support regulatory approval for bemarituzumab for the general patient population and may require more clinical data from other patient populations to support regulatory approval for bemarituzumab. This could prevent us from obtaining approval for and commercializing bemarituzumab on a timely basis or at all.

In addition, if we were to obtain approval for any of our product candidates, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or establishment of risk evaluation and mitigation strategy, or REMS, drug safety programs, 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 that could delay or prevent their regulatory approval, limit their commercial profiles, if approved, or result in significant negative consequences following any marketing approval.

Our product candidates may cause undesirable side effects in patients, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority or otherwise limit the commercial potential of any such product candidate. Our clinical trial results could reveal an unacceptable severity or prevalence of side effects. If this were to occur, we may elect to suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease our clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could negatively affect patient recruitment, cause enrolled patients to drop out of a clinical trial and result in product liability claims. Any of these occurrences may significantly harm our business, financial condition and prospects.

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, numerous potentially significant negative consequences could result, including:

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

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

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

Certain of our current product candidates, including bemarituzumab and FPA150, may be effective only in selected patient populations. For any such product candidate, we expect that the FDA and comparable foreign regulatory authorities may require the development and regulatory approval of at least one companion diagnostic as a condition to approving such product candidate for use in patients within the selected patient population. We do not have experience in or capabilities for developing or commercializing companion diagnostics and have depended and will continue to depend on the sustained cooperation and effort of our third-party diagnostic development collaborators to perform these functions.

For example, we are developing bemarituzumab to treat a subset of patients with front-line gastric or GEJ cancer whose tumors overexpress FGFR2b. We have developed, in collaboration with third-party diagnostic development partners, both an IHC-based assay and a ctDNA blood-based assay to identify gastric and GEJ cancer patients with FGFR2 overexpression or *FGFR2* gene amplification who may benefit from treatment with bemarituzumab in combination with mFOLFOX6. In addition, we are developing FPA150 to treat patients with tumors that overexpress B7-H4. We have developed, in collaboration with a third-party diagnostic development partner, an IHC-based assay that we are using in our Phase 1a/1b clinical trial of FPA150 to identify patients with B7-H4 overexpression.

For example, we expected that approximately 10% of the previously untreated, advanced gastric and GEJ cancer patients that we pre-screened for the FIGHT trial would test positive for FGFR2b overexpression or *FGFR2* gene amplification, as detected by the IHC and ctDNA tests we are using to identify patients eligible for enrollment in the trial. We also expected that the majority of patients that test positive for FGFR2b overexpression by IHC would also test positive for *FGFR2* gene amplification by ctDNA. As of July 26, 2019, more than 30% of the patients that we have pre-screened for possible enrollment in the FIGHT trial have tested positive for FGFR2b overexpression, as measured by the IHC test alone. This is significantly higher than we expected at the time we started the trial. In addition, contrary to our initial expectations, the vast majority of patients that test positive for FGFR2b overexpression do not test positive for *FGFR2* gene amplification. We believe, based on evaluations to date, that our IHC and ctDNA tests are performing properly and that the higher rate of FGFR2b overexpression without *FGFR2* gene amplification is not due to the performance, sensitivity or specificity of our IHC and ctDNA tests. If, however, upon further evaluation we determine that either or both of our IHC or ctDNA tests are not performing properly or otherwise do not select the patient population we originally expected to enroll, we and our partners may be required to redesign such companion diagnostics or may experience delays in obtaining or may fail to obtain regulatory approval for such companion diagnostics, which could delay their development and harm our business.

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. For any companion diagnostic that we develop for use with one of our product candidates, we or our collaboration partners may experience delays in obtaining or may fail to obtain regulatory approval for such companion diagnostic, which could delay its development and harm our business. If we or our collaboration partners are unable to obtain necessary regulatory approvals for our companion diagnostics, including those for bemarituzumab or FPA150, or experience delays in doing so, we may suffer significant negative consequences, including:

- the applicable product candidate may not receive marketing approval if its safe and effective use depends on use of a companion diagnostic; or
- we may not realize the full commercial potential of the applicable product candidate if, among other reasons, we are unable to appropriately identify patients that are likely to respond to treatment with such product candidate.

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

Even if our product candidates receive regulatory approval, they may face future development and regulatory difficulties, which may prevent us from commercializing our products and generating revenue.

Even if we obtain regulatory approval for a product candidate in a particular jurisdiction, the product would be subject to ongoing requirements by the FDA or applicable comparable foreign regulatory authorities governing such product's 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 after approval. If the FDA or any comparable foreign regulatory authority becomes aware of new safety information after approval of any of our product candidates, it may require labeling changes or establishment of a REMS or similar program, impose significant restrictions on the product's indicated uses or marketing, or impose ongoing requirements for costly post-approval studies or post-market surveillance.

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

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

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

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

In the United States, engaging in the impermissible promotion of products for off-label uses can also subject a company to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which such company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims or that such company caused another entity or individual to present such false or fraudulent claims for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will receive a portion of any fines or settlement funds. Since 2004, False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements involving fines exceeding $1.0 billion based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend against false claims actions, 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 any of our products that may receive marketing approval, we may become subject to such litigation and our inability to successfully defend the company in such litigation may material adversely affect our business, financial condition and results of operations.

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

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

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

We are conducting certain of our clinical trials in countries outside of the United States and will need to obtain marketing approval for our product candidates in each such country before we can sell our products there. For example, we are conducting our FIGHT trial for bemarituzumab in China in collaboration with Zai Lab and are relying on Zai Lab's ability to obtain approval for bemarituzumab in China, Taiwan, Hong Kong and Macau, or collectively, Greater China, from the China Food and Drug Administration. However, Zai Lab's ability to obtain approval in Greater China depends on Zai Lab's and our ability to comply with the government policies, laws and regulations applicable to conducting clinical trials and obtaining approval for and commercializing drug products in Greater China. The government policies, laws and regulations in China are evolving rapidly and future changes are difficult to predict. If any such government policies, laws or regulations evolve in a way that make it more difficult or inefficient for Zai Lab or us to clinically develop, obtain approval for or commercialize bemarituzumab in China, the conduct of our FIGHT trial may be delayed, which will delay our ability to obtain approval for and commercialize bemarituzumab.

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

We face substantial competition from third parties that may discover, develop or commercialize products before or more successfully than we do.

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

Our competitors may obtain regulatory approval for their products more rapidly than we do 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 accepted or less costly or have better safety profiles than our product candidates and may also be more successful in manufacturing and marketing their products than we are with respect to our product candidates.

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

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

If cabiralizumab were approved for the treatment of cancer, it could face competition from products currently in development as single agents or in combination with anti-PD-1/PD-L1 agents or other immuno-oncology agents, including Syndax Pharmaceuticals Inc.'s SNDX-6352 anti-CSF1R monoclonal antibody, Pfizer Inc.'s, or Pfizer's, PD-0360324 CSF1 monoclonal antibody, Novartis Pharmaceuticals Corporation's BLZ945 CSF1R-directed small molecule and lacnotuzumab (MCS110) CSF1 monoclonal antibody, Daiichi Sankyo Company, Limited's pexidartinib (PLX3397), PLX73086 and PLX7486 small molecule tyrosine kinase inhibitors, or TKIs, Array Biopharma Inc.'s ARRY-382 CSF1R small molecule TKI or Deciphera Pharmaceuticals LLC's DCC-3014 CSF1R small molecule TKI, each of which acts in the same pathway as cabiralizumab.

If bemarituzumab were approved for the treatment of previously untreated, advanced gastric or GEJ cancer, it could face competition from currently-approved and marketed products, including 5-fluorouracil, S-1, capecitabine, doxorubicin, cisplatin, oxaliplatin, carboplatin, paclitaxel, irinotecan, and docetaxel, as well as antibodies that bind to PD-1/PD-L1, including BMS/Ono Pharmaceutical Co., Ltd.'s, or Ono's, *Opdivo* monotherapy and *Opdivo* in combination with BMS/Ono's *Yervoy*® (ipilimumab) anti-CTLA-4 antibody, Merck & Co., Inc.'s *Keytruda*® (pembrolizumab), Merck KGaA/Pfizer's *Bavencio*® (avelumab), AstraZeneca UK Limited/MedImmune, LLC's *Imfinzi*® (durvalumab) anti-PD-L1 antibody, BeiGene Ltd.'s tislelizumab, Innovent Biologics Inc.'s *Tyvyt*® (sintilimab), Incyte Corporation, or Incyte/Zai Lab's INCMGA0012, Incyte/Jiangsu Hengrui Medicine Co., Ltd.'s SHR-1210, Fudan University Shanghai Cancer Center's apatinib, Astellas's zolbetuximab and AstraZeneca UK Limited/MedImmune, LLC's tremelimumab anti-CTLA4 antibody.

If FPA150 were approved for the treatment of various cancers, it could face competition from currently-approved and marketed products, including cisplatin, carboplatin, gemcitabine, doxorubicin, paclitaxel, topotecan, Genentech, Inc.'s, or Genentech's, *Avastin*® (bevacizumab), Celgene Corporation's *Abraxane*® (paclitaxel protein-bound), Genentech's *Xeloda*® (capecitabine), Sagent Pharmaceuticals, Inc.'s *Navelbine*® (vinorelbine), and Eisai Inc.'s *Halaven*® (eribulin mesylate); antibodies that bind to PD-1/PD-L1, including *Opdivo* monotherapy and *Opdivo* in combination with *Yervoy* (ipilimumab), *Keytruda* (pembrolizumab), *Bavencio* (avelumab), Genentech's *Tecentriq*® (atezolizumab), *Imfinzi* (durvalumab), and tremelimumab; Immunomedics, Inc.'s sacituzumab govitecan (IMMU-132) anti-Trop-2-SN-38 ADC; small molecule poly ADP-ribose polymerase inhibitors, including AstraZeneca UK Limited's *Lynparza*® (olaparib), GlaxoSmithKline plc/Tesaro, Inc.'s *Zejula*® (niraparib), Clovis Oncology, Inc.'s *Rubraca*® (rucaparib), Pfizer's talazoparib and AbbVie Inc.'s veliparib; and other product candidates that are in or may enter clinical development, such as ImmunoGen, Inc.'s mirvetuximab soravtansine (IMGN853) ADC that targets folate receptor alpha.

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

Our product candidates may not achieve the level of 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 the level of market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success. Commercial success of our product candidates also depends on coverage of and adequate reimbursement for these product candidates by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be available or otherwise obtained in all jurisdictions in which we may seek to market our approved product candidates. The degree of market acceptance of any of our approved product candidates will depend on numerous factors, including:

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

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

The regulations that govern marketing approvals, pricing, coverage 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, even if we obtain marketing approval for a product in a particular country, we may be subject to price regulations that delay the commercial launch of such product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of such product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

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

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 any comparable foreign regulatory authority. Moreover, eligibility for coverage and reimbursement does not guarantee that a drug will be paid for in all cases or at a rate that covers our costs, including with respect to 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 provided on a temporary basis. Reimbursement rates may vary depending on the approved uses for the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any of our approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Enacted and future legislation may increase the difficulty and cost of commercialization of our product candidates and affect the prices we may charge for such product candidates.

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

In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The federal Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that became effective on January 1, 2019 and repealed the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which payment is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the individual mandate was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2027 unless Congress takes additional action. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed and enacted federal legislation designed to, among other things, increase transparency in drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contains additional drug price control measures that could be enacted during the budget process or in other future legislation including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost. The Trump administration also released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. On January 31, 2019, the U.S. Department of Health and Human Services Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, both Congress and the Trump administration have indicated that they will continue to seek new legislative, administrative and executive measures, including the President's issuance of future executive orders, as applicable, to control drug costs. At the state level, state governments are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologics product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage product importation from other countries and bulk purchasing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative, administrative or executive action. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, which could materially 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 or maintain profitability or commercialize our products.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The Right to Try Act, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing testing to seek FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients under the Right to Try Act.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by patients, including those enrolled in our clinical trials, healthcare providers or others that use, administer or sell 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, product liability claims may result in:

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

We currently hold $10.0 million in clinical trial liability insurance coverage, which may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates, but we may be unable to obtain product liability insurance on commercially reasonable terms for any of our products that have been approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, 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 any of our products that have received marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- The federal false claims laws, including the civil federal False Claims Act (which can be enforced by private citizens through whistleblower or *qui tam* actions), impose civil and criminal penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing any money or other assets of a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare fraud offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their implementing regulations, also impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- The federal Open Payments program requires manufacturers of drugs, devices, biologics or medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS 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 such physicians and their immediate family members; and
- Analogous state and foreign laws and regulations impose similar restrictions to those described above, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to report information on the pricing of certain drugs, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, including the European Union, or EU, General Data Protection Regulation, or GDPR, which imposes privacy and security obligations on any entity that collects or processes health data from individuals located in the EU and became enforceable on May 25, 2018. As well as complicating our compliance efforts, these laws could subject us to penalties or significant legal liability in the event that we fail or are unable to comply. For example, significant non-compliance with the GDPR may result in the imposition of fines of up to 20 million euros or up to four percent of the annual global turnover of the responsible entity, whichever is greater.

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

We must attract and retain highly skilled employees to succeed.

To succeed, we must recruit, develop, retain, manage and motivate qualified clinical, scientific, technical, general and administrative and management personnel while facing significant competition for experienced personnel. In January 2019, we announced our implementation of a corporate restructuring, or the restructuring, to focus our resources on our clinical development and late-stage research programs. In connection with the restructuring, we eliminated 41 employee positions, representing approximately 20% of our then-current headcount. The restructuring could harm our ability to attract and retain qualified personnel. The restructuring could also result in reduced morale and productivity among our remaining personnel. Our inability or failure to successfully attract and retain qualified personnel, particularly at the management level, 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 if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

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

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

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

Our business operations depend significantly on information technology systems, and a cyber-attack or other significant disruption or breach of our information technology systems, or those of third parties on whom we may rely or with whom we share confidential information, could cause us significant financial, legal, regulatory, business and reputational harm.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information belonging to us and to third parties. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We also outsource elements of our operations, including elements of our information technology infrastructure, to third-party vendors, and as a result, these vendors may have access to our computer networks or our confidential information. In addition, many of those vendors subcontract or outsource to other third parties some of their responsibilities under our agreements with such vendors. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the nature of the sensitive information stored on these systems, make such systems particularly vulnerable to internal and external attacks, both unintentional and malicious. Potential vulnerabilities can be exploited through inadvertent or intentional actions of our employees, third-party vendors, and business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity and are being conducted by sophisticated and organized groups and individuals, including organized criminal groups, "hacktivists," nation-states and others, with a wide range of motives, including industrial espionage, and expertise. In addition to the extraction of sensitive information, such attacks could involve the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of such information. In addition, the prevalent use of mobile devices increases the risk of the occurrence of data security incidents.

Data security incidents or other significant disruptions affecting our, our vendors' or our business partners' information technology systems could adversely affect our business operations and result in loss or misappropriation of, or unauthorized access to, use or disclosure of, or the prevention of access to, sensitive information, which could cause us financial, legal, regulatory, business and reputational harm. In addition, disruptions to our information technology systems could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce such data.

There is no way to know with certainty whether we have experienced any data security incidents that we have not yet discovered. While we have no reason to believe this to be the case, attackers have become sophisticated with respect to concealing their access to systems, and many companies whose information security systems have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including personal information of our employees or patients or investigators in our clinical trials, could disrupt our business, harm our reputation, compel us to comply with applicable federal, state or foreign breach notification laws, subject us to time-consuming, distracting and expensive litigation, regulatory investigations and oversight or mandatory corrective action, require us to verify the correctness of certain stored information, or otherwise subject us to liability under applicable laws, regulations and our contracts with third parties, including those that require us to protect the privacy and security of personal information. This could cause us to incur significant costs and expose us to significant legal and financial liability and reputational harm. In addition, if there is any failure or perceived failure by us or our vendors or business partners to comply with our or their privacy, confidentiality or data security-related legal or other obligations to third parties, or if there are any security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, we may be the subject of governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, third parties, including clinical trial sites, regulators or current and potential business partners, may lose trust in us, and we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other unauthorized access can be difficult to detect, and any delay in identifying such incidents or unauthorized access may lead to increased harm of the types described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures have prevented or will prevent service interruptions or security incidents.

Our employees, consultants, collaborators and other third parties may engage in misconduct or other improper activities, including insider trading and activities that violate regulatory standards and requirements.

Our employees, consultants, collaborators and other third parties with whom we interact may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct that violates United States and international laws and regulations, including laws requiring the true, complete and accurate reporting of financial and other information or data, drug manufacturing standards and healthcare fraud and abuse laws and regulations. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceutical products, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Such laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to detect, identify and deter misconduct by our employees or third parties, and the precautions we take to detect and prevent this activity may not be effective to control risks or losses or protect us from governmental investigations or other actions or lawsuits stemming from an actual or perceived failure to comply with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, such actions could result in the imposition of significant monetary fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, this could cause us to incur substantial costs, including legal fees, and divert the attention of management in our defending against any such actions or responding to related investigations.

Risks Related to Our Dependence on Third Parties

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

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

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

In addition, we could be adversely affected by:

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

The occurrence of any of the foregoing could adversely impact the likelihood and timing of any milestone payments we are eligible to receive under our collaboration agreements with BMS and Zai Lab, could have a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline. In addition, reimbursement for our research and development expenses and other payments we may receive from BMS or Zai Lab may fluctuate from period to period, which may adversely affect our stock price.

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

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 product development collaborations, including collaborations with major biotechnology or pharmaceutical companies. We face significant competition in seeking appropriate partners for additional product development collaborations 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 arrangement for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, development of our product candidates and programs may be deemed to be too early in development for collaborative efforts or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or otherwise become marketable products if approved. 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 the applicable product candidate is delayed or sales of such product candidate, once approved, are disappointing. Any delay in entering into new development collaboration agreements related to our product candidates could delay the development and commercialization of such 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:

- 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;
- if we are unable to secure additional financing, the development of certain of our current or future product candidates may be delayed or terminated;
- we may be required to hire additional employees for which we have not budgeted, or otherwise develop expertise in areas in which we may have limited experience, such as sales and marketing; and
- we will bear all the risk related to the development of any such product candidates.

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

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

We and our CROs are required to comply with GCP, which are regulations, standards 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 product candidates in clinical development. Regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot ensure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials are being conducted in accordance with GCP requirements. In addition, we must conduct our clinical trials using drug product produced and developed in accordance with GMP and GLP requirements. Our failure, or the failure of our clinical trial sites or CROs or CMOs, to comply with applicable GCP, GMP and GLP may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Our CROs and their representatives that perform services for us are not our employees. Except for remedies available to us in connection with our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or 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. In such a case, 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 or significantly limited.

Risks Related to Intellectual Property

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

Our success depends in significant part on our ability and the ability of our licensors and collaborators to obtain, maintain and defend patents and other intellectual property rights and to operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed patent and other intellectual property rights to and from our partners and other third parties. Pursuant to some of these licenses, we have the right to prepare, file and prosecute patent applications and maintain and enforce the patents that are the subject of these licenses, whereas our partners or other third parties have such rights under other licenses.

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

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

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

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

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

Filing, prosecuting, enforcing and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States may be less extensive than those in the United States. Moreover, the requirements for patentability in certain foreign countries, particularly developing countries, differ materially from those of the United States and such requirements also vary among foreign countries. For example, compared to the United States, China's patentability requirements are more stringent and may limit the scope of a patent's claims solely to the specific examples described in the patent. Therefore, it may be more difficult to obtain patent protection in certain countries relative to others.

The laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors or collaborators may not be able to prevent third parties from using our and our licensors' or collaborators' inventions in certain countries outside the United States. In jurisdictions where we have not obtained patent protection, competitors may use our and our licensors' or collaborators' technologies to develop their own products. Competitors may also export infringing products to territories where we and our licensors or collaborators have patent protection but enforcement is not as strong or effective as 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 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 in certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business and could provoke third parties to assert counterclaims against us or our licensors or collaborators, which could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate and, even if we or our licensors or collaborators prevail, the damages or other remedies awarded, if any, may not be commercially meaningful, particularly in light of any expenses incurred in connection with the initiation and conduct of such lawsuits.

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

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

The ability of a party to obtain and enforce patents in the biopharmaceutical industry is inherently uncertain, due in part to ongoing changes to applicable patent laws. Depending on decisions by Congress, the federal courts, and the U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents.

For example, several of the Supreme Court's rulings in patent cases in recent years have either narrowed the scope of patent protection available under certain circumstances or weakened the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value that any of our patents may have once they have issued. Additionally, significant changes to the patent laws under the Leahy-Smith America Invents Act of 2011, or the Leahy-Smith Act, have affected how patent applications are prosecuted and challenged in the U.S. Those changes include implementation of a "first-to-file" system, effective in 2013, for determining entitlement to inventions claimed by more than one party, as well as creation of new administrative proceedings for challenging issued patents. As such, there is increased uncertainty with respect to both outcome and costs associated with the prosecution of patent applications and the enforcement or defense of issued patents controlled by us or our licensors or collaborators, which could have a material adverse effect on our business and financial condition.

Obtaining and maintaining patent protection requires compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

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

We may need to protect or enforce our intellectual property through litigation or other proceedings, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

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

Derivation or interference proceedings in the United States or similar proceedings in other jurisdictions may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome in these proceedings could require us or our licensors or collaborators to cease using the technology covered by the applicable patents or patent applications and commercializing our product candidates or to attempt to license rights to such technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license or offers a license on terms that are not commercially reasonable or are otherwise unfavorable to us. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, allowing our competitors to gain 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, potential collaborators may be dissuaded from partnering with us with respect to the development or commercialization of our affected current or future product candidates. Even if we prevail in such a proceeding, such a proceeding may cause us to incur substantial costs and distract our management and other employees from our business and operations.

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

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

Our commercial success depends upon our ability, and the ability of our licensors and collaborators, to discover and validate protein therapeutic targets and to identify, test, develop, manufacture, market and sell product candidates without infringing the proprietary rights of third parties. Third parties currently, and may in the future, hold intellectual property rights, including patent rights, that are important or necessary for the development or commercialization of our product candidates. As a result, we are a party to a number of licenses that are important to our business and expect to enter into additional licenses in the future. For example, we have entered into non-exclusive licenses with third parties, including BioWa, Inc. and Lonza Sales AG, to use their proprietary protein expression and cell line technologies, which are necessary to produce our product candidates, 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 license 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 candidate that, or the development or manufacturing of which, is covered by the rights licensed under these agreements and may face other contractual penalties. Such an occurrence could materially adversely affect the value of any product candidate being developed using technology licensed under any such agreement. Termination of, or reduction or elimination of our rights under, these agreements may require us to negotiate new or reinstated agreements, which may not be available to us on equally favorable or otherwise commercially reasonable terms, or at all, or cause us to lose our rights we had under the original 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 any of these proceedings 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 the intellectual property rights controlled by these third parties, 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 these third parties, including in oppositions, interferences, reexaminations, *inter partes* reviews, post-grant reviews or derivation proceedings in the United States or comparable proceedings in 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 in any of these proceedings could require us or our licensors or collaborators to cease using the relevant technology or developing or commercializing our product candidates, or to attempt to license any necessary rights to such technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license, or otherwise offers a license on terms that are not commercially reasonable or are otherwise unfavorable to us. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages if we are found to have infringed a patent, including treble damages and attorneys' fees if such infringement was willful. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

Furthermore, because of intellectual property litigation and certain other legal proceedings require discovery, which may in some cases be substantial, there is a risk that our confidential information could be compromised by disclosure during the course of such proceedings involving third party intellectual property rights. There could also be public announcements of the results of hearings, motions or other interim rulings or developments in the proceedings, and if securities analysts or investors perceive these results to be negative, the price of shares of our common stock may be materially adversely affected.

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

Many of our employees, including members of our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we work to ensure that our employees do not use the proprietary information or know-how of others in their work for us, including through written contractual obligations, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of a former employer of any such employee. Litigation may be necessary to defend against these claims.

If we are unable to successfully defend against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be determined to be owned by a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available to us at all, may not be available to us on commercially reasonable terms or may include obligations that are otherwise unfavorable for us. Even if we successfully defend against such claims, litigation could result in substantial costs and distract management from our day-to-day operations.

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

In addition to seeking patents covering 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 confidentiality agreements with parties who have access to them, including our employees, corporate collaborators, scientific collaborators, contract manufacturers, advisors and other third parties. We also enter into confidentiality and intellectual property, including patent, assignment agreements with our employees and consultants. Despite these efforts, any of these parties, including our current or former employees or consultants and those of our service providers or collaborators, may breach the applicable agreements and disclose our confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breach. Additionally, bringing a claim against a party for illegally disclosing or misappropriating a trade secret is difficult, expensive and time-consuming, the outcome of such a claim is unpredictable and any such litigation involving our trade secrets puts us at significant risk that such trade secrets will be publicly disclosed, thereby significantly reducing or eliminating their value and potentially increasing competition and otherwise harming our business. Further, 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 any such trade secret to compete with us, which could harm our competitive position.

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 with an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, have not generated any revenue from product sales to date and 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 up-front payment we received from BMS under our license and collaboration agreement for cabiralizumab, and the fiscal year ended December 31, 2011, due primarily to an upfront payment we received from a collaboration partner. For the quarter ended June 30, 2019, we reported a net loss of $34.4 million.

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

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

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

- successfully complete research and clinical development of current and future product candidates;
- establish and maintain supply and manufacturing relationships with third parties to ensure adequate, timely and compliant manufacturing of bulk drug substances and drug products to maintain our or our partners' supply of such bulk drug substances and drug products;
- launch and commercialize any product candidates for which we obtain marketing approval, and if we launch independently or with certain partners, successfully establish a sales force and marketing and distribution infrastructure;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- successfully and timely develop, validate and obtain any necessary regulatory approvals for companion diagnostics to any of our approved product candidates;
- achieve market acceptance for any of our or our partners' approved products;
- acquire rights to and otherwise establish, maintain and protect intellectual property rights necessary to develop and commercialize our product candidates; and
- attract, hire and retain qualified personnel.

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

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

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

As a research and development company, our operations have consumed substantial amounts of cash since inception. We have sufficient cash and cash equivalents to fund our projected operating expenses and capital expenditure requirements for at least the next 12 months and, as a result of our restructuring and other cost control measures, we expect our expenses to decrease in the short term. However, we expect our research and development expenses will increase substantially in connection with our ongoing activities, particularly as we advance our product candidates further into clinical development, advance additional product candidates into clinical trials and increase the number and size of our clinical trials. In addition, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we move our product candidates through preclinical studies and into clinical development, we may observe adverse results that require us or one of our collaboration partners to terminate the program for a product candidate. Alternatively, we may be required to conduct additional research or development activities or studies for a product candidate or substantially redesign a product candidate, each of which could lengthen the development process and increase our development costs for such product candidate. If we initiate additional clinical trials for certain product candidates, we may need to raise additional funds or otherwise obtain funding through product collaborations beyond the collaborations we currently have in place. In any event, we will require additional capital to develop, obtain regulatory approval for and to commercialize our current and future product candidates.

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

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

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

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

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

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

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

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

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

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

Risks Related to the Ownership of Our Common Stock

The market price of our stock is volatile.

The trading price of our common stock has been and is likely to continue to be volatile. Since shares of our common stock were sold in our initial public offering in September 2013, our closing stock price as reported on The Nasdaq Global Market and The Nasdaq Global Select Market has ranged from $5.02 to $60.89 through August 7, 2019. The following factors, in addition to other risk factors described in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, may have a significant impact on the market price of our common stock:

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

In addition, the stock market in general, and The Nasdaq Global Select Market and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the relevant 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 become a 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, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 44% of our common stock. This concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, acting together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

We are subject to the periodic reporting requirements of the Securities and Exchange Act of 1934, as amended, or 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 below and are incorporated herein by reference.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the company's Current Report on Form 8-K (File No. 001-36070), 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).
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*	Certification 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*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of 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 this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Five Prime Therapeutics, Inc.
(Registrant)

/s/ Aron M. Knickerbocker

Date: August 8, 2019

Aron M. Knickerbocker
President and Chief Executive Officer
(Principal Executive Officer)

/s/ David V. Smith

Date: August 8, 2019

David V. Smith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Aron M. Knickerbocker, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 8, 2019

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

Exhibit 31.2

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

I, David V. Smith, certify that:

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

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

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

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

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: August 8, 2019

/s/ David V. Smith
David V. Smith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Five Prime Therapeutics, Inc. ("Five Prime") for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Aron M. Knickerbocker, President and Chief Executive Officer of Five Prime, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

Dated: August 8, 2019

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Five Prime Therapeutics, Inc. ("Five Prime") for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David V. Smith, Executive Vice President and Chief Financial Officer of Five Prime, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

Dated: August 8, 2019

/s/ David V. Smith
David V. Smith
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)