FIVE PRIME THERAPEUTICS INC
Form 10-Q
May 08, 2018

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 March 31, 2018

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)

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	(Do not check if a smaller reporting company)	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 Exchange Act Rule 12b-2)
Yes No

As of May 1, 2018, the number of outstanding shares of the registrant’s common stock was 35,209,289.

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Signatures

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

- our estimates regarding our expenses, revenues, anticipated capital requirements and our needs for additional financing;
- our receipt of future milestone payments or royalties, and the timing of such payments;
- our or our partners’ ability to timely advance drug candidates into and through clinical data readouts and successful completion of clinical trials;
- the timing of the initiation, progress and results of preclinical studies and research and development programs;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- the implementation, timing and likelihood of success of our plans to develop companion diagnostics for our product candidates;
- our ability to establish and maintain collaborations and necessary licenses;
- the implementation of our business model and strategic plans for our business, 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 timing or likelihood of regulatory filings and approvals;
- 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 statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in 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 Quarterly Report on Form 10- 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 studies and publications is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal research is reliable and the market definitions we use are appropriate, neither such research nor such definitions have been verified by any independent source.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Condensed Balance Sheets

(In thousands, except per share amounts)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$65,941	$ 59,790
Marketable securities	323,485	232,900
Receivables from collaborative partners	4,269	13,133
Prepaid and other current assets	9,348	5,367
Total current assets	403,043	311,190
Restricted cash	1,543	1,543
Property and equipment, net	30,290	30,762
Other long-term assets	1,838	552
Total assets	$436,714	$ 344,047
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$1,831	$ 2,237
Accrued personnel-related expenses	4,188	7,156
Other accrued liabilities	29,348	27,519
Deferred revenue, current portion	4,443	12,713
Deferred rent, current portion	1,356	1,356
Total current liabilities	41,166	50,981
Deferred revenue, long-term portion	14,816	10,223
Deferred rent, long-term portion	18,266	17,641
Other long-term liabilities	250	—
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 35,265,857 issued and 34,334,645 outstanding at March 31, 2018. 28,982,056 issued and 28,178,639 outstanding at December 31, 2017	34	28
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Additional paid-in capital	537,391	421,257
Accumulated other comprehensive loss	(586)	(476)

Accumulated deficit	(174,623)	(155,607)
Total stockholders' equity	362,216	265,202
Total liabilities and stockholders' equity	$436,714	$ 344,047

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Operations

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2018	2017
Collaboration revenue	$32,486	$10,135
Operating expenses:		
Research and development	43,552	33,760
General and administrative	10,478	10,486
Total operating expenses	54,030	44,246
Loss from operations	(21,544)	(34,111)
Interest and other income, net	1,159	668
Other loss, net	(5)	—
Loss before income tax	(20,390)	(33,443)
Income tax (provision) benefit	—	—
Net loss	$(20,390)	$(33,443)
Basic and diluted net loss per common share	$(0.63)	$(1.21)
Weighted-average shares used to compute basic and diluted net loss per common share	32,314	27,657

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Comprehensive Loss

(In thousands)

	Three Months Ended March 31,	
	2018	2017
Net loss	$(20,390)	$(33,443)
Other comprehensive loss:		
Unrealized loss on marketable securities	(110)	(205)
Comprehensive loss	$(20,500)	$(33,648)

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(In thousands)

	Three Months Ended March 31,	
	2018	2017
Operating activities		
Net loss	$(20,390)	$(33,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,151	515
Stock-based compensation expense	7,820	9,887
Amortization of premiums and discounts on marketable securities	13	708
Loss on disposal of property and equipment	5	—
Changes in operating assets and liabilities:		
Receivables from collaborative partners	8,864	(1,950)
Income tax receivable	—	(7)
Prepaid, other current assets, and other long-term assets	(5,267)	1,453
Accounts payable	(406)	473
Accrued personnel-related expenses	(2,968)	(4,279)
Deferred revenue	(2,304)	(3,183)
Deferred rent	625	(216)
Other accrued liabilities and other long-term liabilities	2,235	2,113
Net cash used in operating activities	(10,622)	(27,929)
Investing activities		
Purchases of marketable securities	(153,957)	(125,701)
Maturities of marketable securities	63,250	205,750
Purchases of property and equipment	(840)	(1,824)
Net cash (used in) provided by investing activities	(91,547)	78,225
Financing activities		
Proceeds from public offering of common stock, net	107,613	—
Proceeds from exercise of stock options	1,704	1,048
Repurchase of shares to satisfy tax withholding obligations	(997)	(11,813)
Net cash provided by (used in) financing activities	108,320	(10,765)
Net increase in cash and cash equivalents and restricted cash	6,151	39,531
Cash, cash equivalents and restricted cash at beginning of period	61,333	9,196
Cash, cash equivalents and restricted cash at end of period	$67,484	$48,727
Supplemental schedule of noncash investing activities		
Unpaid property and equipment included in accrued liabilities	$531	$1,548
Supplemental cash flow information		
Cash and cash equivalents at beginning of period	$59,790	$7,653
Restricted cash at beginning of period	1,543	1,543
Cash, cash equivalents and restricted cash at beginning of period	$61,333	$9,196

Cash and cash equivalents at end of period	$65,941	$47,184
Restricted cash at end of period	1,543	1,543
Cash, cash equivalents and restricted cash at end of period	$67,484	$48,727

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

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements

March 31, 2018

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 March 31, 2018 is unaudited. The condensed financial statements included in this report reflect all adjustments (consisting only of normal recurring adjustments) that our management considers necessary for the fair statement of the results of operations for the interim periods covered and of our financial condition at the date of the interim balance sheet. The accompanying unaudited condensed 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 condensed 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, 2017, or our Annual Report, filed with the U.S. Securities and Exchange Commission, or the SEC, on February 27, 2018, as amended by our Annual Report on Form 10-K/A, as filed with the SEC on March 12, 2018, or, collectively 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. 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 for the duration of this lease, the amount of which is subject to reduction starting on January 1, 2023, if certain conditions are met.

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 March 31, 2018.

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):

	March 31, 2018			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$19,119	$19,119	$—	$ —
U.S. Treasury securities	309,415	309,415	—	—
Corporate bonds	15,183	—	15,183	—
Commercial paper	31,523	—	31,523	—
Certificate of deposit	1,543	—	1,543	—
Total	$376,783	$328,534	$48,249	$ —

	December 31, 2017			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$31,802	$31,802	$—	$ —
U.S. Treasury securities	232,900	232,900	—	—
Certificate of deposit	1,543	—	1,543	—
Total	$266,245	$264,702	$1,543	$ —

Revenue Recognition

Effective January 1, 2018, we adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606), or Topic 606, using the modified retrospective transition method. 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) identify the contract; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the company satisfies a performance obligation.

The terms of our collaborative research and development agreements include up-front and license fees, research funding, milestone and other contingent payments to us for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of commercialized products. Arrangements that include up-front payments are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform obligations under these arrangements. We record research funding payable to us as accounts receivable when our right to consideration is unconditional. The event-based milestone payments represent variable consideration, and we use the most likely

amount method to estimate this variable consideration. Given the high degree of uncertainty around achievement of these milestones, we determine the milestone amounts to be fully constrained and do not recognize revenue 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 to our collaborative partners and is the unit of account in Topic 606. A contract's transaction price is allocated to each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the performance obligation is satisfied. Under Topic 606, we elected to use the practical expedients permitted related to adoption, which do not require us to disclose certain information regarding our remaining performance obligations as of the end of the reporting period. Topic 606 is applicable for revenue recognized in accordance with the practical expedient for measuring progress toward satisfaction of a performance obligation, and variable consideration classified as a sales-based or usage-based royalty promised in exchange for a license.

Net Loss Per Share of Common Stock

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

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

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	4,032	3,711
Restricted stock awards (RSAs)	829	1,047
	4,861	4,758

Accounting Pronouncements Adopted in 2018

In May 2014, the Financial Accounting Standards Board, or FASB, issued Topic 606, which supersedes nearly all existing revenue recognition guidance under GAAP. The FASB subsequently issued amendments to Topic 606 that have the same effective date and transition date. The core principle of Topic 606 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Topic 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

We adopted this new guidance, effective January 1, 2018, using the modified retrospective transition method, in which the standard is applied as of the date of initial adoption. We recorded the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings. The adoption of the new revenue recognition guidance resulted in a decrease of $1.4 million to deferred revenue and an increase of $1.4 million to retained earnings as of January 1, 2018. We determined that the classification between deferred revenue, current portion, and deferred revenue, long-term portion, will change from the adoption of Topic 606. We concluded that we will classify deferred revenue for all licensing and collaboration arrangements as deferred revenue, long-term and reclassified to deferred revenue, current when the remaining term of the estimated performance period is one year or less.

Our adoption of Topic 606 on January 1, 2018 affected the following financial statement line items:

Condensed Statements of Operations

	Three Months ended March 31, 2018

(in thousands, except per share data)	Under Topic 606	Under Topic 605	Effect of change
Collaboration and license revenue	$32,486	$33,693	$(1,207)
Operating expenses	54,030	54,030	—
Operating loss	$(21,544)	$(20,337)	$(1,207)
Net loss	$(20,390)	$(19,183)	$(1,207)
Net loss per share applicable to common stockholders - basic and diluted	$(0.63)	$(0.59)	$(0.04)

Condensed Balance Sheets

	As of March 31, 2018		
(in thousands)	Under Topic 606	Under Topic 605	Effect of change
Receivable from collaborative partner	$4,269	$4,269	$—
Deferred revenue, current portion	4,443	11,773	(7,330)
Deferred revenue, long-term portion	14,816	7,652	7,164
Accumulated deficit	(174,623)	(174,789)	166

Condensed Statements of Cash Flows

	Three Months ended March 31, 2018		
(in thousands)	Under Topic 606	Under Topic 605	Effect of change
Net loss	$(20,390)	$(19,183)	$(1,207)
Decrease in deferred revenue in connection with Topic 606 adoption	1,373	—	1,373
Changes in operating assets and liabilities			
Receivable from collaborative partner	8,864	8,864	—
Deferred revenue	(3,677)	(3,511)	(166)
Cash, cash equivalents and restricted cash at beginning of period	61,333	61,333	—
Cash, cash equivalents and restricted cash at end of period	67,484	67,484	—

In May 2017, FASB issued ASU 2017-09 Compensation-Stock Compensation (Topic 718) – Scope of Modification Accounting, or ASU 2017-09, which amends the scope of modification accounting for share-based payment arrangements. Specifically, an entity would not apply modification accounting to an equity award if the fair value, vesting conditions, and classification of such award are the same immediately before and after the modification. We adopted the standard effective January 1, 2018 to be applied prospectively to awards modified on or after the effective date. We do not have any arrangements within the scope of ASU 2017-09 as of the adoption date and do not expect the adoption to have a material impact on our consolidated financial statements.

In November 2016, FASB issued ASU 2016-18 Statement of Cash Flows (Topic 230) – Restricted Cash, or ASU 2016-18. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted ASU 2016-18, effective January 1, 2018, to be applied retrospectively and revised the beginning and ending balance of our statement of cash flows to include restricted cash. Other than the change in presentation in the accompanying consolidated statement of cash flows, the adoption of this guidance had no effect on our financial position, results of operations or liquidity.

Accounting Pronouncements Not Yet Adopted

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. ASU 2016-02 will become effective January 1, 2019 and will apply to all annual and interim reporting periods thereafter. Early adoption is permitted. Under ASU 2016-02, agreements executed prior to January 1, 2019 that are currently considered leases are expected to be recognized on the consolidated balance sheet as a right-to-use lease asset and a lease liability. We expect that our recognition of expense on our statement of operations under ASU 2016-02 will be similar to our recognition of expense under the current accounting standard.

3.Cash Equivalents and Marketable Securities

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

	March 31, 2018			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$19,119	$ —	$ —	$19,119
U.S. Treasury securities	309,997	—	(582)	309,415
Corporate bonds	15,184	1	(2)	15,183
Commercial paper	31,526	4	(7)	31,523
Total cash equivalents and marketable securities	375,826	5	(591)	375,240
Less: cash equivalents	(51,751)	(5)	1	(51,755)
Total marketable securities	$324,075	$ —	$ (590)	$323,485

	December 31, 2017			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Money market funds	$31,802	$ —	$ —	$31,802
U.S. Treasury securities	233,376	—	(476)	232,900
Total cash equivalents and marketable securities	265,178	—	(476)	264,702
Less: cash equivalents	(31,802)	—	—	(31,802)
Total marketable securities	$233,376	$ —	$ (476)	$232,900

As of March 31, 2018, 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	$304,214	$303,652
In one to two years	19,861	19,833
Total marketable securities	$324,075	$323,485

We determined that the gross unrealized losses on our marketable securities as of March 31, 2018 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 March 31, 2018. 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, 2017	3,867,645	$ 30.35	
Options granted	527,850	$ 18.72	
Options exercised	(182,820)	$ 9.32	
Options forfeited	(19,775)	$ 38.30	
Options expired	(134,705)	$ 36.60	
Balance at March 31, 2018	4,058,195	$ 29.54	7.26
Options exercisable at March 31, 2018	1,897,326	$ 24.42	6.05

We have granted restricted stock awards, or RSAs, to certain of our employees, some of which are subject to performance 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 based the fair value of RSAs on the closing sale price of our common stock on the grant date. For awards 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.

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, 2017	803,417	$ 40.24
RSAs granted	274,250	$ 18.82
RSAs vested	(128,359)	$ 42.29
RSAs forfeited	(18,096)	$ 36.13
Unvested balance at March 31, 2018	931,212	$ 33.73

As of March 31, 2018, there were 1,894,733 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 March 31,	
	2018	2017
Research and development	$3,934	$5,286
General and administrative	$3,886	$4,601
Total	$7,820	$9,887

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 March 31,	
	2018	2017
Expected term (years)	6.0-6.3	6.0-6.3
Expected volatility	70%	68%
Risk-free interest rate	2.6%	2.1%

Expected dividend yield	0%	0%

As of March 31, 2018, we had $43.7 million of total unrecognized compensation expense related to unvested employee and director stock options that we expect to recognize over a weighted-average period of 2.7 years. Additionally, we had $24.4 million of total unrecognized compensation expense related to employee and director RSAs that we expect to recognize over a weighted-average period of 2.1 years.

5.License and Collaboration Arrangements

See Note 9 to the audited consolidated financial statements included in Part V, Item 15 of our Annual Report for information on our license and collaboration agreements.

The following table presents changes during the three months ended March 31, 2018 in the balances of our contract assets, including receivables from collaborative 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, 2017	$ 13,133
Additions	30,296
Deductions	(39,160)
Balance at March 31, 2018	$ 4,269

(in thousands)	Contract Liabilities
Balance at December 31, 2017	$ 22,936
Additions for advanced billings	1,015
Deductions for performance obligations satisfied in current period	(3,319)
Deductions for performance obligations satisfied in previous periods in connection with Topic 606 adoption	(1,373)
Balance at March 31, 2018	$ 19,259

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 with BMS for the research license to access our technology, the exclusive commercial license and research activities. BMS' options to select additional collaboration 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 includes the $20.0 million non-refundable up-front 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 they were considered to be constrained as it is probable that the inclusion of such variable consideration could result in a significant reversal in revenue in the future. We will recognize any consideration related to sales-based milestones (including 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. For the three months ended March 31, 2018, no adjustments were made to the transaction price.

Upon adoption of Topic 606, we recognized an additional $0.7 million of revenue, through a decrease to deferred revenue and an increase to beginning retained earnings, based on the difference between the input method currently used under Topic 606 and the ratable recognition previously used under Topic 605. 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. Revenue allocated to the performance obligation, $1.6 million, was recognized under Topic 606 for the three months ended March 31, 2018. Through March 31, 2018, we had recognized $30.1 million of the transaction price as collaboration revenue under the agreement. The remaining transaction price of $6.0 million will be recognized as revenue under the input method over the estimated performance period.

License and Collaboration Agreement

In October 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 Phase 1a/1 clinical trial of cabiralizumab in combination with Opdivo® (nivolumab) and the manufacturing and supply of cabiralizumab. The transaction price consists of the $30.0 million non-refundable up-front fee under the original collaboration agreement. We concluded that the transaction price should include the variable consideration for reimbursements when received as part of the transfer of services.

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 for clinical research organizations, or CROs, and laboratory services 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. No adjustment was necessary upon adoption of Topic 606. We recognized $1.4 million of revenue allocated to the performance obligation under Topic 606 for the three months ended March 31, 2018. Total revenue recognized for the quarter, including progress made toward the performance obligation and reimbursements, was $4.5 million. Through March 31, 2018, we recognized $19.6 million of the transaction price as collaboration revenue under the agreement. The remaining transaction price of $10.4 million is recorded in deferred revenue as of March 31, 2018 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) license to BMS; and (2) transfer of licensed know-how to BMS. The transaction price consists of the $350.0 million non-refundable up-front fee. We concluded that the transaction price should not yet include the milestone payments as they are fully constrained. We will recognize any consideration related to sales-based milestones (including royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore are recognized on the later to occur of satisfaction of the performance obligation, or 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 months ended March 31, 2018, no adjustments were made to the transaction price.

The $350.0 million non-refundable up-front fee was fully recognized concurrent with the transfer of the license and know-how in 2015. As such, no adjustment to revenue is necessary under Topic 606. In January 2018, we recognized $25.0 million related to a milestone achieved for the dosing of the first patient in BMS’s randomized Phase 2 clinical trial of cabiralizumab in combination with Opdivo® (nivolumab), with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer.

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 (Shanghai) Co., Ltd., or Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan, each a region, and collectively, the territory.

We evaluated the China collaboration agreement under Topic 606. Based on that evaluation, we identified the following performance obligations: (1) license grant to Zai Lab along with the transfer of licensed know-how,

development drug supply and global development activities; (2) commercial drug supply; and (3) development of companion diagnostics. The $5.0 million non-refundable up-front fee, net of value-added tax and other withholdings of $0.8 million and the $8.3 million of expected reimbursement from Zai Lab for global development activities are included as part of the transaction price. We determined the $8.3 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 clinical and regulatory development milestone payments in the transaction price as all such milestone amounts are fully constrained. We will recognize any consideration related to sales-based milestones (including royalties) when the related sales occur, as we 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 related sales. Zai Lab’s option to purchase commercial drug supply from us represents a material right and we will include the additional consideration to us for such supply in the transaction price as Zai’s payment obligations for such supply become due under the commercial supply agreement we and Zai Lab would enter into. 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 in an amount that corresponds directly to the value to the customer 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 months ended March 31, 2018, 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 grant, transfer of licensed know-how, development drug supply and global development activities. We concluded that revenue will be recognized based on actual costs incurred for CROs as a percentage of total budgeted costs as we complete our performance obligation. We will recognize revenue from reimbursements for commercial drug supply and for the development of companion diagnostics when we have the right to invoice Zai Lab.

No adjustment was necessary upon adoption of Topic 606. For the three months ended March 31, 2018, revenue for the first performance obligation was $0.3 million. Total revenue recognized for the third performance obligation during the quarter was $0.9 million. Of the remaining transaction price of $12.2 million, $4.4 million is recorded in deferred revenue and will be recognized over the estimated performance period for satisfaction of the performance obligation. $7.8 million of the transaction price will be recorded in deferred revenue when invoiced as global development activities are incurred.

GlaxoSmithKline LLC

Respiratory Diseases and Muscle Diseases Collaborations

In April 2012, we entered into a research collaboration and license agreement, or the respiratory diseases collaboration, with GlaxoSmithKline LLC, 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. In July 2010, we entered into a research collaboration and license agreement, or the muscle diseases collaboration with GSK, to identify potential drug targets and drug candidates to treat skeletal muscle diseases. We conducted three customized cell-based screens and one in vivo screen of our protein libraries under the muscle diseases collaboration. The research term under the muscle diseases collaboration ended in May 2014 and the agreement expired in April 2018.

We assessed the respiratory diseases collaboration and muscle diseases collaboration in accordance with Topic 606. Based on that assessment, we identified the one performance obligation under each collaboration for the research license and research activities. The non-refundable up-front fees and the equity premiums are included as part of the transaction prices for each collaboration. We will include the variable consideration for research services in the transaction prices of the respective agreements when received as part of the transfer of services. The clinical and regulatory development milestone payments have not been included in the transaction prices, as all such milestone amounts are fully constrained. We will recognize any consideration related to sales-based milestones, including 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 related sales. Under the respiratory diseases collaboration, GSK’s option to add research funding were also not included in the transaction price. As the muscle diseases collaboration with GSK expired in April 2018, we are no longer eligible to receive milestone payments or royalties under that agreement. 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 months ended March 31, 2018, no adjustments were made to the transaction prices of the collaborations with GSK.

Under the respiratory diseases collaboration and the muscle diseases collaboration, the non-refundable up-front fees, the equity premiums and the payment for research activities were fully recognized in 2016 and 2014, respectively. As the performance obligations were satisfied in prior years, no adjustment to revenue is necessary under Topic 606.

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 disorders.

We assessed the fibrosis and CNS collaboration under Topic 606. Based on that assessment, 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 includes the $6.0 million non-refundable up-front fee, the $6.6 million technology access fee, the $1.0 million reimbursement for reagent costs and the $2.0 million of research funding. We have not included the clinical and regulatory development milestone payments in the transaction price as all such milestone amounts are fully constrained. We will recognize any consideration related to sales-based milestones, including 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 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 months ended March 31, 2018, there was no change in the transaction price.

Upon adoption of Topic 606, we recognized an additional $0.6 million of revenue, through a decrease to deferred revenue and an increase to beginning retained earnings, based on the difference between the input method currently used under Topic 606 and the ratable recognition previously used under Topic 605. We use the input method to measure progress toward completion of the performance obligation and concluded that revenue will be recognized based on actual full time equivalent labor hours expended as a percentage of total budgeted costs. The $0.6 million adjustment recorded upon the adoption of Topic 606 recognized the remainder of the transaction price. In March 2018, UCB triggered a $0.3 million milestone payment to us upon selection of an undisclosed confirmed target for further development.

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2017 included in our Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission, or the SEC, on February 27, 2018, as amended by our Annual Report on Form 10-K/A, as filed with the SEC on March 12, 2018, or, collectively, 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. We have an emphasis in immuno-oncology, an area in which we have clinical, preclinical, research and discovery programs and product and discovery collaborations. In addition, we plan to use companion diagnostics where appropriate to allow us to select patients most likely to benefit from treatment with our product candidates. Our most advanced product candidates are identified below.

- Cabiralizumab (FPA008) is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we are studying in clinical trials as a monotherapy in tenosynovial giant cell tumor, also known as diffuse pigmented villonodular synovitis, or PVNS, and in multiple cancers in combination with Bristol-Myers Squibb Company's PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab). In October 2015, we entered into a license and collaboration agreement, or the cabiralizumab collaboration agreement, with Bristol-Myers Squibb Company, or BMS, pursuant to which we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- Bemarituzumab (FPA144) is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are studying 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 entered into a license and collaboration agreement, or the China collaboration agreement, with Zai Lab (Shanghai) Co., Ltd., or Zai Lab, pursuant to which we granted Zai Lab an exclusive license to develop and commercialize bemarituzumab in China, Hong Kong, Macau and Taiwan.
- FPA150 is a CD8 T cell checkpoint inhibitor antibody that targets B7-H4 that we are studying in clinical trials as monotherapy in multiple cancers.

We have a differentiated target discovery platform and comprehensive libraries of transmembrane and extracellular soluble proteins that we believe encompass substantially all the body's medically important targets for protein therapeutics. We have identified approximately 700 of these proteins, which we refer to as the immunome, that we believe modulate immune cell interactions and may be important in understanding and treating cancer in patients using immuno-oncology therapeutics. Our target discovery platform and capabilities position us well to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and the focus of our research activities. We are applying our biologics discovery platform, including cell-based screening, immunome-by-immunome biophysical interaction screening, in vivo screening, receptor-ligand matching technologies and bioinformatics, to our immuno-oncology research programs. We have identified several targets that we believe could be useful in immuno-oncology that we are actively validating. We are also conducting research to discover additional targets. We generate and preclinically test therapeutic proteins, including antibodies and fusion proteins, containing or directed to the targets we discover and validate. We plan to continue to advance selected therapeutic candidates into clinical development.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. We 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 our inception 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 cabiralizumab collaboration agreement, and the fiscal year ended December 31, 2011, due primarily to an up-front payment we received from a collaboration partner. For the three months ended March 31, 2018 and 2017, we reported a net loss of $20.4 million and $33.4 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 Quarterly Report on Form 10-Q, 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.

Clinical Pipeline

The following table shows the stage of development of our most advanced product candidates:

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* Partnered with BMS – see "Part I—Item 1. Collaborations" of our Annual Report for a description of our collaboration agreements with BMS.

** 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.

† Excludes investigator-sponsored trials.

‡ Clinical development is being conducted exclusively by BMS.

Cabiralizumab (FPA008)

Cabiralizumab in Immuno-Oncology

We are conducting 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 the trial and continue to treat patients still on study. In the Phase 1b portion of the trial, we are evaluating the safety, tolerability and preliminary efficacy of cabiralizumab in combination with Opdivo in the following tumor settings:

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

In parallel with advancing into the Phase 1b portion of the trial, we expanded the Phase 1a portion of the trial to continue to study cabiralizumab as monotherapy and in combination with Opdivo in patients with certain tumor types beyond those addressed in the Phase 1b cohorts, including in patients whose tumors are refractory to PD-1 checkpoint inhibitors.

Based on the clinical data we observed in the cohort of patients with pancreatic cancer in the Phase 1b portion of the trial, we enrolled 35 additional patients with second- or later-line pancreatic cancer in the expansion of the Phase 1a portion of our Phase 1a/1b clinical trial to further evaluate the combination of cabiralizumab and Opdivo in this patient population. We are collecting pre- and on-treatment tumor biopsy samples from these patients and are conducting comprehensive biomarker analyses to evaluate potential biomarker signatures that may predict responsiveness to this therapeutic combination and to assess changes that occur in the tumor microenvironment following treatment.

Additionally, based on such data, BMS opened and is currently enrolling patients in a randomized, open label, multi-arm Phase 2 clinical trial to determine the efficacy of cabiralizumab in combination with Opdivo, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer (NCT03336216). BMS plans to enroll approximately 160 patients with pancreatic cancer in the study, each of whom will be randomized to one of four study arms based on the patient's prior therapy. In January 2018, the dosing of the first patient in the trial by BMS triggered a $25 million milestone payment to us pursuant to our cabiralizumab collaboration agreement.

The American Society of Clinical Oncology, or ASCO, has accepted our abstract titled "Pharmacodynamics (PD) and Genomic Profiling of Pts Treated with cabiralizumab (cabira) + nivolumab (NIVO) Provide Evidence of On-Target Tumor Immune Modulations and Support Future Clinical Applications" for a poster presentation at its 2018 Annual Meeting, which will take place in June 2018.

Cabiralizumab in PVNS

We are conducting a Phase 1/2 clinical trial of cabiralizumab monotherapy as a potential treatment for diffuse PVNS. In the Phase 2 portion of the trial, we are evaluating tumor response rate and duration and measures of pain and joint function in PVNS patients. While a small number of patients with inoperable localized tenosynovial giant cell tumor may be included in the trial, our target patient population and a significant majority of the patients enrolled in the trial are patients with diffuse PVNS. We are currently enrolling up to 30 additional patients with PVNS in the Phase 2 portion of the trial to refine the dosing schedule and optimize the therapeutic index of cabiralizumab in PVNS. Data from these additional patients are intended to support the design of a potential pivotal trial of cabiralizumab in PVNS. We plan to decide in the second half of 2018, based on the data we obtain from the new dosing schedule, whether to advance cabiralizumab in 2019 to a pivotal trial in diffuse PVNS patients.

Bemarituzumab (FPA144)

We are completing a Phase 1 clinical trial of bemarituzumab to evaluate the safety, pharmacokinetics, or PK, and efficacy of bemarituzumab as monotherapy in patients with metastatic gastric and GEJ cancer and bladder cancer whose tumors overexpress FGFR2b. In April 2018, after evaluating the feasibility and timing of activating necessary clinical trial sites, the rate of patient enrollment in the bladder cancer cohort of the trial and the current landscape of potential treatment options for bladder cancer patients, we decided to close the bladder cancer cohort. We previously closed enrollment in the four cohorts of patients with gastric and GEJ cancer in the expansion portion of the trial in order to focus our efforts on our Phase 1/3 global registrational trial evaluating bemarituzumab in combination with mFOLFOX6 as front-line treatment of patients with gastric or GEJ cancer that overexpresses FGFR2b, or our FIGHT trial. Following the completion of treatment for patients in the bladder cancer cohort who are currently on study, we will close this Phase 1 clinical trial.

We are currently dosing patients in the Phase 1 safety lead-in portion of our FIGHT trial, during which we are evaluating the safety, tolerability, PK and pharmacodynamics of bemarituzumab in combination with mFOLFOX6 to identify a recommended dose of bemarituzumab to use in the Phase 3 portion of the trial. We expect to initiate the global randomized, controlled Phase 3 portion of the trial in the second half of 2018.

Because the observed incidence of gastric and GEJ cancer is higher in Asian populations than in other populations, in December 2017, we entered into 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, and pursuant to which Zai Lab will conduct the Phase 3 portion of the FIGHT trial in China. We believe that our collaboration with Zai Lab will allow us to expedite the initiation of the Phase 3 portion of the FIGHT trial in China and will enhance our ability to enroll patients at clinical sites in China, which we believe will reduce the overall time to fully enroll the Phase 3 portion of the FIGHT trial.

In addition, we are currently dosing patients in a Phase 1 clinical trial in Japan evaluating bemarituzumab monotherapy to treat patients with gastric or GEJ cancer. We expect to complete this trial in 2018. This trial is intended to enable the inclusion of Japanese patients in the FIGHT trial.

In the Phase 3 portion of the FIGHT trial, we will identify patients using an immunohistochemistry, or IHC, test, which measures FGFR2b overexpression in tumor tissue, and a circulating tumor DNA, or ctDNA, blood-based test, which measures FGFR2 gene amplification in the blood. FGFR2 gene amplification causes FGFR2b overexpression, and measuring this gene amplification in the blood is an indirect way of identifying tumors with overexpression that we may otherwise not identify using an IHC test. We are developing both companion diagnostics in parallel with our clinical development of bemarituzumab in collaboration with third-party diagnostic development partners and plan to use both companion diagnostics concurrently to more effectively identify gastric and GEJ cancer patients whose tumors overexpress FGFR2b or amplify the FGFR2 gene. We plan to pursue regulatory approval of each companion diagnostic contemporaneously with regulatory approval of bemarituzumab.

ASCO has accepted our abstract titled “FIGHT: A Phase 3 Randomized, Double-Blind, Placebo Controlled Study Evaluating (Bemarituzumab) FPA144 and Modified FOLFOX6 (mFOLFOX6) in Patients with Previously Untreated Advanced Gastric and Gastroesophageal Cancer with a Dose Finding Phase 1 Lead-In” for a poster presentation at its 2018 Annual Meeting, which will take place in June 2018.

FPA150

In December 2017, we filed an investigational new drug application, or IND, to initiate a Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of FPA150 monotherapy as a potential treatment for patients with a variety of cancers. In January 2018, we received clearance from the FDA to proceed with the clinical development of FPA150.

We are conducting a Phase 1a/1b clinical trial of FPA150 in multiple cancers. In March 2018, we initiated patient dosing in the Phase 1a portion of the trial, during which we will evaluate FPA150 in escalating doses in advanced solid tumors. Because FPA150 is expected to have an immunomodulatory effect and our Phase 1 trial is the first-in-human evaluation of FPA150, the starting dose of the dose escalation portion of the trial is lower than we would have selected for a development candidate that does not have an immunomodulatory effect. We expect that the Phase 1a dose-escalation portion of our trial will continue into 2019. In the Phase 1b portion of the trial, we plan to evaluate FPA150 in various disease-specific cohorts, including in breast cancer, ovarian cancer, endometrial cancer and urothelial bladder cancer. We are developing an IHC-based assay in collaboration with a diagnostic development partner to select patients whose tumors overexpress B7-H4 during the Phase 1b portion of the trial.

FPT155

We are currently conducting IND-enabling activities for FPT155, with the goal of submitting an IND or its foreign equivalent in the second half of 2018.

Immuno-Oncology Drug Discovery

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

“brakes” on immune cells, other discoveries in immuno-oncology have focused on identifying ways to “press on the gas” to amplify the anti-tumor immune response. This second approach targets stimulatory pathways in immune cells. Agents that agonize stimulatory pathways can help immune cells overcome inhibitory signals in the tumor microenvironment, resulting in the killing of tumor cells.

While checkpoint inhibitor therapies have been validated in the clinic with agents targeting the PD-1/PD-L1 and CTLA-4 pathways to release the “brakes,” a significant proportion of patients do not respond to these treatments. New targets for immuno-oncology are needed to address those patients who do not respond to or cannot tolerate traditional therapies or agents currently in development. We are applying all aspects of our differentiated discovery platform to identify protein partners for molecules or other targets known to be involved in the anti-tumor immune response. We believe we have identified promising new antibody targets and ligand traps and are actively researching and validating additional immuno-regulatory targets.

Financial Overview

Collaboration and License Revenue

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

Summary Revenue under Collaboration and License Agreements

The following is a comparison of collaboration and license revenue for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,	
(in millions)	2018	2017
Milestone Payments		
Cabiralizumab Collaboration - BMS	$25.0	$—
Fibrosis and CNS Collaboration - UCB	0.3	0.2
Other Payments		
China Collaboration - Zai Lab	1.1	—
Cabiralizumab Collaboration - BMS	4.5	7.2
Immuno-oncology Research Collaboration - BMS	1.6	1.9
Fibrosis and CNS Collaboration - UCB	—	0.8
Total	$32.5	$10.1

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 and other payments we receive in the course of our existing collaborations and licenses 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 for our own and for sponsored and collaborative research and development activities. We expense research and development costs as they are incurred. Research and development costs include employee salaries and benefits for employees in our research and clinical functions, including associated stock-based compensation, laboratory supplies and facility costs, as well as fees we pay to third parties that conduct certain research and development activities on our behalf. We estimate preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions, CROs and clinical manufacturing organizations, or CMOs, that conduct and manage preclinical studies and clinical trials on our behalf based on actual time and expenses that they incur. Further, we accrue expenses related to clinical trials based on the level of patient enrollment and activity contemplated by the applicable agreement with the clinical trial site. We

monitor patient enrollment levels and related activity to the extent reasonably possible and adjust estimates accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not experienced significant changes in our estimates of preclinical studies and clinical trial expense accruals.

We expense payments for the acquisition and development of technology as research and development costs if, at the time of payment, the technology is under development, has not been approved by the U.S. Food and Drug Administration, or FDA, or other comparable regulatory agencies for marketing, has not reached technical feasibility, or otherwise has no foreseeable alternative future use.

The following is a comparison of our research and development expenses for the three months ended March 31, 2018 and 2017:

(in millions)	Three Months Ended March 31, 2018	2017
Clinical development programs:		
Cabiralizumab	$5.5	$10.1
Bemarituzumab	16.0	7.4
FPA150	6.0	0.1
Subtotal clinical development programs	27.5	17.6
Preclinical programs	6.6	7.4
Discovery collaborations	0.9	1.4
Early research and discovery	8.6	7.4
Total research and development expenses	$43.6	$33.8

We expect that most of the research and development expenses we incur will continue to relate to activities to support our cabiralizumab, bemarituzumab and FPA150 clinical development programs and our immuno-oncology preclinical, research and discovery efforts. We expect our research and development expenses to increase as we advance our current product candidates through clinical development and additional product candidates into preclinical and clinical development, in particular, as we increase the number and size of our clinical trials, including by advancing into registrational trials, and as we expand our internal immuno-oncology preclinical, research and discovery efforts. We expect that our bemarituzumab development-related expenses will increase at a faster rate than our other research and development expenses as we advance bemarituzumab in our Phase 1/3 FIGHT trial to evaluate bemarituzumab in combination with standard of care chemotherapy. We also expect our FPA150 development-related expenses to increase as our FPA150 program advances through our Phase 1a/1b clinical trial.

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

The successful development of our drug candidates is highly uncertain and may not result in products that are approved for marketing by either the FDA or any comparable foreign regulatory authority. Completion dates and completion costs 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, we are unable to predict the duration and completion costs of the current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our approved drug candidates. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the outcome of research, 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 or may seek to enter into additional product collaborations in the future to advance and complete the development and commercialization of our 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 resource and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing and tax and legal services, including intellectual property-related legal services.

Interest Income

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

Critical Accounting Policies and Estimates

We based our management's discussion and analysis of financial condition and results of operations upon our unaudited condensed financial statements, which we prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our critical accounting policies and estimates on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, 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 may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited condensed financial statements and in Note 2 of our audited financial statements contained in our Annual Report.

Results of Operations

Comparison for the Three Months Ended March 31, 2018 and 2017

	Three Months Ended March 31,	
(in millions)	2018	2017
Collaboration and license revenue	$32.5	$10.1
Operating expenses:		
Research and development	43.6	33.8
General and administrative	10.5	10.5
Total operating expenses	54.1	44.3
Interest and other income, net	1.2	0.7
Loss before income tax	(20.4)	(33.4)
Income tax (provision) benefit	—	—
Net loss	$(20.4)	$(33.4)

Collaboration and License Revenue

Collaboration and license revenue increased by $22.4 million, or 222%, to $32.5 million for the three months ended March 31, 2018 from $10.1 million for the three months ended March 31, 2017. This increase was primarily due to $25.0 million of revenue recognized under our cabiralizumab collaboration with BMS for the achievement of the developmental milestone for the dosing of the first patient in BMS's randomized Phase 2 clinical trial of cabiralizumab in combination with Opdivo, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer. There was also an increase in collaboration and license revenue of $1.1 million as a result of our China collaboration with Zai Lab. These increases were offset by a $2.7 million decrease in collaboration funding from our cabiralizumab collaboration with BMS.

Research and Development

Our research and development expenses increased by $9.8 million, or 29%, to $43.6 million for the three months ended March 31, 2018 from $33.8 million for the three months ended March 31, 2017. This increase was primarily

due to an increase of $9.0 million in manufacturing and companion diagnostics development costs to advance our bemarituzumab development program.

General and Administrative

Our general and administrative expenses were consistent for the three months ended March 31, 2018 from the three months ended March 31, 2017.

Income Tax Provision

We did not record an income tax provision as a result of our net operating losses for the three months ended March 31, 2018 and 2017.

Liquidity and Capital Resources

As of March 31, 2018, we had $389.4 million in cash, cash equivalents and marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, corporate bonds and commercial paper with maturities of 14 months or less.

In addition to our existing cash and cash equivalents, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain nonclinical, clinical, regulatory and sales-based events and royalty payments under our collaboration and license agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' and licensees' research and development activities and remain 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 supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and contract manufacturers provides us with flexibility in managing our spending and limits our cost commitments at any point in time.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot 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 March 31, 2018 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 three months ended March 31, 2018 and 2017:

	Three Months Ended

(in millions)	March 31, 2018	2017
Net cash used in operating activities	$(10.6)	$(27.9)
Net cash (used in) provided by investing activities	(91.5)	78.2
Net cash provided by (used in) financing activities	108.3	(10.8)

Net Cash Used in Operating Activities

Net cash used in operating activities was $10.6 million for the three months ended March 31, 2018 and consisted of net loss of $20.4 million, offset by $9.0 million in net non-cash charges. Net non-cash charges included $1.2 million of depreciation and amortization expenses and $7.8 million for stock-based compensation expense.

Net cash used in operating activities was $27.9 million during the three months ended March 31, 2017 and consisted of net loss of $33.4 million, which was offset by $11.1 million in net non-cash charges, and $5.6 million from changes in operating assets and liabilities. Net non-cash charges included $0.5 million of depreciation and amortization expenses, $9.9 million for stock-based compensation expense and $0.7 million for amortization of premium on marketable securities.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $91.5 million for the three months ended March 31, 2018 . Net cash used in investing activities primarily relates to the purchase of marketable securities exceeding maturities of such marketable securities. Payments for the purchases of property and equipment were $0.8 million during the three months ended March 31, 2018 .

Net cash provided by investing activities was $78.2 million for three months ended March 31, 2017. Net cash provided by investing activities for the period primarily relates to the maturities of marketable securities exceeding purchases of such marketable securities. Payments for the purchases of property and equipment were $1.8 million during the three months ended March 31, 2017. The property and equipment purchases consisted primarily of purchases of laboratory equipment.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $108.3 million for the three months ended March 31, 2018, and consisted primarily of $107.6 million in net proceeds from the public offering of our common stock in January 2018 and $1.7 million received from employee stock option exercises. This was partially offset by $1.0 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards.

Net cash used in financing activities was $10.8 million during the three months ended March 31, 2017, primarily related to $11.8 million paid to satisfy our tax withholding obligations from the net share issuance of restricted stock awards offset by $1.0 million received from employee stock option exercises.

Contractual Obligations and Contingent Liabilities

During the three months ended March 31, 2018, 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 March 31, 2018, we had cash and cash equivalents and marketable securities of $389.4 million, consisting of bank deposits, interest-bearing money market accounts, U.S. Treasury securities, 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 six months and the longest maturity is fourteen 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 Interim 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 Interim 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 Interim 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 to these targets or in these target pathways. We are clinically developing our cabiralizumab, bemarituzumab and FPA150 product candidates, and our preclinical FPT155 product candidate is in IND-enabling studies. Our ability to generate product revenues, which we do not expect to occur for many years, if ever, will depend heavily on our ability to identify and validate new targets and identify and advance preclinical product candidates into and through clinical development. The outcome of preclinical studies of our product candidates may not predict the success of 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 studies, but such product candidates have nonetheless failed in clinical development. Our inability to successfully complete preclinical development of our product candidates could result in additional costs to us, 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 for the sale of our product candidates, we or our partners must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety

profiles, notwithstanding promising results in earlier trials. Despite the results already reported from our clinical trials and preclinical studies for our product candidates, we do not know whether the clinical trials we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of our product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials for one or more of our product candidates do not produce favorable results, we or our partners may be unable to achieve regulatory approval for such product candidates.

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 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 or unsuccessful completion of clinical development include:

- delays in reaching an agreement with or failure in obtaining 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 or 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 agreement on acceptable terms with prospective CROs, clinical trial sites, laboratory service providers, CMOs and other service providers we engage to support the conduct of our clinical trials;
- 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, to satisfy their contractual duties or meet expected deadlines;
- delays in the testing, validation and manufacturing of product candidates and in 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 in 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 identification and auditing of central or other laboratories or the transfer and validation of assays or tests used to identify selected patients;
- with respect to patients in any our clinical trials, delays in completing their participation in such clinical trial or returning for post-treatment follow-up;
- the occurrence of side effects, disease progression or other reasons 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 as a result of any clinical trial site investigator ceasing his or her affiliation with any such site, changing standards 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, we are conducting the Phase 3 portion of our global Phase 1/3 registrational trial of bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, a standard of care chemotherapy regimen known as mFOLFOX6, as front-line treatment for patients with gastric and gastroesophageal, or GEJ, cancer with tumors that overexpress FGFR2b, or our FIGHT trial, in China in collaboration with Zai Lab (Shanghai) Co., Ltd., or Zai Lab. Given the greater potential patient population in China, we believe that our ability to enroll patients at clinical trial sites in China will reduce the overall time to fully enroll the Phase 3 portion of our FIGHT trial and will therefore allow us to advance and complete the Phase 3 portion of the FIGHT trial within a shorter time period. However, Zai Lab's ability to initiate and 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 and obtaining approval for and commercializing drug products 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 make 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 and in fully enrolling the Phase 3 portion of the trial, which will 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 such product candidates may be impaired.

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

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

- the size and nature of the patient population;
- the number and location of clinical trial sites;
- competition with other companies for clinical trial sites or patients;
- the eligibility and exclusion criteria for the clinical trial;
- the design of the clinical trial;
- the ability to obtain and maintain patient consents; and
- risk that enrolled patients will drop out before completion;
- 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 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.

For example, we are conducting a Phase 2 clinical trial of cabiralizumab in patients with diffuse PVNS. Very little data regarding the incidence and prevalence of diffuse PVNS exist, but data we have gathered suggest that the prevalence of diffuse PVNS in the United States may be approximately 28,000 patients. We expect that the limited size of the diffuse PVNS patient population will limit patient enrollment rates. Daiichi Sankyo Co., Ltd./Plexxikon Inc., or Daiichi Sankyo, has conducted a Phase 3 clinical trial (ENLIVEN) of pexidartinib (PLX3397) in PVNS, and we believe Daiichi Sankyo plans to pursue approval of pexidartinib for use in PVNS. If pexidartinib is approved in any region where we are conducting clinical trials of cabiralizumab in PVNS, it may impact our ability to enroll and timely complete those trials. In addition, Novartis AG, or Novartis, is conducting a Phase 2 clinical trial of its MCS110 CSF1 monoclonal antibody in PVNS and F. Hoffmann-La Roche AG, or Roche, has clinically tested its emactuzumab (RO5509554, RG7155) antibody in PVNS. If either or both of Novartis or Roche continue the clinical development of their respective products in PVNS, we would potentially compete with them for patient enrollment in this rare patient population, which may adversely impact the rate of patient enrollment in and the timely completion of our Phase 2 clinical trial of cabiralizumab in PVNS.

In addition, we are conducting multiple clinical trials of bemarituzumab in gastric and GEJ cancer patients whose tumors overexpress FGFR2b or amplify the FGFR2 gene, including our FIGHT trial. Although we believe selecting patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the FGFR2 gene using an IHC- or ctDNA blood-based companion diagnostic should increase the percentage of patients eligible for and the probability of success in our clinical trials of bemarituzumab in gastric and GEJ cancer, these selection criteria limit the number of patients eligible for enrollment. Additionally, Astellas Pharma Inc., or Astellas, is conducting a Phase 3 clinical trial of its claudiximab (IMAB362) anti-Claudin 18.2 antibody in combination with mFOLFOX6 as front-line treatment in patients with HER2-negative gastric and GEJ cancer. If Astellas continues the clinical development of IMAB362 in gastric and GEJ cancer, we may compete for patient enrollment in this patient population, which may adversely impact the rate of patient enrollment in and the timely completion of our FIGHT trial.

We may not successfully identify, test, develop or commercialize our current or future product candidates, which may force us to abandon our development efforts for one or more programs.

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

- our research methodology, including our screening technology, may not successfully identify medically relevant protein therapeutic targets or potential product candidates;
- our discovery platform 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 increase the cost of goods, cause delays or make our product candidates unmarketable;
- third parties on whom we may rely to generate antibody or other candidates may fail to produce candidates that we can successfully validate or that have the scientific or clinical characteristics necessary to become marketable product candidates;
- 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 not demonstrate 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 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 cause us to cease operations. Research programs to identify new product targets and candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential discovery efforts, programs or product candidates that ultimately prove to be unsuccessful.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.

The process of manufacturing our 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 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 to 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 or decrease in the availability of these raw materials could considerably delay the manufacture of our product candidates, which could adversely impact the timing of any planned 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 currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. In the past we have 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. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates and the progress of our clinical trials, which could harm our results of operations.

For example, Bristol-Myers Squibb Company, or BMS, has the exclusive right to manufacture cabiralizumab under our cabiralizumab collaboration agreement with BMS. Under this agreement, BMS will supply us with cabiralizumab, at its cost and expense, for our use in the conduct of our clinical trial evaluating cabiralizumab in combination with Opdivo in multiple tumor types and our Phase 2 clinical trial of cabiralizumab in patients with PVNS and will supply us with cabiralizumab, in exchange for a service fee, for our conduct of our independent development activities with respect to cabiralizumab.

We have not contracted with alternate suppliers in the event that our current CMOs are unable to scale production or if we otherwise experience any problems with these parties. 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, we may be delayed in the development of our product candidates.

Our reliance on third-party manufacturers subjects us to risks to which we would not be subject if we manufactured product candidates 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 or nonrenewal of the 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 testing, manufacture, 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 foreign regulatory authorities that any such product candidate, and any parties involved in its testing and manufacturing, complied with current Good Manufacturing Practices, or GMP, and current Good Laboratory Practices, or GLP, regulations and standards during such testing and manufacturing. The time required to obtain approval to market a product candidate by 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 substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during 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 any future product candidates will ever obtain regulatory approval.

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

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

The FDA or a comparable foreign regulatory authority may require more information to support approval of a product candidate, including additional preclinical or clinical data, 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. 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 may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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

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 a high and unacceptable severity or prevalence of side effects or unexpected characteristics. In such an event, we may elect to suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease our trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or could result in potential 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 risk evaluation and mitigation strategy, or REMS, or a similar strategy 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 market approval or acceptance for a product candidate or otherwise materially harm the commercial prospects for such product candidate, if approved, and could significantly harm our business, results of operations and prospects.

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

We plan to develop a companion diagnostic for certain of our product candidates, including bemarituzumab and FPA150. We are collaborating with third-party diagnostic development partners to develop both an IHC- and a ctDNA blood-based assay to use as companion diagnostics for bemarituzumab to identify patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the FGFR2 gene. 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 bemarituzumab for use in patients that overexpress the FGFR2b protein or amplify the FGFR2 gene. We are initially seeking to develop bemarituzumab to treat a subset of patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the FGFR2 gene. Because the IHC-based companion diagnostic will allow us to determine FGFR2b overexpression in tumor tissue samples from patients with gastric or GEJ cancer and the blood-based companion diagnostic will allow us to detect FGFR2 gene amplification by ctDNA from patients with gastric or GEJ cancer, we plan to use both companion diagnostics concurrently in our FIGHT trial to more effectively identify patients with gastric or GEJ cancer who may qualify for enrollment in the trial.

In addition, we are seeking to develop FPA150 to treat patients with a variety of cancers whose tumors express the B7-H4 protein, as identified by an IHC diagnostic test. 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 FPA150 for use in patients whose tumors express the B7-H4 protein. We have collaborated with a third-party diagnostic development partner to develop an IHC assay to use as a lab-developed test to identify patients whose tumors express B7-H4 and plan to use this IHC assay in the Phase 1b portion of our Phase 1a/1b clinical trial of FPA150.

We do not have experience or capabilities in developing or commercializing diagnostics and will depend on the sustained cooperation and effort of our third-party collaborators to perform these functions.

Companion diagnostics are also subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization, which may cause delays in their development and harm our business.

If we or our collaboration partners are unable to successfully develop and receive any necessary approvals for companion diagnostics for bemarituzumab or FPA150 or experience delays in doing so, we may suffer significant negative consequences, including:

- the development of bemarituzumab or FPA150, as applicable, may be adversely affected because we may be unable to appropriately select patients for enrollment in our clinical trials;
- bemarituzumab or FPA150, as applicable, 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 bemarituzumab or FPA150 if, among other reasons, we are unable to appropriately identify patients with FGFR2b or B7-H4 protein overexpression, respectively.

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 inhibit our ability to commercialize our products and generate revenue.

Even if we obtain regulatory approval for a product candidate, the product would be subject to ongoing requirements by the FDA and 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 even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on the product's indicated uses or marketing, or impose ongoing requirements for post-approval studies or post-market surveillance, which may be costly.

In addition, drug product manufacturers and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and GLP regulations and standards. If we or a regulatory authority discover previously unknown problems with one of our product candidates, such as 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 include imposition of various monetary fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or bring other court action to impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications that we have filed;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may 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, 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. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of 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, these 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 a false claims action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, such actions 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 the adoption of new requirements or

policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

In order to market and sell our products in other jurisdictions, we or our collaboration partners must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. 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 includes 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 delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We may not obtain foreign regulatory approvals on a timely basis, if at all.

For example, we are conducting the Phase 3 portion of 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, we may experience delays in initiating, conducting or completing the FIGHT trial at our clinical trial sites in China and in fully enrolling the Phase 3 portion of the FIGHT trial, which will delay our ability to obtain approval for and commercialize bemarituzumab.

Further, results and data 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 may have a negative effect on the regulatory approval process in other countries 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. If we fail to comply with the regulatory requirements in international jurisdictions, we may not receive the necessary marketing approvals for our product candidates and 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, which may result in third parties discovering, developing or commercializing products before or more successfully than we do.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide 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 of 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 used 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.

Our competitors also currently and will in the future compete with us 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 standard of care will change as our product candidates progress through clinical development.

If cabiralizumab were approved for the treatment of cancer or PVNS, it could face competition from products currently in development as single agents or in combination with anti-PD1/PD-L1 agents or other immuno-oncology agents, including Roche's emactuzumab (RO5509554, RG7155) anti-CSF1R antibody, Eli Lilly and Company's LY3022855 (IMC-CS4) anti-CSF1R antibody, Amgen Inc.'s AMG 820 anti-CSF1R antibody, 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, or Novartis', BLZ945 CSF1R-directed small molecule and MCS110 CSF1 monoclonal antibody, Daiichi Sankyo'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, with respect to cancer, and Daiichi Sankyo's pexidartinib (PLX3397) and PLX73086 small molecule TKIs or Novartis' MCS110 CSF1 monoclonal antibody, with respect to PVNS, each of which acts in the same pathway as cabiralizumab.

If bemarituzumab were approved for the treatment of gastric and GEJ cancer, it could face competition from currently-approved and marketed products, including 5-fluorouracil, S-1, capecitabine, doxorubicin, cisplatin, oxaliplatin, carboplatin, paclitaxel, irinotecan, docetaxel and Cyramza™ (ramucirumab), and from products currently in development, including AstraZeneca plc's AZD4547 and erdafitinib (JNJ-42756493) pan-FGFR small molecules and Daiichi Sankyo's DS-1123 FGFR2 non isoform specific antibody, as well as antibodies that bind to PD-1/PD-L1, including BMS's Opdivo monotherapy and Opdivo in combination with BMS's Yervoy® (ipilimumab) anti-CTLA-4 antibody, Merck & Co., Inc.'s Keytruda® (pembrolizumab), Merck KGaA, Darmstadt, Germany/Pfizer's Bavencio® (avelumab), Roche's Tecentriq® (atezolizumab), AstraZeneca UK Limited/MedImmune, LLC's Imfinzi™ (durvalumab) anti-PD-L1 antibody, Astellas's claudiximab (IMAB362) anti-Claudin 18.2 antibody 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, Avastin® (bevacizumab), Abraxane® (paclitaxel protein-bound), Xeloda® (capecitabine), Navelbine® (vinorelbine), and Halaven® (eribulin mesylate); antibodies that bind to PD-1/PD-L1, including BMS's Opdivo monotherapy and Opdivo in combination with BMS's Yervoy® (ipilimumab) anti-CTLA-4 antibody, Merck & Co., Inc.'s Keytruda® (pembrolizumab), Merck KGaA, Darmstadt, Germany/Pfizer's Bavencio® (avelumab), Roche's Tecentriq® (atezolizumab), AstraZeneca UK Limited/MedImmune, LLC's Imfinzi™ (durvalumab), and AstraZeneca UK Limited/MedImmune, LLC's tremelimumab anti-CTLA4 antibody; Seattle Genetics and Astellas' enfortumab vedotin anti-nectin-4 antibody drug conjugate, or ADC; small molecule poly ADP-ribose polymerase inhibitors, including AstraZeneca UK Limited's Lynparza® (olaparib), 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, a receptor that exhibits a high level of overlap in its expression level with B7-H4.

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 necessary for commercial success among physicians, patients, healthcare payors and others in the medical community.

Even if our product candidates receive regulatory approval, they may not gain the level of market acceptance necessary for commercial success among physicians, patients, healthcare payors and others in the medical community. 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 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;
- 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 that 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;
- 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
- unfavorable publicity relating to the product candidate.

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

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

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that

could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if those 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 and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and reimbursement of medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary depending on the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any 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 for us to commercialize 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 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 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 Tax Act includes a provision that, effective January 1, 2019, repeals 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.” Additionally, 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. Congress will likely consider other legislation to replace elements of the Affordable Care Act. We continue to evaluate the effect of the Affordable Care Act and its possible repeal and replacement on our business.

In addition, 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 2025 unless Congress takes additional action. Recently, 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 bills 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 state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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 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 seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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;
- significant costs to defend the related litigation;
- substantial monetary awards payable to clinical trial patients;
- 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 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 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 customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency, privacy and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products 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 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, or collectively, 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 health care benefit program, willfully obstructing a criminal investigation of a healthcare fraud offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA also imposes obligations on certain health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program 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 the U.S. Department of Health and Human Services information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by 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; 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 will become 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 to 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 4% 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.

We are experiencing significant growth in our operations as we expand the scope of our research and clinical activities, including our conduct of a Phase 2 clinical trial of cabiralizumab in PVNS, a Phase 1a/1b clinical trial of cabiralizumab in combination with Opdivo in multiple cancers, clinical trials, including our FIGHT trial, of bemarituzumab in gastric and GEJ cancer, a Phase 1a/1b clinical trial of FPA150 in multiple cancers and our preclinical development and immuno-oncology research activities. Our success will depend in part on our ability to manage our growth, including increases to our headcount, effectively. To succeed, we must continue to recruit, develop, retain, manage and motivate qualified clinical, scientific, technical and management personnel while facing significant competition for experienced personnel. If we do not successfully attract and retain qualified personnel, particularly at the management level, this could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and 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 against which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better or more chances for 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 experiments or otherwise impair our ability to operate, which could result in delays in the advancement of our programs or cause us to incur costs to recover or reproduce lost data. Our facility is 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. 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.

We are increasingly dependent on information technology systems to operate our business, 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, 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 that belongs 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 have also outsourced elements of our operations, including elements of our information technology infrastructure, to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third-party vendors subcontract or outsource some of their responsibilities under our agreements to other third parties. 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 sensitive information stored on these systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, 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 with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation-states and others. In addition to the extraction of sensitive information, such attacks could include 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 information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Data security incidents or other significant disruptions affecting our, our third-party vendors’ or our business partners’ information technology systems could adversely affect our business operations and result in the loss, misappropriation 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 or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing 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 very sophisticated at concealing their access to systems, and many companies that 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 or state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting and expensive litigation, regulatory investigations and oversight or mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under applicable laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us and cause us significant legal and financial exposure and reputational harm. In addition, 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 any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical trial sites, regulators or current and potential partners, to lose trust in us, or 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 inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type 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 will successfully prevent service interruptions or security incidents.

Our employees, consultants and collaborators may engage in misconduct or other improper activities, including insider trading and non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceuticals, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These 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 identify and deter misconduct by our employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, 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, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

Risks Related to Our Dependence on Third Parties

BMS has exclusive global rights for the development and commercialization of cabiralizumab, and Zai Lab has exclusive rights for the development and commercialization of bemarituzumab in Greater China. BMS 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 with 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 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 and could result in a material adverse effect on our business, results of operations and prospects and would likely cause our stock price to decline.

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

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

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees 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 third-party 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, and 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 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 current Good Clinical Practices, or GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities, for all 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 comply with GCP requirements. In addition, we must conduct our clinical trials using product produced and developed in accordance with GMP and GLP requirements. Our failure, or the failure of our clinical trial sites or CROs or contract manufacturing organizations, 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 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, 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.

Risks Related to Intellectual Property

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

Our success depends in significant part on our 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. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, whereas other licenses do not give us such rights.

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 our partners, and we may have to rely on our partners 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 may hinder our ability to obtain patent protection for these inventions or may limit the scope of patent protection we 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 on such patent rights, are uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which 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 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 commercialized. 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, in certain foreign countries, particularly developing countries, the requirements for patentability differ from those of the United States and among these countries. For example, China has a heightened requirement for patentability as compared to the United States, which specifically requires a detailed description of medical uses for a claimed drug. 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. Competitors may use our and our licensors' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and 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 effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems 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, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and could provoke third parties to assert counterclaims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate and, even if we prevail, the damages or other remedies awarded, if any, may not be commercially meaningful, particularly in light of any expenses incurred to initiate 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 that 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.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes numerous significant changes to U.S. patent law, including provisions that affect how patent applications are prosecuted and may also affect litigation with respect to issued patents. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, including the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what impact, if any, the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents controlled by us or our licensors or collaborators, all of 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 in several stages over the lifetime of any issued patent. The USPTO and various foreign patent agencies also require compliance with a number of 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 for such product candidates, which would have a material adverse effect on our business.

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

Third parties may infringe our or our licensors' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights 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 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 legal actions, we or our licensors or collaborators may not be able to prevent third parties from infringing or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in 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 other party from using the technology at issue on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. Any litigation proceeding could put one or more of our or our licensors' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

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, giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade other companies from collaborating 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, it may require us to incur substantial costs and distract our management and other employees from our business and operations.

Furthermore, because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during the course of litigation proceedings. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in the litigation, 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 for or necessary to 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 a non-exclusive license with BioWa, Inc. and Lonza Sales AG to use their Potelligent® CHOK1SV technology, which is necessary to produce our bemarituzumab antibody, and non-exclusive licenses with each of the National Research Council of Canada and the Board of Trustees of the Leland Stanford Junior University to use materials and technologies that we use in the production of our protein library. If we fail to comply with the obligations under these 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 that is covered by 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 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 third parties' intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by these third parties, including in oppositions, interferences, reexaminations, inter partes 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 the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during the course of proceedings involving third party intellectual property rights. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in the litigation 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 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 or sustain damages. 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, may not be available 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 for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, including our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, 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, and the outcome of such a claim is unpredictable. 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 that 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 up-front capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2001, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million 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 up-front payment we received from a collaboration partner. For the three months ended March 31, 2018, we reported a net loss of $20.4 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.

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

To date, we have not generated any revenue from commercialization of our product candidates. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or with our partners, to successfully commercialize products, including any of our current product candidates or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. Our ability to generate future product revenue from our current or future product candidates also depends on 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 future product candidates for which we obtain marketing approval, if any, 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 our product candidates;
- achieve market acceptance for our or our partners' products, if any;
- acquire rights to and otherwise establish, maintain and protect intellectual property 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 development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased 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 comparable foreign regulatory authorities 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 product candidates or develop new product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. Although we have sufficient cash and cash equivalents to fund our projected operating expenses and capital expenditure requirements for at least the next 12 months, we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates further into clinical development, advance additional product candidates into clinical trials and 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 encounter adverse results that require us or one of our collaboration partners to terminate the program for a product candidate, conduct additional research or development activities or studies or substantially redesign a product candidate. Any of these events may lengthen the development process or increase our development costs. We may need to raise additional funds or otherwise obtain funding through product collaborations beyond the collaborations we currently have in place if we choose to initiate additional clinical trials for certain product candidates. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, current and future product candidates.

If we need to secure additional financing, these 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 prevented from pursuing development and commercialization efforts, which could have a material adverse effect on our business, operating results and prospects.

Our forecast of 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 future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential that such authorities may require us to perform more studies than those that we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, 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 potentially 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 dilute our existing stockholders or increase fixed payment obligations. 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, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

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

On December 22, 2017, the federal Tax Cuts and Jobs Act of 2017, or 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 $8.49 to $60.89 through May 7, 2018. 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 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 competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our or our partners' growth rates relative to our competitors;
- 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 other 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 these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and material adverse impact on the market price of our common stock.

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

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may 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.

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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 March 31, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 42% 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 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).
10.1	Consulting Agreement by and between the company and Marc Belsky effective as of April 7, 2018.
10.2	Amendment to Stock Option Agreements by and between the company and Marc Belsky, effective as of April 6, 2018.
10.3	Confidential Consulting Agreement, by and between the company and FLG Partners, LLC, effective as of April 13, 2018.
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	Financial statements from the Quarterly Report on Form 10-Q of the company for the quarter ended September 30, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets; (ii) the Condensed Statements of Operations; (iii) the Condensed Statements of Comprehensive Loss; (iv) the Condensed Statements of Cash Flows; and (v) Notes to Condensed Financial Statements.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the 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.

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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)
Date: May 8, 2018	/s/ Aron M. Knickerbocker Aron M. Knickerbocker President and Chief Executive Officer (Principal Executive Officer)
Date: May 8, 2018	/s/ Linda Rubinstein Linda Rubinstein Interim Chief Financial Officer (Principal Financial and Accounting Officer)