FIVE PRIME THERAPEUTICS INC
Form 10-Q
November 06, 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 September 30, 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

As of October 30, 2018, the number of outstanding shares of the registrant's common stock was 35,465,722.

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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, or this report, contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “int “could,” “would,” “project,” “plan,” “expect,” or similar expressions, or the negative or plural of these words or expressions. These forward-looking statements include statements concerning the following:

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

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

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

We obtained the industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. While we believe that the information in each of these publications, surveys and studies is reliable, we have not independently verified market and industry data from third-party sources. While we believe our internal estimates and research are reliable and the market definitions we use are appropriate, such estimates, research and definitions have not been verified by any independent source.

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

FIVE PRIME THERAPEUTICS, INC.

Condensed Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2018 (Unaudited)	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 64,045	$ 59,790
Marketable securities	257,551	232,900
Receivables from collaborative partners	5,015	13,133
Prepaid and other current assets	6,246	5,367
Total current assets	332,857	311,190
Restricted cash	1,543	1,543
Property and equipment, net	29,276	30,762
Other long-term assets	2,688	552
Total assets	$ 366,364	$ 344,047
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,495	$ 2,237
Accrued personnel-related expenses	6,814	7,156
Other accrued liabilities	27,167	27,519
Deferred revenue, current portion	1,687	12,713
Deferred rent, current portion	1,356	1,356
Total current liabilities	39,519	50,981
Deferred revenue, long-term portion	11,400	10,223
Deferred rent, long-term portion	18,667	17,641
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized, 35,507,393 issued and 34,531,817 outstanding at September 30, 2018 and 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	552,921	421,257
Accumulated other comprehensive loss	(250)	(476)

Accumulated deficit	(255,927)	(155,607)
Total stockholders' equity	296,778	265,202
Total liabilities and stockholders' equity	$ 366,364	$ 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)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$5,771	$8,333	$45,837	$26,290
Operating expenses:				
Research and development	44,687	42,733	121,619	118,237
General and administrative	9,832	9,674	30,092	29,523
Total operating expenses	54,519	52,407	151,711	147,760
Loss from operations	(48,748)	(44,074)	(105,874)	(121,470)
Interest income	1,531	792	4,212	2,162
Other loss, net	(27)	—	(32)	—
Loss before income tax	(47,244)	(43,282)	(101,694)	(119,308)
Income tax provision	—	—	—	(1,703)
Net loss	$(47,244)	$(43,282)	$(101,694)	$(121,011)
Basic and diluted net loss per common share	$(1.37)	$(1.54)	$(3.01)	$(4.34)
Weighted-average shares used to compute basic and diluted net loss per common share	34,482	28,020	33,740	27,883

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Comprehensive Loss

(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(47,244)	$(43,282)	$(101,694)	$(121,011)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	128	83	226	(182)
Comprehensive loss	$(47,116)	$(43,199)	$(101,468)	$(121,193)

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

FIVE PRIME THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(101,694)	$(121,011)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,729	1,731
Stock-based compensation expense	22,889	26,712
Amortization of premiums and discounts on marketable securities	(984)	1,467
Loss on disposal of property and equipment	5	2
Changes in operating assets and liabilities:		
Receivables from collaborative partners	8,118	(397)
Income tax receivable	—	4,670
Prepaid, other current assets and other long-term assets	(3,015)	1,891
Accounts payable	258	2,555
Accrued personnel-related expenses	(342)	(1,755)
Deferred revenue	(8,475)	(9,997)
Deferred rent	1,026	2,516
Other accrued liabilities	8,549	6,895
Net cash used in operating activities	(69,936)	(84,721)
Investing activities		
Purchases of marketable securities	(282,443)	(318,864)
Maturities of marketable securities	259,000	447,000
Purchases of property and equipment	(11,147)	(3,627)
Proceeds from disposal of property and equipment	—	12
Net cash (used in) provided by investing activities	(34,590)	124,521
Financing activities		
Proceeds from public offering of common stock, net	107,613	—
Proceeds from exercise of stock options	3,023	2,579
Repurchase of shares to satisfy tax withholding obligations	(1,855)	(13,584)
Net cash provided by (used in) financing activities	108,781	(11,005)
Net increase in cash and cash equivalents and restricted cash	4,255	28,795
Cash, cash equivalents and restricted cash at beginning of period	61,333	9,196
Cash, cash equivalents and restricted cash at end of period	$65,588	$37,991
Supplemental schedule of noncash investing activities		
Unpaid property and equipment included in accrued liabilities	$132	$1,213

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	$64,045	$36,448
Restricted cash at end of period	1,543	1,543
Cash, cash equivalents and restricted cash at end of period	$65,588	$37,991

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

FIVE PRIME THERAPEUTICS, INC.

Notes to Condensed Financial Statements

September 30, 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 September 30, 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, 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, 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, the amount of which is subject to reduction starting on January 1, 2023 if certain conditions are met, for the duration of this lease.

Fair Value of Financial Instruments

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

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

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

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

We determine the fair value of Level 1 assets using quoted prices in active markets for identical assets. We review trading activity and pricing for Level 2 investments as of each measurement date. Level 2 inputs, which are obtained from various third-party data providers, represent quoted prices for similar assets in active markets and were derived from observable market data, or, if not directly observable, were derived from or corroborated by other observable market data. There were no transfers between Level 1 and Level 2 securities in the periods presented.

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

	September 30, 2018			
		Basis of Fair Value Measurements		
	Total	Level 1	Level 2	Level 3
Assets				
Money market funds	$43,518	$43,518	$—	$ —
U.S. Treasury securities	173,337	173,337	—	—
Agency bonds	16,340	16,340	—	—
Corporate bonds	7,443	—	7,443	—
Commercial paper	60,431	—	60,431	—
Certificate of deposit	1,543	—	1,543	—
Total	$302,612	$233,195	$69,417	$ —

	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 Financial Accounting Standards Board, or FASB, Accounting Standard Update, or ASU 2014-09, Revenue from Contracts with Customers (Topic 606), or Topic 606, using the modified retrospective transition method. 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 upfront and license fees, research, development and other funding or reimbursements, milestone and other contingent payments for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of commercialized products. Arrangements that include upfront payments 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 and other contingent payments represent variable

consideration, and we use the most likely amount method to estimate this variable consideration. Given the high degree of uncertainty around occurrence of these events, we determine the milestone and other contingent amounts to be fully constrained until the uncertainty associated with these payments is resolved. We will recognize revenue from sales-based royalty payments when or as the sales occur. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

A performance obligation is a promise in a contract to transfer a distinct good or service and is the unit of accounting in Topic 606. A contract's transaction price is allocated among each distinct performance obligation based on relative standalone selling price and recognized as revenue when, or as, the applicable performance obligation is satisfied. Under Topic 606, we elected to use the practical 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 applies to 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Options to purchase common stock	3,830	3,848	3,934	3,813
Restricted stock awards (RSAs)	1,078	850	975	909
	4,908	4,698	4,909	4,722

Accounting Pronouncements Adopted in 2018

In May 2014, FASB issued Topic 606, which supersedes nearly all existing revenue recognition guidance under GAAP. 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 as a result, more judgment and estimates may be required in the course of the revenue recognition process, including with respect to 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 Topic 606, effective January 1, 2018, using the modified retrospective transition method, in which the new 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. Additionally, we determined that the classification between deferred revenue, current portion, and deferred revenue, long-term portion, changed as a result of adoption of Topic 606. We concluded that we will classify deferred revenue for all licensing and collaboration arrangements as deferred revenue, long-term portion, and will reclassify to deferred revenue, current portion, when the remaining term of the estimated performance period is one year or less.

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

Condensed Statements of Operations

(in thousands, except per share data)	Three Months ended September 30, 2018

	Under Topic 606	Under Topic 605	Effect of change
Collaboration and license revenue	$5,771	$8,131	$(2,360)
Operating expenses	54,519	54,519	—
Operating loss	$(48,748)	$(46,388)	$(2,360)
Net loss	$(47,244)	$(44,884)	$(2,360)
Net loss per share applicable to common stockholders - basic and diluted	$(1.37)	$(1.30)	$(0.07)

	Nine Months ended September 30, 2018		
(in thousands, except per share data)	Under Topic 606	Under Topic 605	Effect of change
Collaboration and license revenue	$45,837	$47,184	$(1,347)
Operating expenses	151,711	151,711	—
Operating loss	$(105,874)	$(104,527)	$(1,347)
Net loss	$(101,694)	$(100,347)	$(1,347)
Net loss per share applicable to common stockholders - basic and diluted	$(3.01)	$(2.97)	$(0.04)

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Condensed Balance Sheets

	As of September 30, 2018		
(in thousands)	Under Topic 606	Under Topic 605	Effect of change
Receivables from collaborative partner	$5,015	$5,015	$—
Deferred revenue, current portion	1,687	8,817	(7,130)
Deferred revenue, long-term portion	11,400	4,296	7,104
Accumulated deficit	(255,927)	(255,953)	26

Condensed Statements of Cash Flows

	Nine Months ended September 30, 2018		
(in thousands)	Under Topic 606	Under Topic 605	Effect of change
Net loss	$(101,694)	$(100,347)	$(1,347)
Decrease in deferred revenue in connection with Topic 606 adoption	1,373	—	1,373
Changes in operating assets and liabilities			
Receivables from collaborative partner	8,118	8,118	—
Deferred revenue	(9,848)	(9,822)	(26)
Cash, cash equivalents and restricted cash at beginning of period	61,333	61,333	—
Cash, cash equivalents and restricted cash at end of period	65,588	65,588	—

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 did not have any arrangements within the scope of ASU 2017-09 as of the adoption date, and therefore the adoption of ASU 2017-09 had no effect on our financial position, results of operations or liquidity.

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 ASU 2016-18 had no effect on our financial position, results of operations or liquidity.

In June 2018, FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting, or ASU 2018-07. ASU 2018-07 expanded the scope of Topic 718, which previously included only share-based payments to employees, to include share-based payments issued to

nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity–Equity-Based Payments to Non-Employees. ASU 2018-07 is effective for public companies for fiscal years, and interim fiscal periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606. We early adopted ASU 2018-07 in the second quarter of 2018. No adjustment was required as a result of this adoption.

Accounting Pronouncements Not Yet Adopted

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

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

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

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 right-to-use lease assets and lease liabilities. 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. Further, we expect to recognize lease liabilities and right-of use assets on our balance sheet.

3.Cash Equivalents and Marketable Securities

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

	September 30, 2018		
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value

Money market funds	$43,518	$ —	$ —	$43,518
U.S. Treasury securities	173,573	—	(235)	173,338
Agency bonds	16,353	—	(14)	16,339
Corporate bonds	7,444	—	(1)	7,443
Commercial paper	60,431	2	(2)	60,431
Total cash equivalents and marketable securities	301,319	2	(252)	301,069
Less: cash equivalents	(43,518)	—	—	(43,518)
Total marketable securities	$257,801	$ 2	$ (252)	$257,551

	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 September 30, 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	$257,801	$257,551
Total marketable securities	$257,801	$257,551

We determined that the gross unrealized losses on our marketable securities as of September 30, 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 September 30, 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	668,600	18.35	
Options exercised	(230,267)	9.60	
Options forfeited	(277,106)	34.19	
Options expired	(306,909)	35.82	

Balance at September 30, 2018	3,721,963	28.74	7.08
Options exercisable at September 30, 2018	2,184,478	25.65	6.01

We have granted restricted stock awards, or RSAs, some of which were 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	656,675	18.07
RSAs vested	(282,056)	40.37
RSAs forfeited	(202,460)	34.24
Unvested balance at September 30, 2018	975,576	26.53

As of September 30, 2018, there were 1,985,457 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$4,084	$3,411	$12,073	$14,627
General and administrative	3,549	3,653	10,816	12,085
Total	$7,633	$7,064	$22,889	$26,712

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (years)	6.3	6.3	5.5-6.3	5.5-6.3
Expected volatility	68%	66%	68%-70%	66%-68%
Risk-free interest rate	2.9%	1.9%	2.6-2.9%	1.9-2.1%
Expected dividend yield	0%	0%	0%	0%

As of September 30, 2018, we had $30.8 million of total unrecognized compensation expense related to unvested stock options that we expect to recognize over a weighted-average period of 2.4 years. Additionally, we had $19.9 million of total unrecognized compensation expense related to employee and director RSAs that we expect to recognize over a weighted-average period of 1.9 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 nine months ended September 30, 2018 in the balances of our contract assets, including receivables from collaboration partners, and contract liabilities, including deferred revenue, as compared to what we disclosed in our Annual Report.

(in thousands)	Contract Assets
Balance at January 1, 2018	$ 13,133
Additions	36,950
Deductions	(45,068)
Balance at September 30, 2018	$ 5,015

(in thousands)	Contract Liabilities
Balance at January 1, 2018	$ 21,563
Additions for advance billings	3,590
Deductions for performance obligations satisfied in current period	(9,887)
Deductions for performance obligations satisfied in the prior periods in connection with updates to the measure of progress	(2,179)
Balance at September 30, 2018	$ 13,087

Bristol-Myers Squibb Company

Immuno-Oncology Research Collaboration

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

We identified one performance obligation under the immuno-oncology research collaboration for the research license to access our technology, the exclusive commercial license and research activities. BMS's 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 upfront fee, $13.7 million of research funding and $2.4 million of equity premium. We concluded that the transaction price should not include the variable consideration related to maintenance fees and unachieved clinical and regulatory development milestones as this consideration was considered to be constrained 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 payments (including milestones and royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation, or the occurrence of the related sales. We will re-evaluate the transaction price at each reporting period. For the three and nine months ended September 30, 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 method 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 was $1.7 million and $4.9 million, for the three and nine months ended September 30, 2018, respectively. Through September 30, 2018, we have recognized $33.4 million of the transaction price as collaboration revenue under the agreement. We will recognize the remaining transaction price of $2.6 million 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 a Phase 1a/1b 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 upfront 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 by our clinical research organization, or CRO, as a percentage of total budgeted costs as we complete our performance obligation. We will recognize revenue from reimbursements when we have the right to invoice BMS. No adjustment was necessary upon adoption of Topic 606. We recognized $0.8 million and $6.1 million of revenue allocated to the performance obligation for the three and nine months ended September 30, 2018, respectively. Total revenue recognized for the three and nine months ended September 30, 2018, including progress made toward the performance obligation and reimbursements and excluding milestones, was $2.6 million and $11.5 million, respectively. Through September 30, 2018, we recognized $24.3 million of the transaction price as collaboration revenue under the original collaboration agreement. The remaining transaction price of $5.7 million is recorded in deferred revenue as of September 30, 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 grant 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 milestone payments that may become due as they are fully constrained. We will recognize any consideration related to royalties when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized upon the occurrence of the related sales. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and nine months ended September 30, 2018, no adjustments were made to the transaction price.

The $350.0 million non-refundable upfront fee was fully recognized concurrent with the transfer of the license and know-how in 2015. As such, no adjustment to revenue was 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. For the three months ended September 30, 2018, no milestone payments were triggered under the cabiralizumab collaboration agreement.

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.

In our evaluation of the China collaboration agreement under Topic 606, we identified the following performance obligations: (1) license grant to Zai Lab together with the transfer of licensed know-how, development drug supply and global development activities; (2) commercial drug supply; and (3) development of companion diagnostics. In September 2018, we recorded a $1.7 million receivable related to Zai Lab's $2.0 million clinical development milestone payment, net of value-added tax and other withholdings of $0.3 million, which became due upon dosing of the first patient in the Phase 3 registrational trial of bemarituzumab (FPA144) in combination with mFOLFOX6 as front-line treatment of patients with gastric or GEJ cancer that overexpresses FGFR2b, which we refer to as our FIGHT trial. The $5.0 million non-refundable upfront fee, net of value-added tax and other withholdings of $0.8 million, the $9.7 million of expected reimbursement from Zai Lab for global development activities and the $1.7 million clinical development milestone payment are included as part of the transaction price. We determined the $9.7 million of expected reimbursements from Zai Lab based on the probability-weighted amounts of a range of possible consideration amounts. We have not included the regulatory milestone payments in the transaction price as all such milestone amounts are fully constrained. We will recognize any consideration related to royalties when the related sales occur, as we determined that these amounts relate predominantly to the license granted and therefore will be recognized upon the occurrence of the related sales. Zai Lab has the option to purchase commercial drug supply from us pursuant to a separate commercial supply agreement to be negotiated in the future and we will include any additional consideration to us for such supply in the transaction price. We concluded that the reimbursement of costs incurred for the development of companion diagnostics qualifies for the practical expedient under Topic 606, which allows us to recognize revenue in the amount for which we have a right to invoice if our right to consideration is an amount that corresponds directly to the value to Zai 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 September 30, 2018, there was a $1.4 million increase in the transaction price to $15.6 million from June 30, 2018 of $14.2 million, primarily due to the milestone payment triggered by the dosing of the first patient in the Phase 3 FIGHT trial.

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 by our CRO as a percentage of total budgeted costs as we complete our performance obligation. We will recognize revenue from reimbursements for commercial drug supply pursuant to any commercial supply agreement 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 and nine months ended September 30, 2018, revenue recognized for the license grant performance obligation was $0.5 million and $1.1 million, respectively. Total revenue recognized for the companion diagnostics development performance obligation was $1.0 million and $3.0 million for the three and nine months ended September 30, 2018, respectively. Of the remaining transaction price of $14.5 million, we recorded $5.7 million in deferred revenue, which we will recognize over the estimated performance period for satisfaction of the performance obligations. The remaining $8.8 million of the transaction price will be recorded in deferred revenue when invoiced as we complete global development activities.

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 Glaxo Group Limited, or GSK, to identify new therapeutic approaches to treat refractory asthma and chronic obstructive pulmonary disease, or COPD, with a particular focus on identifying novel protein therapeutics and antibody targets. In January 2016, we amended our respiratory diseases collaboration to extend the research term by three months to July 2016 to allow additional validation of the protein targets we discovered and to increase the research funding. In July 2010, we entered into a research collaboration and license agreement, or the muscle diseases collaboration, with GlaxoSmithKline LLC, 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 terminated in April 2018.

Based on our assessment of the respiratory diseases collaboration and the muscle disease collaboration under Topic 606, we identified one performance obligation under each collaboration for the research license and research activities. The non-refundable upfront fees, the equity premiums and the variable consideration for research activities are included as part of the transaction prices for each collaboration. 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 payments (including milestones royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation, or the occurrence of the related sales. Under the respiratory diseases collaboration, additional research funding that GSK had the option to add was also not included in the transaction price. As the muscle diseases collaboration with GlaxoSmithKline LLC terminated in April 2018, we are no longer eligible to receive milestone payments or royalties under that collaboration. We will re-evaluate the transaction price for the respiratory diseases collaboration in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and nine months ended September 30, 2018, no adjustments were made to the transaction prices of the collaborations with GSK or GlaxoSmithKline LLC.

Under the respiratory diseases collaboration and the muscle diseases collaboration, the non-refundable upfront fees, the equity premiums and the payment for research activities were fully recognized in 2016 and 2014, respectively. As the performance obligations were fully satisfied in prior years, no adjustment to revenue was 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, or CNS, disorders.

Based on our assessment of the fibrosis and CNS collaboration under Topic 606, 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 upfront fee, the $6.6 million technology access fee, the $1.0 million reimbursement for reagent costs and the $2.0 million of research funding. 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 payments (including milestones and royalties) when the related sales occur, as we have determined that these amounts relate predominantly to the license granted and therefore will be recognized on the later to occur of satisfaction of the performance obligation, or the occurrence of the related sales. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur. For the three and nine months ended September 30, 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 method 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. For the three months ended September 30, 2018, no milestone payments were triggered under

the fibrosis and CNS collaboration.

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, or this report, 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. Our primary focus is in immuno-oncology, an area in which we have clinical, preclinical, research and discovery programs and 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. The most advanced product candidates we or our partners are advancing are identified below.

- Bemarituzumab (FPA144) is an antibody that inhibits fibroblast growth factor receptor 2b, or FGFR2b, that we are studying in a clinical trial in combination with 5-fluorouracil (5-FU), leucovorin and oxaliplatin, a standard-of-care chemotherapy regimen known as mFOLFOX6, as front-line treatment of patients with gastric (stomach) or gastroesophageal junction, or GEJ, cancer that overexpresses FGFR2b. In December 2017, we 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.
- Cabiralizumab (FPA008) is an antibody that inhibits colony stimulating factor-1, or CSF1, receptor, or CSF1R, that we and our partner Bristol-Myers Squibb Company, or BMS, are studying in clinical trials in multiple cancers in combination with BMS'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 BMS pursuant to which we granted BMS an exclusive worldwide license for the development and commercialization of cabiralizumab.
- FPA150 is a CD8 T-cell checkpoint inhibitor antibody that targets B7-H4 that we are studying in a clinical trial as monotherapy in multiple cancers.
    - FPT155 is a soluble CD80 fusion protein that activates T-cells through multiple pathways that we are studying in a clinical trial as monotherapy in multiple cancers.
- BMS-986258 is an anti-T-cell immunoglobulin and mucin domain-3, or TIM-3, antibody that our partner, BMS, is studying in a clinical trial as a single agent and in combination with each of Opdivo and Halozyme Therapeutics, Inc.'s recombinant human hyaluronidase enzyme, or rHuPH20, in patients with advanced malignant tumors.

Our differentiated target discovery platform and protein therapeutic capabilities position us to explore pathways in cancer and inflammation and their intersection in immuno-oncology, an area of oncology with significant therapeutic potential and the focus of our activities. We apply our biologics discovery platform to identify and validate targets that we believe could be useful in immuno-oncology and generate and preclinically test therapeutic proteins, including antibodies and fusion proteins, directed to or containing the targets we identify and validate. We plan to continue to advance selected therapeutic candidates into clinical development.

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 upfront payment we received from a collaboration partner. For the nine months ended September 30, 2018 and 2017, we reported a net loss of $101.7 million and $121.0 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 this report which we prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim periods and with Regulation S-X promulgated under the Securities and Exchange Act of 1934, as amended, or the Exchange Act.

Product Pipeline

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

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* Partnered with Zai Lab – see "Part I—Item 1. Collaborations" of our Annual Report for a description of our China collaboration agreement with Zai Lab.

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

† Clinical development is being conducted exclusively by BMS.

†† Clinical development is being conducted by the University of California, San Diego, the sponsor of the trial, in collaboration with Stand Up To Cancer and BMS.

‡ Clinical development is being conducted by the Yale Cancer Center, the sponsor of the trial, in collaboration with Apexigen, Inc. and BMS.

Bemarituzumab (FPA144)

We are conducting a Phase 3 registrational trial of bemarituzumab in combination with mFOLFOX6 as front-line treatment of patients with gastric or GEJ cancer that overexpresses FGFR2b, which we refer to as our FIGHT trial. In September 2018, we completed the Phase 1 safety lead-in and initiated the randomized, controlled Phase 3 FIGHT trial. In the FIGHT trial, we will evaluate bemarituzumab at a dose of 15mg/kg in combination with mFOLFOX6 against placebo in combination with mFOLFOX6 in approximately 550 patients with advanced gastric or GEJ cancer. We will conduct the FIGHT trial at over 200 clinical trial sites in North America, Europe and Asia. We are conducting the trial in China in collaboration with Zai Lab. We continue to engage with regulatory authorities in several countries to obtain approval to initiate the FIGHT trial in those countries.

We are identifying patients for inclusion in the FIGHT trial using both 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 FGFR2 gene amplification in the blood is an indirect way of identifying tumors with FGFR2b 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 and are using them concurrently to more effectively identify the estimated 10% of gastric and GEJ cancer patients whose tumors overexpress FGFR2b or amplify the FGFR2 gene and would be eligible to participate in this trial. We plan to pursue regulatory approval of each companion diagnostic contemporaneously with regulatory approval of bemarituzumab.

An abstract featuring data on bemarituzumab in combination with mFOLFOX6 from the Phase 1 safety lead-in of our FIGHT trial has been accepted as a poster presentation at the American Society of Clinical Oncology's Gastrointestinal

Cancers Symposium in January 2019.

Cabiralizumab (FPA008)

Cabiralizumab in Immuno-Oncology

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

BMS 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 in the study approximately 160 pancreatic cancer patients from the United States, Canada, Europe, Japan, Korea and Taiwan, each of whom will be randomized to one of four study arms based on the patient's prior therapy.

Cabiralizumab in PVNS

We are completing a Phase 2 clinical trial of cabiralizumab monotherapy as a potential treatment for diffuse PVNS. In the trial, we are evaluating tumor response rate and duration and measures of pain and joint function in PVNS patients. We initially enrolled and treated 31 patients in the Phase 2 portion of the trial with dosing once every two weeks. Although we observed efficacy, many of these patients did not tolerate this dosing schedule. We amended the Phase 2 trial to add a second cohort to test a less frequent dosing regimen, involving treatment every four to six weeks after two initial doses two weeks apart, that also provides the treating physicians with some flexibility in the dosing schedule in an effort to improve tolerability and optimize the therapeutic index of cabiralizumab in this chronic, non-fatal disease. Although we observed efficacy in this second cohort, the frequency of dose interruptions and discontinuations suggests that the revised dosing schedule is unlikely to be optimal for a pivotal trial in PVNS. Accordingly, we have suspended enrollment in the trial and have decided not to advance cabiralizumab into a pivotal trial in PVNS.

FPA150

We are conducting a Phase 1a/1b clinical trial of FPA150 in multiple cancers. We are currently dosing patients in the Phase 1a dose escalation portion of the trial, during which we are evaluating FPA150 monotherapy in advanced solid tumors. We are advancing through the Phase 1a dose escalation portion of the trial and are currently evaluating the seventh of eight expected dose levels.

In October 2018, we completed a Phase 1a dose escalation cohort testing a dose that has shown efficacy in preclinical models. After completing this Phase 1a dose cohort, we initiated patient dosing at this dose in an exploratory cohort to investigate FPA150 monotherapy in patients with tumors that overexpress B7-H4, with the objective of gaining additional data on safety, pharmacokinetics and potential preliminary clinical activity of FPA150 at multiple dose levels. We plan to enroll up to 10 patients whose tumors overexpress B7-H4 in this exploratory cohort. All patients in the exploratory cohort will undergo pre- and on-treatment biopsies to assess the pharmacodynamic effects of FPA150 on the tumor and the tumor microenvironment.

After completing the Phase 1a dose escalation portion of the trial, we plan to select a dose and initiate the Phase 1b expansion portion of the trial. In the Phase 1b expansion portion of the trial, we plan to evaluate FPA150 monotherapy in various disease-specific cohorts of patients whose tumors overexpress B7-H4, initially, in HR+/HER2- and triple negative breast cancers, ovarian cancer and endometrial cancer. We may also evaluate FPA150 in combination with other therapies during the course of the Phase 1b expansion portion of the trial.

We have developed a lab-developed IHC-based assay to identify patients whose tumors overexpress B7-H4 and would be eligible for inclusion in the exploratory cohort and the Phase 1b portion of the trial.

FPT155

In October 2018, we opened enrollment in a Phase 1a/1b clinical trial of FPT155 in Australia in patients with solid tumors. Because we expect FPT155 to have an immunomodulatory effect and our Phase 1a/1b trial is the first-in-human evaluation of FPT155, the starting dose of the dose escalation portion of the trial will be lower than what we would select for a development candidate that does not have an immunomodulatory effect. We plan to also open an exploratory cohort during the Phase 1a dose escalation portion of the trial after completing a cohort testing a dose that has shown efficacy in preclinical models. In the exploratory cohort, we will investigate FPT155 monotherapy in patients with solid tumors, with the objective of gaining data on safety, pharmacokinetics and potential preliminary single agent clinical activity of FPT155. In the Phase 1b expansion portion of the trial, we plan to evaluate FPT155 in various disease-specific cohorts of patients.

BMS-986258

BMS is conducting a Phase 1/2 clinical trial of BMS-986258, its anti-TIM-3 antibody, as a single agent, in combination with Opdivo, and in combination with Halozyme Therapeutics, Inc.'s rHuPH20 in patients with advanced malignant tumors (NCT03446040). BMS-986258 is BMS's first clinical candidate arising from our March 2014 immuno-oncology research collaboration with BMS.

BMS submitted an abstract titled "Preclinical Studies of TIM-3 Blockade Supporting Clinical Development of BMS-986258, an Anti TIM-3 Monoclonal Antibody" for presentation at the Society for Immunotherapy of Cancer Annual Meeting.

Financial Overview

Collaboration and License Revenue

We have not generated any revenue from product sales. We have derived our revenue to date from upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaboration partners and licensees. We currently have an active immuno-oncology research collaboration and our cabiralizumab license and collaboration agreement with BMS and an active collaboration and license agreement with Zai Lab. We completed the research terms of our research collaboration in respiratory diseases with GSK and of 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 and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2018	2017	2018	2017
Milestone Payments				
Cabiralizumab Collaboration - BMS	—	—	25.0	—
Fibrosis and CNS Collaboration - UCB	—	0.1	0.3	0.3
Respiratory Diseases Collaboration - GSK	—	0.5	—	0.5
Other Payments				
China Collaboration - Zai Lab	1.5	—	4.1	—
Cabiralizumab Collaboration - BMS	2.6	5.2	11.5	17.8
Immuno-oncology Research Collaboration - BMS	1.7	1.7	4.9	5.4
Fibrosis and CNS Collaboration - UCB	—	0.8	—	2.3
Total	$ 5.8	$ 8.3	$45.8	$26.3

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

of entry into any new collaborations and license agreements.

Research and Development

Research and development expenses consist of costs we incur 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 discovery, preclinical study and clinical trial expenses based on the services performed pursuant to contracts with clinical research institutions, or CROs, and contract manufacturing organizations, or CMOs, that conduct and manage preclinical studies and clinical trials and produce clinical trial material 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. We have experienced changes in our estimates of research and development accruals.

We expense costs for the acquisition and development of technology as research and development costs if, at the time of incurring the obligation, 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 and nine months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2018	2017	2018	2017
Clinical development programs:				
Cabiralizumab	$4.4	$6.4	$12.4	$22.9
Bemarituzumab	23.0	12.2	50.4	25.7
FPA150	3.8	—	13.2	—
FP-1039	—	0.7	—	1.4
Subtotal clinical development programs	31.2	19.3	76.0	50.0
Preclinical programs	3.9	15.9	15.8	42.5
Discovery collaborations	0.9	0.7	2.5	3.2
Early research and discovery	8.7	6.8	27.3	22.5
Total research and development expenses	$44.7	$42.7	$121.6	$118.2

We expect that most of the research and development expenses we incur will continue to relate to activities to support our cabiralizumab, bemarituzumab, FPA150 and FPT155 clinical development programs, preclinical programs and other 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 our development-related expenses to increase as our bemarituzumab program advances through our Phase 3 FIGHT trial and as our FPA150 and FPT155 programs advance through Phase 1a/1b clinical trials and beyond.

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

The successful development of our drug candidates is highly uncertain and may not result in products that are approved for marketing by the FDA or any comparable foreign regulatory authority. The costs and duration of the processes necessary to achieve marketing approval for each drug candidate can vary significantly and are difficult to predict. Given the uncertainty associated with clinical trial patient enrollment and the risks inherent in the development process, estimating the duration and completion costs of current or future clinical trials of our drug candidates or if, or to what extent, we will generate revenues from the commercialization and sale of any of our approved drug candidates is difficult and uncertain. We anticipate we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the outcome of

research, preclinical and clinical activities with respect to each drug candidate, as well as ongoing assessments as to each drug candidate's commercial potential. We will need to raise additional capital and may seek to enter into additional collaborations in the future to advance and complete the development and commercialization of our current and future drug candidates.

General and Administrative

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

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 ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, and these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results under different assumptions and conditions may differ from these estimates. Our significant accounting policies are more fully described in Note 2 of the accompanying unaudited 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 September 30, 2018 and 2017

	Three Months Ended September 30,	
(in millions)	2018	2017
Collaboration and license revenue	$5.8	$8.3
Operating expenses:		
Research and development	44.7	42.7
General and administrative	9.8	9.7
Total operating expenses	54.5	52.4
Interest income	1.5	0.8
Loss before income tax	(47.2)	(43.3)
Net loss	$(47.2)	$(43.3)

Collaboration and License Revenue

Collaboration and license revenue decreased by $2.5 million, or 30%, to $5.8 million for the three months ended September 30, 2018 from $8.3 million for the three months ended September 30, 2017. This decrease was primarily due to a $2.7 million decrease in collaboration funding from our cabiralizumab collaboration with BMS as our Phase 1a/1b trial of cabiralizumab in combination with Opdivo, or our Phase 1a/1b combination trial, completed enrollment, a $0.8 million decrease in revenue from the fibrosis and CNS collaboration with UCB primarily due to the completion of the performance obligation under this agreement and a $0.5 million decrease in revenue from the respiratory diseases collaboration with GSK. This was offset by a $1.5 million increase in collaboration and license revenue from our China collaboration with Zai Lab.

Research and Development

Our research and development expenses increased by $2.0 million, or 4.7%, to $44.7 million for the three months ended September 30, 2018 from $42.7 million for the three months ended September 30, 2017. This increase was due to $10.4 million in milestone payments triggered by the dosing of the first patient in our Phase 3 FIGHT trial, a $1.6

million increase in employee compensation, an increase in clinical trial expenses of $1.8 million and $0.8 million for our FIGHT trial and our Phase 1a/1b FPA150 trial, respectively, a $0.5 million increase in facility costs and $0.3 million in other items. The increases were offset by a $7.8 million decrease in manufacturing costs to advance our FPA150 and FPA155 preclinical programs and for the FPA154 program, which we terminated in 2017. Further, there was a $3.3 million decrease in companion diagnostic expense directed towards our bemarituzumab development program, a decrease in clinical trial expenses of $1.8 million related to our cabiralizumab program, and a decrease of $0.7 million in licensing fees for FPA150.

General and Administrative

Our general and administrative expenses increased by $0.1 million, or 1%, to $9.8 million for the three months ended September 30, 2018 from $9.7 million for the three months ended September 30, 2017. This increase was primarily due to a $0.5 million increase in patent and legal expenses and a $0.2 million increase in expenses related to temporary employees, contractors, consultants and outside service providers offset by decreases of $0.3 million in compensation costs and $0.3 million in other miscellaneous costs.

Income Tax Provision

We did not record an income tax provision as a result of our net operating losses for the three months ended September 30, 2018 or for the three months ended September 30, 2017.

Comparison for the Nine Months Ended September 30, 2018 and 2017

(in millions)	Nine Months Ended September 30, 2018	2017
Collaboration and license revenue	$45.8	$26.3
Operating expenses:		
Research and development	121.6	118.2
General and administrative	30.1	29.5
Total operating expenses	151.7	147.7
Interest income	4.2	2.2
Loss before income tax	(101.7)	(119.3)
Income tax provision	—	(1.7)
Net loss	$(101.7)	$(121.0)

Collaboration and License Revenue

Collaboration and license revenue increased by $19.5 million, or 74%, to $45.8 million for the nine months ended September 30, 2018 from $26.3 million for the nine months ended September 30, 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 Phase 2 clinical trial of cabiralizumab in combination with Opdivo, with and without chemotherapy, as a treatment for patients with second-line pancreatic cancer as well as an increase of $4.1 million of collaboration and license revenue from our collaboration with Zai Lab. This increase was offset by a $6.3 million decrease in collaboration funding from our cabiralizumab collaboration with BMS as our Phase 1a/1b combination trial completed enrollment, a $2.3 million decrease from the fibrosis and CNS collaboration with UCB due to the completion of the performance obligation under this agreement, a $0.5 million decrease from our immuno-oncology research collaboration with BMS and a $0.5 million decrease in revenue from the respiratory diseases collaboration with GSK.

Research and Development

Our research and development expenses increased by $3.4 million, or 2.9%, to $121.6 million for the nine months ended September 30, 2018 from $118.2 million for the nine months ended September 30, 2017. This increase was due to $10.4 million in milestone payments associated with the first patient dosed in our FIGHT trial, a $6.4 million increase in the cost to develop companion diagnostics for use in our bemarituzumab development program, a $3.1 million increase in facility and depreciation costs, a $1.6 million increase in expense related to temporary employees, contractors, consultants and other outside services and a $0.7 million increase in lab supplies and other lab costs. These increases were offset by a $12.2 million decrease in manufacturing costs to advance our FPA150 and FPT155 programs and for the FPA154 program, which we terminated in 2017, a $6.1 million decrease in preclinical expenses to advance FPA150 towards clinical development in 2017 and for preclinical expenses and licensing fees associated with the FPA154 program, which we terminated in 2017 and a $0.4 million decrease in employee compensation.

General and Administrative

Our general and administrative expenses increased by $0.6 million, or 2.0%, to $30.1 million for the nine months ended September 30, 2018 from $29.5 million for the nine months ended September 30, 2017. The increase was primarily due to a $1.7 million increase in expenses related to temporary employees, contractors, consultants and outside services and $0.9 million increase in legal and patent expenses. This increase was offset by a $2.0 million decrease in compensation costs primarily due to lower stock compensation expense.

Income Tax Provision

We did not record an income tax provision as a result of our net operating losses for the nine months ended September 30, 2018. We recognized a tax expense of $1.7 million for the nine months ended September 30, 2017 as a result of deficiency interest based on the Internal Revenue Service reducing our tentative net operating loss carryback refund claim filed in March 2017.

Liquidity and Capital Resources

As of September 30, 2018, we had $321.6 million in cash, cash equivalents and marketable securities invested in a U.S. Treasury money market fund, U.S. Treasury securities, agency bonds, corporate bonds and commercial paper with maturities of 11 months or less.

In addition to our existing cash and cash equivalents, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain nonclinical, clinical, regulatory and sales-based events and royalty payments under our collaboration and license agreements. Our ability to earn these milestone and contingent payments and the timing of receiving any such payments is primarily dependent upon the outcome of our collaborators' and licensees' research and development activities and remains uncertain. Our rights to payment under our collaboration and license agreements are our only committed external sources of funds.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third party clinical and preclinical research and development services, including clinical trial, manufacturing, laboratory and related services and supplies, legal, patent and other regulatory expenses and general overhead costs. We believe our use of CROs and CMOs provides us with flexibility in managing our spending and limits our cost commitments at any point in time.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot predict the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether or when we may achieve profitability. Until such time that we can generate substantial product revenues, if ever, we expect to finance our cash needs through collaboration arrangements and, if necessary, equity or debt financings. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone or royalty payments under our agreements with them, we will not have any committed external sources of liquidity. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of September 30, 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 nine months ended September 30, 2018 and 2017:

	Nine Months Ended

(in millions)	September 30, 2018	2017
Net cash used in operating activities	$(69.9)	$(84.7)
Net cash (used in) provided by investing activities	(34.6)	124.5
Net cash provided by (used in) financing activities	108.8	(11.0)

Net Cash Used in Operating Activities

Net cash used in operating activities was $69.9 million for the nine months ended September 30, 2018 and consisted of net loss of $101.7 million, offset by $25.6 million in net non-cash charges and $4.6 million from changes in operating assets and liabilities. Net non-cash charges included $3.7 million of depreciation and amortization expenses, $22.9 million for stock-based compensation expense and $1.0 million for amortization of premiums and discounts on marketable securities. Net cash used in operating activities included $34.5 million from milestones and upfront payments from our collaboration partners.

Net cash used in operating activities was $84.7 million for the nine months ended September 30, 2017 and consisted of our net loss of $121.0 million, offset by $29.9 million in net non-cash charges and $6.4 million from changes in operating assets and liabilities. Net non-cash charges included $1.7 million of depreciation and amortization expenses, $26.7 million for stock-based compensation expense and $1.5 million for amortization of premiums and discounts on marketable securities.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $34.6 million for the nine months ended September 30, 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 $11.1 million during the nine months ended September 30, 2018. The property and equipment purchases consisted primarily of charges related to tenant improvement to our corporate office and laboratory facility and purchases of laboratory equipment to support our research and development activities.

Net cash provided by investing activities was $124.5 million for the nine months ended September 30, 2017. Net cash provided by investing activities for the period presented primarily relates to maturities of marketable securities exceeding purchase of such marketable securities. Payments for the purchases of property and equipment was $3.6 million during the nine months ended September 30, 2017. The property and equipment purchases consisted primarily of purchases of laboratory equipment to support our research and development activities.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $108.8 million for the nine months ended September 30, 2018, which consisted primarily of $107.6 million in net proceeds from the public offering of our common stock in January 2018 and $3.0 million received from employee stock option exercises. This was offset by $1.8 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards.

Net cash used in financing activities was $11.0 million for the nine months ended September 30, 2017 and consisted primarily of $13.6 million paid to satisfy tax withholding obligations from the net share issuance of restricted stock awards offset by $2.6 million received from employee stock option exercises.

Contractual Obligations and Contingent Liabilities

During the three months ended September 30, 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 September 30, 2018, we had cash and cash equivalents and marketable securities of $321.6 million, consisting of bank deposits, interest-bearing money market accounts, a U.S. Treasury money market fund, U.S. Treasury securities, agency bonds, corporate bonds and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our cash equivalents and marketable securities have an average maturity of approximately five months and the longest maturity is 11 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 bemarituzumab, cabiralizumab, FPA150 and FPT155 product candidates. Our ability to generate product revenues, which we do not expect to occur for many years, if ever, will depend heavily on our and our partners' ability to successfully develop our cabiralizumab, bemarituzumab, FPA150 and FPT155 product candidates and our ability to identify and validate new targets and product candidates and identify and advance preclinical product candidates into and through clinical development. The outcome of preclinical studies of our product candidates may not predict the success of such product candidates in clinical trials. Moreover, preclinical results regarding a product candidate are often susceptible to varying interpretations and analyses and may not translate into similar results when the product candidate is tested clinically in humans. Many companies have believed their product candidates performed satisfactorily in preclinical and early clinical studies, but such product candidates have nonetheless failed during clinical development. Our inability to successfully complete preclinical or clinical development of our product candidates could cause us to incur additional costs, delay or prevent our ability to advance product candidates into clinical development or commercialization, or impair our ability to receive development, regulatory, commercialization or sales milestone payments from our current or future collaboration partners, or to generate and receive royalties on product sales or product revenues from our current or future collaboration partners.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our partners must conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive and difficult to design and implement, generally takes many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a

clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles of their product candidates, notwithstanding promising results in earlier trials. Despite the results already reported from preclinical studies and clinical trials of our product candidates, we do not know whether the clinical trials of those of our product candidates that we or our partners may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of these product candidates in any particular jurisdiction or jurisdictions. If later-stage clinical trials for one or more of our product candidates do not produce favorable results, we or our partners may be unable to 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 and when planned, will need to be amended or restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Events which may result in a delay in or unsuccessful completion of clinical development include:

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

For example, we are planning to conduct our Phase 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 or gastroesophageal junction, or GEJ, cancer with tumors that overexpress FGFR2b, or our FIGHT trial, at over 200 clinical trial sites in North America, Europe and Asia. Our ability to conduct the FIGHT trial in accordance with our timelines will depend on our ability to timely contract with, initiate and enroll patients at each of these clinical trial sites. We have not undertaken a trial of this scale as an organization. Delays in contracting with or initiating or conducting our FIGHT trial at one or more of these clinical trial sites may delay our ability to fully enroll the trial in accordance with our timelines and may delay our ability to

obtain approval for and commercialize bemarituzumab.

Moreover, we are conducting the 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 FIGHT trial and will therefore allow us to advance and complete 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 in 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 trial, which would delay our ability to obtain approval for and commercialize bemarituzumab.

In addition, our ability to initiate and conduct the FIGHT trial in each country depends on our ability to obtain sufficient clinical supplies of each component of mFOLFOX6 to administer the mFOLFOX6 regimen to patients in such country. If we have difficulty obtaining or are unable to obtain sufficient supply of any component of the mFOLFOX6 regimen in certain countries, we may experience delays in initiating or conducting our FIGHT trial at clinical trial sites in those countries and in timely enrolling the trial, which would delay our ability to obtain approval for and commercialize bemarituzumab.

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

If we or our partners are unable to timely enroll patients in 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;
- the risk that enrolled patients will drop out before completion; and
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

We 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 our FIGHT trial to evaluate bemarituzumab in gastric and GEJ cancer patients whose tumors overexpress FGFR2b or amplify the FGFR2 gene. Although we believe selecting patients with gastric and GEJ cancer whose tumors overexpress FGFR2b or amplify the FGFR2 gene using an immunohistochemistry-, or IHC-, based or circulating tumor DNA, or ctDNA, blood-based companion diagnostic should increase the percentage of patients eligible for and the probability of success in our FIGHT trial, these selection criteria limit the number of patients eligible for enrollment. Also, if our assumptions regarding the percent of patients with tumors that overexpress FGFR2b or amplify the FGFR2 gene that we expect to identify in the FIGHT trial are lower than we

actually observe, the FIGHT trial will take longer to enroll, we will incur higher costs and the commercial potential for bemarituzumab would be adversely affected. Additionally, Astellas Pharma Inc., or Astellas, is conducting two Phase 3 clinical trials of its zolbetuximab (IMAB362, claudiximab) anti-Claudin 18.2 antibody in combination with mFOLFOX6 or capecitabine and oxaliplatin (CAPOX) as front-line treatment in patients with HER2-negative, Claudin 18.2-positive gastric and GEJ cancer. If Astellas continues the clinical development of zolbetuximab in gastric and GEJ cancer, we may compete with Astellas 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 terminate our development efforts for one or more programs.

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

- our research methodology, including our screening technology, may not successfully identify medically relevant protein therapeutic targets or potential product candidates;
- our discovery platform often identifies novel, untested targets that may be challenging to validate because of the novelty of the target or that we may be unable to validate at all after further research;
- product manufacturing difficulties may limit product yield or produce undesirable product characteristics that 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 product candidates may fail to produce candidates that we can successfully validate or that have the characteristics necessary develop into 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 provide a meaningful benefit to patients or have an unacceptable safety profile; 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 these resources and our efforts on potential discovery efforts, programs or product candidates that ultimately prove to be unsuccessful.

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

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

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

that fail to meet specifications, or 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 or significant increase in the price of these raw materials could considerably delay the manufacture of our product candidates, which could adversely impact the timing of any planned clinical trials or the regulatory approval of those product candidates.

We have process development and small-scale preclinical manufacturing capabilities. We do not have and we do not have current plans to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials or commercialization. In the past we have engaged, and we expect in the future to engage, CMOs for the manufacture of bulk drug substance and drug product for our clinical trials and additional third parties for our supply chain. Any problems we experience with any of these third parties could delay the manufacturing of our product candidates or the progress of our clinical trials, which could harm our results of operations.

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 CMOs. 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 of or a decision not to renew such agreement by such third party, based on its own business priorities, at a time when our finding and retaining a replacement manufacturer may be costly or damaging to our business.

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

The FDA and comparable foreign regulatory authorities extensively and rigorously regulate and evaluate the 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, development and manufacturing, complied with current Good Manufacturing Practices, or GMP, current Good Laboratory Practices, or GLP, and current Good Clinical Practices, or GCP, regulations and standards during such testing and manufacturing. The time required to obtain approval to market a product candidate from the FDA or any comparable foreign regulatory authority is unpredictable but typically takes many years following the commencement of clinical trials and depends on numerous factors, including our and our partners’ conduct of testing, development and manufacturing activities and the substantial discretion of the applicable regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to obtain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any of our product candidates and it is possible that none of our existing product candidates or potential future product candidates will ever obtain regulatory approval.

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

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

The FDA or a comparable foreign regulatory authority may require 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. For example, given the greater potential patient population in China, we plan to enroll a substantial number of the patients in our Phase 3 FIGHT trial at clinical trial sites in China in order to reduce the overall time to fully enroll the FIGHT trial and potentially advance and complete the FIGHT trial within a shorter time period. However, we are currently unable to provide regulators with data that demonstrate that patients from our clinical trial sites in China are representative of the general patient population and will respond to bemarituzumab the same way as other patient populations. If we obtain a greater percentage of our positive clinical data from clinical trial sites in China, and an analysis of the data from Chinese patients suggest that other patient populations may not have similar outcomes, the FDA and comparable foreign regulatory authorities may determine that the data we observe in Chinese patients are not sufficient to support regulatory approval for bemarituzumab for the general patient population and may require more clinical data from other patient populations to support regulatory approval for bemarituzumab. This may significantly delay or prevent our ability to timely obtain approval for and to commercialize bemarituzumab.

In addition, if we were to obtain approval for any of our product candidates, regulatory authorities may approve any such product candidate for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or risk evaluation and mitigation strategy, or REMS, drug safety programs, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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

Our product candidates may cause undesirable side effects in patients, which could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority or otherwise limit the commercial potential of any such product candidate. Our clinical trial results could reveal an unacceptable severity or prevalence of side

effects or unexpected characteristics. In such an event, we may elect to suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease our clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment, cause enrolled patients to drop out of a clinical trial and result in product liability claims. Any of these occurrences may significantly harm our business, financial condition and prospects.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by any such product, numerous potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, such product;
- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label for such product;
- regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- regulatory authorities may require the establishment or modification of 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, if approved, and could significantly harm our business, results of operations and prospects.

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

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

For example, we are developing bemarituzumab to treat a subset of patients with gastric or GEJ cancer whose tumors overexpress FGFR2b. We have developed, in collaboration with third-party diagnostic development partners, both an IHC-based assay and a ctDNA blood-based assay to identify gastric and GEJ cancer patients with FGFR2 overexpression or FGFR2 gene amplification who may benefit from treatment with bemarituzumab. We are using both companion diagnostics concurrently to more effectively screen patients for participation in the FIGHT trial. In addition, we are developing FPA150 to treat patients with a variety of cancers whose tumors overexpress the B7-H4 protein. We have developed, in collaboration with a third-party diagnostic development partner, an IHC-based assay for use in clinical trials to identify patients whose tumors overexpress B7-H4. We plan to use this IHC-based assay in the Phase 1b portion of our Phase 1a/1b clinical trial of FPA150.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization, which could delay their development and harm our business. For example, if we or our collaboration partners are unable to obtain any necessary regulatory approvals for our companion diagnostics for bemarituzumab or FPA150, or experience delays in doing so, we may suffer significant negative consequences, including:

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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 overexpression or B7-H4 overexpression, as applicable.

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 in a particular jurisdiction, the product would be subject to ongoing requirements by the FDA or applicable comparable foreign regulatory authorities governing such product's manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or any comparable foreign regulatory authority becomes aware of new safety information after approval of any of our product candidates, it may require labeling changes or establishment of a REMS or similar 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 to evaluate 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 side effects or adverse events of unanticipated severity or frequency, or problems with the facility where such product candidate is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of such product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

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

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

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

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

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

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

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

For example, we are conducting our FIGHT trial for bemarituzumab in China in collaboration with Zai Lab and are relying on Zai Lab’s ability to obtain approval for bemarituzumab in China, Taiwan, Hong Kong and Macau, or collectively, Greater China, from the China Food and Drug Administration. However, Zai Lab’s ability to obtain approval in Greater China depends on Zai Lab’s and our ability to comply with the government policies, laws and regulations applicable to conducting clinical trials and obtaining approval for and commercializing drug products in Greater China. The government policies, laws and regulations in China are evolving rapidly and future changes are difficult to predict. If any such government policies, laws or regulations evolve in a way that make it more difficult or inefficient for Zai Lab or us to clinically develop, obtain approval for or commercialize bemarituzumab in China, we may experience delays in initiating, conducting or completing the FIGHT trial at our clinical trial sites in China and in fully enrolling the FIGHT trial, which will delay our ability to obtain approval for and commercialize bemarituzumab.

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

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

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. We face 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 for their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely 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.

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

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

If cabiralizumab were approved for the treatment of cancer, it could face competition from products currently in development as single agents or in combination with anti-PD-1/PD-L1 agents or other immuno-oncology agents, including 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' BLZ945 CSF1R-directed small molecule and lacnotuzumab (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, each of which acts in the same pathway as cabiralizumab.

If bemarituzumab were approved for the treatment of gastric or GEJ cancer, it could face competition from currently-approved and marketed products, including 5-fluorouracil, S-1, capecitabine, doxorubicin, cisplatin, oxaliplatin, carboplatin, paclitaxel, irinotecan, docetaxel and Cyramza® (ramucirumab), 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/Pfizer's Bavencio® (avelumab), Roche's Tecentriq® (atezolizumab), AstraZeneca UK Limited/MedImmune, LLC's Imfinzi® (durvalumab)

anti-PD-L1 antibody, Astellas's zolbetuximab and AstraZeneca UK Limited/MedImmune, LLC's tremelimumab anti-CTLA4 antibody.

If FPA150 were approved for the treatment of various cancers, it could face competition from currently-approved and marketed products, including cisplatin, carboplatin, gemcitabine, doxorubicin, paclitaxel, topotecan, 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/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, Inc.'s and Astellas' enfortumab vedotin anti-nectin-4 antibody drug conjugate, or ADC; Immunomedics, Inc.'s sacituzumab govitecan (IMMU-132) anti-Trop-2-SN-38 ADC; small molecule poly ADP-ribose polymerase inhibitors, including AstraZeneca UK Limited's Lynparza® (olaparib), 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 among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

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

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

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate 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, even if we obtain marketing approval for a product in a particular country, we may be subject to price regulations that delay the commercial launch of such product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of such product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Our ability to successfully commercialize any products will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover, establish reimbursement levels for medications and attempt to control costs by limiting such coverage and reimbursement levels. Increasingly, third-party payors are requiring that pharmaceutical companies provide such third-party payors with predetermined discounts from list prices and are challenging the prices charged for medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only at 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 any comparable foreign regulatory authority. Moreover, eligibility for coverage and reimbursement does not guarantee that a drug will be paid for in all cases or at a rate that covers our costs, including with respect to research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be provided on a temporary basis. Reimbursement rates may vary depending on the approved uses for the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any of our approved products could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

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

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

In March 2010, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, which includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The federal Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision that, 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, since the Affordable Care Act was enacted, other legislative changes have been proposed and adopted that may impact the extent to which we are able to successfully commercialize any of our product candidates that receive regulatory approval. 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, two percent 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 or maintain 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 from our clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards payable to patients, including those enrolled in our clinical trials;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- inability to commercialize any products that we may develop.

We currently hold $10 million in clinical trial liability insurance coverage, which may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for one or more of our product candidates, but we may be unable to obtain product liability insurance on commercially reasonable terms for any of our products

that have been approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

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

- The federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- The federal false claims laws, including the civil 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 became enforceable on May 25, 2018. As well as complicating our compliance efforts, these laws could subject us to penalties or significant legal liability in the event that we fail 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 four percent of the annual global turnover of the responsible entity, whichever is greater.

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

We must attract and retain highly skilled employees to succeed.

We continue to grow our operations and capabilities as we advance our research and clinical activities, including our advancement of FPA150 and FPT155 into clinical development in multiple cancers, the initiation of our Phase 3 FIGHT trial of bemarituzumab in gastric and GEJ cancer and advancement of our research and preclinical programs. 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, general and administrative and management personnel while facing significant competition for experienced personnel. Our inability or failure to successfully attract and retain qualified personnel, particularly at the management level, could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

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

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

Our computer and other systems, or those of our partners, CROs or other service providers, may fail or be interrupted, including due to fire, earthquake or other natural disasters, hardware, software, telecommunication or electrical failures or terrorism, which could significantly disrupt or harm our business or operations. For example, a computing system failure could result in the loss of research or preclinical or clinical data important to our discovery, research or development programs, interrupt the conduct of ongoing research or otherwise impair our ability to operate, which could result in delays in the advancement of our programs or cause us to incur costs to recover or reproduce lost data. Our facility is in a seismically-active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disaster and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses that may occur from interruption of our business and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our protein libraries, most of which we

maintain at our headquarters in South San Francisco, California. We maintain one copy of each of our protein libraries offsite in Central California. If both facilities were impacted by the same event, we could lose all our protein libraries, which would have a material adverse effect on our ability to discover new targets and develop any resulting product candidates.

We significantly depend 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 or with whom we share confidential information, could cause us significant financial, legal, regulatory, business and reputational harm.

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

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

There is no way 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 sophisticated with respect to concealing their access to systems, and many companies whose information security systems have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including personal information of our employees or patients or investigators in our clinical trials, could disrupt our business, harm our reputation, compel us to comply with applicable federal, state or foreign breach notification laws, subject us to time-consuming, distracting and expensive litigation, regulatory investigations and oversight or mandatory corrective action, require us to verify the correctness of certain stored information, or otherwise subject us to liability under applicable laws, regulations and our contracts with third parties, including those that require us to protect the privacy and security of personal information. This could cause us to incur significant costs and expose us to significant legal and financial liability and reputational harm. In addition, if there is any failure or perceived failure by us or our vendors or business partners to comply with our or their privacy, confidentiality or data security-related legal or other obligations to third parties, or if there are any security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, including personally identifiable information, we may be the subject of governmental investigations, enforcement

actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and third parties, including clinical trial sites, regulators or current and potential business partners, may 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 unauthorized access can be difficult to detect, and any delay in identifying them may lead to increased harm of the types described above. While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures have prevented or will prevent service interruptions or security incidents.

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

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

Risks Related to Our Dependence on Third Parties

BMS has exclusive global rights to develop and commercialize cabiralizumab, and Zai Lab has exclusive rights to develop and commercialize bemarituzumab in Greater China. BMS 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. In addition, reimbursement for our research and development expenses and other payments we may receive from BMS or Zai Lab may fluctuate from period to period, which may adversely affect our stock price.

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

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

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

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

- the development of certain of our current or future product candidates may be delayed or terminated;
- 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, 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 of our product candidates in clinical development. Regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators

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

Our CROs are not our employees. Except for remedies available to us in connection with our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. In such a case, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or significantly limited.

Risks Related to Intellectual Property

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

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

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

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

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

which may limit the scope of protection if patents issue from such applications. Our and our licensors', licensees' or collaborators' rights in the technology claimed in patent applications cannot be enforced against third parties using such technology unless and until a patent issues from such applications, and then only to the extent the issued claims effectively cover such technology.

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

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

Filing, prosecuting, enforcing and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' or collaborators' intellectual property rights in some countries outside the United States may be less extensive than those in the United States. Moreover, the requirements for patentability in certain foreign countries, particularly developing countries, differ materially from those of the United States and such requirements also vary among foreign countries. For example, as compared to the United States, China has a heightened requirement for patentability, which specifically requires a patent to include 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. In jurisdictions where we have not obtained patent protection, competitors may use our and our licensors' or collaborators' technologies to develop their own products. Competitors may also export infringing products to territories where we and our licensors or collaborators have patent protection but enforcement is not as strong or effective as in the United States. These products may compete with our product candidates and our and our licensors' or collaborators' patents or other intellectual property rights may not be sufficient to prevent them from competing.

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

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

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

The ability of a party to obtain and enforce patents in the biopharmaceutical industry is inherently uncertain, due in part to ongoing changes to applicable patent laws. Depending on decisions by Congress, the federal courts, and the

U.S. Patent and Trademark Office, or USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, several of the Supreme Court's rulings in patent cases in recent years have either narrowed the scope of patent protection available under certain circumstances or weakened the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value that any of our patents may have once they have issued.

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 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 and compete with 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 proceedings, we or our licensors or collaborators may not be able to prevent third parties from infringing or misappropriating intellectual property rights we or our licensors or collaborators own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in a patent infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to impose monetary damages or enjoin the infringing party from using the technology at issue on the grounds that our or our licensors' or collaborators' patents do not cover the technology in question. Any litigation proceeding involving one or more of our or our licensors' or collaborators' patents could put such patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Derivation or interference proceedings in the United States or similar proceedings in other jurisdictions may be necessary to determine the priority of inventions with respect to our or our licensors' or collaborators' patents or patent applications. An unfavorable outcome in these proceedings could require us or our licensors or collaborators to cease using the technology covered by the applicable patents or patent applications and commercializing our product candidates or to attempt to license rights to such technology from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license or offers a license on terms that are not commercially reasonable or are otherwise unfavorable to us. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, allowing our competitors to gain access to the same technologies licensed to us or our licensors or collaborators. In addition, if the breadth or strength of protection provided by our or our licensors' or collaborators' patents and patent applications is threatened, it could dissuade potential collaborators from partnering

with us with respect to the development or commercialization of our affected current or future product candidates. Even if we prevail in such a proceeding, we may incur substantial costs and our management and other employees may be distracted from our business and operations as a result of such proceeding.

Furthermore, because of the substantial amount of discovery required in intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during the course of the litigation. 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 or necessary for the development or commercialization of our product candidates. As a result, we are a party to a number of licenses that are important to our business and expect to enter into additional licenses in the future. For example, we have entered into a non-exclusive license with BioWa, Inc. and Lonza Sales AG to use their Potelligent® CHOK1SV technology, which is necessary to produce bemarituzumab, and non-exclusive licenses with each of the National Research Council of Canada and the Board of Trustees of the Leland Stanford Junior University to use materials and technologies that we use in the production of our protein library. If we fail to comply with the obligations under these license agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product candidate that, or the development or manufacturing of which, is covered by these agreements and may face other contractual penalties. Such an occurrence could materially adversely affect the value of any product candidate being developed using technology licensed under any such agreement. Termination of, or reduction or elimination of our rights under, these agreements may require us to negotiate new or reinstated agreements, which may not be available to us on equally favorable or otherwise commercially reasonable terms, or at all, or cause us to lose our rights we had under the original agreements, including our rights to intellectual property or technology important to our development programs.

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

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe the intellectual property rights controlled by these third parties, or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by these third parties, including in oppositions, interferences, reexaminations, inter partes reviews 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 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 members of our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we work to ensure that our employees do not use the proprietary information or know-how of others in their work for us, including through written contractual obligations, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of a former employer of any such employee. Litigation may be necessary to defend against these claims.

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

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

In addition to seeking patents covering our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, including our employees, corporate collaborators, scientific collaborators, contract manufacturers, advisors and other third parties. We also enter into confidentiality and intellectual property, including patent, assignment agreements with our employees and consultants. Despite these efforts, any of these parties, including our current or former employees or consultants and those of our service providers or collaborators, may breach the applicable agreements and disclose our confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for any such breach. Additionally, bringing a claim against a party for illegally disclosing or misappropriating a trade secret is difficult, expensive and time-consuming, the outcome of such a claim is unpredictable and any such litigation involving our trade secrets puts us at significant risk that such trade secrets will be publicly disclosed, thereby significantly reducing or eliminating their value and potentially increasing competition and otherwise harming our business. Further, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using any such trade secret to compete with us, which could harm our competitive position.

Risks Related to Our Financial Position and Capital Needs

We expect to incur net losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect with an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, have not generated any revenue from product sales to date and continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2001, with the exception of the fiscal year ended December 31, 2015, due primarily to the $350.0 million up-front payment we received from BMS under our license and collaboration agreement for cabiralizumab, and the fiscal year ended December 31, 2011, due primarily to an upfront payment we received from a collaboration partner. For the nine months ended September 30, 2018, we reported a net loss of $101.7 million.

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

capital.

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

To date, we have not generated any revenue from commercialization of our product candidates. Our ability to generate product revenue and ultimately become profitable depends upon our ability, alone or with our partners, to successfully commercialize products, including our current product candidates 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 any product candidates for which we obtain marketing approval, and if we launch independently or with certain partners, successfully establish a sales force and marketing and distribution infrastructure;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- successfully and timely develop, validate and obtain any necessary regulatory approvals for companion diagnostics to any of our approved product candidates;
- achieve market acceptance for any of our or our partners' approved products;
- acquire rights to and otherwise establish, maintain and protect intellectual property rights necessary to develop and commercialize our product candidates; and
- attract, hire and retain qualified personnel.

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

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

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

As a research and development company, our operations have consumed substantial amounts of cash since inception. 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 observe 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, our current and future product candidates.

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

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

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

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

- the initiation, progress, timing, costs and results of preclinical and clinical studies for our current product candidates and 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 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, including limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of

these events could significantly harm our business, financial condition and prospects.

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

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

Risks Related to the Ownership of Our Common Stock

The market price of our stock is volatile.

The trading price of our common stock has been and is likely to continue to be volatile. Since shares of our common stock were sold in our initial public offering in September 2013, our closing stock price as reported on The Nasdaq Global Market and The Nasdaq Global Select Market has ranged from $8.49 to $60.89 through November 5, 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, status or plans by third parties;
- announcements by us, our partners or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- success or failure of products or technologies that compete or may compete with our product candidates and technologies;
- regulatory actions with respect to our product candidates or our competitors' products;
- actual or anticipated changes in our or our partners' growth rates relative to our competitors;
- failure of our partners to effectively execute or changes in our partners' strategies with respect to our product candidates or collaborations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning our patent applications, issued patents or other proprietary rights;
- our dependence on third parties, including CMOs, CROs and collaboration partners, including those we may engage to develop and provide us with companion diagnostic products;
- recruitment or departure of key personnel;
- level of expenses related to any of our product candidates or clinical development programs;
- results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to our financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be comparable to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry, political and market conditions.

In addition, the stock market in general, and The Nasdaq Global Select Market and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of 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.

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

As of September 30, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 57% of our common stock. This concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. As a result, these stockholders, acting together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

We are subject to the periodic reporting requirements of the Securities and Exchange Act of 1934, as amended, or the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

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

- authorizing the issuance of “blank check” preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth below and are incorporated herein by reference.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the company's Current Report on Form 8-K (File No. 001-36070), as filed with the SEC on September 23, 2013).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.4 to the company's Registration Statement on Form S-1 (File No. 333-190194), as filed with the SEC on July 26, 2013).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of the company for the quarter ended September 30, 2018, 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.

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: November 6, 2018	/s/ Aron M. Knickerbocker Aron M. Knickerbocker President and Chief Executive Officer (Principal Executive Officer)
Date: November 6, 2018	/s/ Linda Rubinstein Linda Rubinstein Interim Chief Financial Officer (Principal Financial and Accounting Officer)