UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-38697

PhaseBio Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**03-0375697**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1 Great Valley Parkway, Suite 30
Malvern, Pennsylvania 19355
(Address including zip code of principal executive offices)

(610) 981-6500
(Registrant's telephone number, including area code)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	PHAS	The Nasdaq Stock Market LLC

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒

Class of Common Stock	Outstanding Shares as of August 6, 2020
Common Stock, $0.001 par value	29,342,892

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PART 1. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

PHASEBIO PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 53,025	$ 74,025
Other receivables	—	1,233
Prepaid expenses and other assets	10,716	3,565
Total current assets	63,741	78,823
Property and equipment, net	4,876	1,924
Operating lease right-of-use assets	2,136	1,715
Other assets	57	32
Total assets	$ 70,810	$ 82,494
Liabilities and stockholders' equity		
Current liabilities:		
Current portion of long-term debt	$ 5,015	$ 2,378
Accounts payable	6,967	2,921
Accrued expenses and other current liabilities	5,820	3,180
Total current liabilities	17,802	8,479
Long-term debt, net	9,768	12,326
Operating lease liabilities, net	1,773	1,508
Development derivative liability	14,686	—
Other long-term liabilities	388	203
Total liabilities	44,417	22,516
Commitments and contingencies (*Note 8*)		
Stockholders’ equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized; zero shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized; 28,891,534 shares issued and 28,861,567 shares outstanding at June 30, 2020; 28,796,371 shares issued and 28,766,404 shares outstanding at December 31, 2019	29	29
Treasury stock, at cost, 29,967 shares as of June 30, 2020 and December 31, 2019	(24)	(24)
Additional paid-in capital	231,593	222,131
Accumulated deficit	(205,205)	(162,158)
Total stockholders’ equity	26,393	59,978
Total liabilities and stockholders' equity	$ 70,810	$ 82,494

See accompanying notes to unaudited condensed financial statements.

PHASEBIO PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Grant revenue	$ —	$ 203	$ 320	$ 856
Revenue under collaborative agreement	—	500	—	500
Total revenue	—	703	320	1,356
Operating expenses:				
Research and development	20,856	7,781	32,305	13,502
General and administrative	3,242	2,404	6,401	4,720
Total operating expenses	24,098	10,185	38,706	18,222
Loss from operations	(24,098)	(9,482)	(38,386)	(16,866)
Other income (expense):				
Loss from remeasurement of development derivative liability	(3,708)	—	(4,162)	—
Interest income	21	491	232	808
Interest expense	(379)	(219)	(757)	(445)
Foreign exchange gain (loss)	22	(22)	26	(22)
Total other income (expense)	(4,044)	250	(4,661)	341
Net loss	$ (28,142)	$ (9,232)	$ (43,047)	$ (16,525)
Net loss per common share, basic and diluted	$ (0.98)	$ (0.33)	$ (1.50)	$ (0.63)
Weighted average common shares outstanding, basic and diluted	28,805,238	27,932,610	28,789,256	26,224,986

See accompanying notes to unaudited condensed financial statements.

PHASEBIO PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	28,796,371	$ 29	(29,967)	$ (24)	$ 222,131	$ (162,158)	$ 59,978
Issuance of common stock warrants	—	—	—	—	7,925	—	7,925
Exercises of stock options	14,236	—	—	—	17	—	17
Stock-based compensation	—	—	—	—	471	—	471
Net loss	—	—	—	—	—	(14,905)	(14,905)
Balance at March 31, 2020	28,810,607	29	(29,967)	(24)	230,544	(177,063)	53,486
Issuance of common stock in public offering, net	80,523	—	—	—	473	—	473
Exercises of stock options	404	—	—	—	1	—	1
Stock-based compensation	—	—	—	—	575	—	575
Net loss	—	—	—	—	—	(28,142)	(28,142)
Balance at June 30, 2020	28,891,534	$ 29	(29,967)	$ (24)	$ 231,593	$ (205,205)	$ 26,393
Balance at December 31, 2018	24,528,242	$ 25	(29,967)	$ (24)	$ 173,837	$ (122,911)	$ 50,927
Issuance of common stock warrants	—	—	—	—	210	—	210
Exercise of stock options	150	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	238	—	238
Net loss	—	—	—	—	—	(7,293)	(7,293)
Balance at March 31, 2019	24,528,392	25	(29,967)	(24)	174,285	(130,204)	44,082
Issuance of common stock warrants	—	—	—	—	86	—	86
Issuance of common stock in public offering, net	4,124,475	4	—	—	46,273	—	46,277
Exercises of stock options	74,740	—	—	—	126	—	126
Stock-based compensation	—	—	—	—	270	—	270
Net loss	—	—	—	—	—	(9,232)	(9,232)
Balance at June 30, 2019	28,727,607	$ 29	(29,967)	$ (24)	$ 221,040	$ (139,436)	$ 81,609

See accompanying notes to unaudited condensed financial statements.

PHASEBIO PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2020	2019
Operating activities		
Net loss	$ (43,047)	$ (16,525)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111	74
Stock-based compensation	1,046	508
Loss from remeasurement of development derivative liability	4,162	—
Non-cash interest expense	261	254
Non-cash research and development expense	5,735	—
Other non-cash transactions	100	—
Changes in operating assets and liabilities:		
Other receivables	1,233	(948)
Prepaid expenses and other assets	(7,107)	(2,008)
Accounts payable	4,302	1,243
Accrued expenses and other current liabilities	419	(1,463)
Net cash used in operating activities	(32,785)	(18,865)
Investing activities		
Purchases of property and equipment	(1,079)	(429)
Acquisition of intellectual property rights	(100)	—
Net cash used in investing activities	(1,179)	(429)
Financing activities		
Proceeds from development derivative liability	12,649	—
Proceeds from issuance of common stock in public offering, net	472	46,308
Payments of deferred stock offering costs	(175)	—
Long-term borrowings, net	—	3,089
Proceeds from exercise of stock options	18	126
Repayments of long-term debt	—	(938)
Net cash provided by financing activities	12,964	48,585
Net (decrease) increase in cash and cash equivalents	(21,000)	29,291
Cash, cash equivalents and restricted cash at the beginning of the period	74,025	61,051
Cash, cash equivalents and restricted cash at the end of the period	$ 53,025	$ 90,342
Supplemental disclosure for cash flow		
Cash paid for interest	$ 496	$ 191
Supplemental disclosure of non-cash investing and financing activities		
Issuance of warrants in conjunction with development derivative liability	$ 7,925	$ —
Accrued interest on term loan refinanced to principal	$ —	$ 308
Issuance of warrants in conjunction with debt	$ —	$ 296
Debt refinanced with new term loan	$ —	$ 6,563
Initial recognition of operating lease right-of-use assets and operating lease liabilities	$ 564	$ 1,991
Deferred stock offering costs included in accounts payable and accrued expenses	$ —	$ 31
Purchases of property and equipment included in accounts payable and accrued expenses	$ 2,741	$ 6

See accompanying notes to unaudited condensed financial statements.

PhaseBio Pharmaceuticals, Inc.
Notes to Condensed Financial Statements
(unaudited)

1. Organization and Description of Business

Description of Business

PhaseBio Pharmaceuticals, Inc. (the "Company") was incorporated as a Delaware corporation on January 10, 2002. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. The Company's lead product candidate, PB2452, is a novel reversal agent for the antiplatelet drug ticagrelor, which the Company is developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. The Company's second product candidate, PB1046, is in Phase 2 development for the treatment of pulmonary arterial hypertension ("PAH") and in a Phase 2 clinical trial for the treatment of hospitalized COVID-19 patients at high risk for rapid clinical deterioration and acute respiratory distress syndrome ("ARDS"), which the Company refers to as the VANGARD trial. PB1046 utilizes the Company's proprietary half-life extending elastin-like polypeptide technology, which also serves as an engine for the Company's preclinical pipeline. The Company is also developing its preclinical product candidate, PB6440, for treatment-resistant hypertension.

Liquidity

The Company has experienced net losses and negative cash flows from operations since its inception and, as of June 30, 2020, had an accumulated deficit of $205.2 million. The Company expects to continue to incur net losses for at least the next several years. As of June 30, 2020, the Company had cash and cash equivalents of $53.0 million and working capital of $45.9 million. In January 2020, the Company entered into a co-development agreement ("SFJ Agreement") with SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals Group company ("SFJ"), pursuant to which SFJ will provide funding and operational support for the clinical development of PB2452. Management believes that its existing cash and cash equivalents as of June 30, 2020, in addition to the $2.4 million received in July 2020 through the issuance of common stock under the Company's ATM Program (as defined below) and the $71.6 million in anticipated services and proceeds that the Company will receive pursuant to the SFJ Agreement, will be sufficient to fund operating expenses and capital requirements into the second half of 2021.

The Company currently has an effective shelf registration statement on Form S-3 ("2019 Shelf Registration Statement") on file with the Securities and Exchange Commission ("SEC"), which expires in January 2023. The 2019 Shelf Registration Statement currently permits the offering, issuance and sale by the Company of up to an aggregate offering price of $200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination, of which $60.0 million may be offered, issued and sold in "at-the-market" sales pursuant to an equity distribution agreement with Citigroup Global Markets Inc. and William Blair & Company, L.L.C. (the "ATM Program").

The Company is continuing to assess the effect that the COVID-19 pandemic may have on its business and operations. The extent to which COVID-19 may impact the Company's business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic distribution of the disease over time, the efficacy and availability of vaccines and antiviral agents against the disease, the continued duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the continued duration of, COVID-19 may be difficult to assess or predict, a continued and growing pandemic could result in significant disruption of global financial markets, reducing the Company's ability to access capital, which could in the future negatively affect its liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of its common stock.

Basis of Presentation

The accompanying condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") for interim financial reporting and the rules and regulations of the SEC. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. All adjustments, consisting only of normal recurring adjustments,

necessary for a fair presentation of the accompanying condensed financial statements have been made. Although these interim condensed financial statements do not include all of the information and footnotes required for complete annual financial statements, management believes the disclosures are adequate to make the information presented not misleading. The unaudited interim results of operations and cash flows for the three and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the full year. The unaudited interim condensed financial statements and footnotes should be read in conjunction with the audited financial statements and footnotes for the year ended December 31, 2019, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 30, 2020, wherein a more complete discussion of significant accounting policies and certain other information can be found.

Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB"). Certain non-significant reclassifications have been made to conform the prior period presentation.

The Company manages its operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

2. Significant Accounting Policies

Use of Estimates

The preparation of the Company's condensed financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's condensed financial statements and accompanying notes. The most significant estimates in the Company's condensed financial statements relate to the valuation of the development derivative liability and the clinical trial accruals. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results could differ materially from those estimates and assumptions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains certain deposit accounts and money market funds in federally insured financial institutions in excess of federally insured limits. The Company could experience losses on the money market funds in the future.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts.

Fair Value of Financial Instruments

The carrying amounts of other receivables, prepaid expenses and other assets, accounts payable and accrued expenses and other current liabilities are reasonable estimates of their fair value because of the short maturity of these items. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair values of the term loan and operating lease liabilities and corresponding right-of-use assets approximate their respective carrying values.

Development Derivative Liability

Development derivative liability is recorded based on the present value of the estimated consideration to be received and the estimated consideration to be paid pursuant to contractual terms of the SFJ Agreement, which was determined to have been fair value. The liability is remeasured quarterly, as a Level 3 derivative, with any change in fair value recorded in the form of a gain (loss) from remeasurement of development derivative liability on the condensed statements of operations.

Property and Equipment

Property and equipment are recorded at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term.

Leases

At lease commencement, the Company records a lease liability based on the present value of lease payments over the expected lease term including any options to extend the lease that the Company is reasonably certain to exercise. The Company calculates the present value of lease payments using an incremental borrowing rate as the Company's leases do not provide an implicit interest rate. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. At the lease commencement date, the Company records a corresponding right-of-use lease asset based on the lease liability, adjusted for any lease incentives received and any initial direct costs paid to the lessor prior to the lease commencement date. The Company may enter into leases with an initial term of 12 months or less ("Short-Term Leases"). For any Short-Term Leases, the Company records the rent expense on a straight-line basis and does not record the leases on the condensed balance sheet. The Company had no Short-Term Leases as of June 30, 2020 or December 31, 2019.

After lease commencement, the Company measures its leases as follows: (i) the lease liability based on the present value of the remaining lease payments using the discount rate determined at lease commencement and (ii) the right-of-use lease asset based on the remeasured lease liability, adjusted for any unamortized lease incentives received, any unamortized initial direct costs and the cumulative difference between rent expense and amounts paid under the lease agreement. Any lease incentives received and any initial direct costs are amortized on a straight-line basis over the expected lease term. Rent expense is recorded on a straight-line basis over the expected lease term.

Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment and right-of-use assets to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate net positive cash flow in future periods as well as the strategic significance of the assets to the Company's business objectives. Should an impairment exist, the impairment loss would be measured based on the extent that the estimated fair value is less than its carrying value. The Company did not recognize any impairment losses in either the six months ended June 30, 2020 or the year ended December 31, 2019.

Preclinical and Clinical Trial Accruals

The Company accrues and expenses amounts incurred in connection with preclinical studies and clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the life of the individual trial and subject enrollment rates in accordance with agreements with clinical research organizations, contract manufacturing organizations and clinical trial sites. The Company determines the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including the Company's clinical development plan.

Management makes estimates of the Company's accrued expenses as of each balance sheet date in the Company's condensed financial statements based on facts and circumstances known to the Company at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Research and Development Expense

Research and development costs are expensed as incurred. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology has no alternative future use.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based compensation based on the estimated fair value at the date of grant. Currently, the Company's stock-based awards consist only of stock options; however, future grants under the Company's equity compensation plan may also consist of shares of restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units. The Company also maintains an employee stock purchase program ("ESPP") under which it may issue shares. The Company estimates the fair value of stock options and shares that will be issued under the ESPP using the Black-Scholes option-pricing model, which requires the use of estimates. The Company recognizes stock-based compensation cost for ratably vesting stock options and for shares that it will issue under the ESPP on a straight-line basis over the requisite service period of the award and records forfeitures in the period in which they occur.

The Black-Scholes option-pricing model requires the input of subjective assumptions, including the risk-free interest rate, the expected dividend yield of the Company's common stock, the expected volatility of the price of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the condensed financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits, if any, within income tax expense, and any accrued interest and penalties are included within the related tax liability line.

Grant Revenue

Grant revenue is derived from government grants that support the Company's efforts on specific research projects. The Company has determined that the government agencies providing grants to the Company are not customers. The Company recognizes grant revenue when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received.

Revenue Under Collaborative Agreement

The Company generates revenues from payments received under a collaborative agreement. Under such collaboration agreements, the Company recognizes revenue when it transfers promised goods or services to partners in an amount

that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with partners, the Company performs the following five steps: (i) identifies the promised goods or services in the contract; (ii) identifies the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determines the transaction price, including the constraint on variable consideration; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the Company satisfies the performance obligations.

For revenue from such collaborative agreements, the Company generally collects an upfront license payment from the collaboration partner and is also entitled to receive event-based payments subject to the collaboration partner's achievement of specified development, regulatory and sales-based milestones. In addition, the Company is generally entitled to royalties if products under the collaboration are commercialized. Although such agreements are in form structured as collaborative agreements, for accounting purposes they represent contracts with partners that are not subject to accounting literature on collaborative arrangements. If the Company grants to collaboration partners a license to the Company’s intellectual property, the Company does not develop assets jointly with the collaboration partner and does not share in significant risks of their development or commercialization activities.

Transaction price for a contract represents the amount to which the Company is entitled in exchange for providing goods and services to the partner. Transaction price does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of revenue when the uncertainty is resolved. Apart from the upfront license payment, all other fees the Company may earn under such collaborative agreements are subject to significant uncertainties of product development. Achievement of many of the event-based development and regulatory milestones may not be probable until such milestones are actually achieved. This generally relates to milestones such as obtaining marketing authorization approvals and successful completion of clinical trials. With respect to other development milestones, e.g. dosing of a first patient in a clinical trial, achievement could be considered probable prior to its actual occurrence, based on the progress towards commencement of the trial. The Company does not include any amounts subject to uncertainties into the transaction price until it is probable that the amount will not result in a significant reversal of revenue in the future. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price.

Because such agreements generally only have one type of performance obligation, a license, which is generally all transferred at the same time as agreement inception, allocation of the transaction price among multiple performance obligations is not required.

Upfront amounts allocated to licenses are recognized as revenue when the licenses are transferred to the collaboration partners. Development milestones and other fees are recognized in revenue when their occurrence becomes probable.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company’s potentially dilutive securities, which include redeemable convertible preferred stock, warrants and outstanding stock options under the Company’s stock option plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company’s net loss position.

The following table sets forth the outstanding, potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	As of June 30,	
	2020	**2019**
Common stock options	3,740,815	2,433,115
Warrants to purchase common stock	2,349,595	125,333
Employee stock purchase program	271,012	—
Total	6,361,422	2,558,448

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820): Changes to the Disclosure Requirements for Fair Value Measurement*. Among the changes, entities are no longer required to disclose the amount of and reasons for transfers between Levels 1 and 2 of the fair value hierarchy, but will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. Effective January 1, 2020, the Company adopted this ASU, which did not have a material impact on its condensed financial statements and related disclosures.

3. Fair Value Measurement

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The Company classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs that are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The Company’s cash equivalents are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. None of the Company’s non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The fair value of the Company's financial commitment to SFJ in conjunction with the SFJ Agreement is presented as a development derivative liability based on Level 3 inputs.

The following table summarizes the Company’s assets and liabilities that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

	Total	Fair Value Measurements at Reporting Date		
		Level 1	Level 2	Level 3
As of June 30, 2020:				
Assets				
Cash equivalents	$ 52,774	$ 52,774	$ —	$ —
Liabilities				
Development derivative liability	$ 14,686	$ —	$ —	$ 14,686
As of December 31, 2019:				
Assets				
Cash equivalents	$ 73,761	$ 73,761	$ —	$ —

4. Property and Equipment

The following table presents the composition of property and equipment, net as of June 30, 2020 and December 31, 2019 (in thousands):

	As of June 30, 2020	As of December 31, 2019
Lab equipment	$ 2,255	$ 2,112
Computer hardware, software and telephone	279	279
Furniture and fixtures	107	107
Leasehold improvements	67	67
Construction in progress	4,238	1,318
	6,946	3,883
Less accumulated depreciation	(2,070)	(1,959)
Property and equipment, net	$ 4,876	$ 1,924

5. Accrued Expenses and Other Current Liabilities

The following table presents the composition of accrued expenses and other current liabilities as of June 30, 2020 and December 31, 2019 (in thousands):

	As of June 30, 2020	As of December 31, 2019
Accrued clinical and related costs	$ 3,935	$ 819
Accrued compensation and related costs	1,162	1,746
Accrued interest	81	84
Operating lease liability, short-term	425	265
Accrued other	217	266
Accrued expenses and other current liabilities	$ 5,820	$ 3,180

6. Debt

Term Loans

October 2017 Loan Agreement with Silicon Valley Bank

In October 2017, the Company entered into a Loan and Security Agreement (“SVB Loan”) with Silicon Valley Bank (“SVB”), pursuant to which the Company could borrow up to $7.5 million, issuable in three separate tranches (“Growth Capital

Advances") of $3.5 million ("Tranche A"), $2.0 million ("Tranche B") and $2.0 million ("Tranche C"). Each of the Growth Capital Advances were available upon the achievement of certain clinical and regulatory milestones. Under the terms of the SVB Loan, as amended, the Company was required to make interest-only payments through December 31, 2018, followed by an amortization period of 24 months of equal monthly payments of principal plus interest amounts until paid in full. The maturity date of the SVB Loan was December 31, 2020.

In connection with the SVB Loan, the Company issued to SVB a warrant to purchase 49,713 shares of Series C-1 at an exercise price of $9.659 per share, which became exercisable for common stock following the Initial Public Offering ("IPO"). The warrant is immediately exercisable and expires on October 18, 2027. The Company was required to make a final payment equal to 7% of the original aggregate principal amount of the Growth Capital Advances at maturity. In November 2017, the Company drew $3.5 million from Tranche A.

The Company had the option to prepay all, but not less than all, of the borrowed amounts, provided that the Company would have been obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made prior to the first anniversary of the effective date of the SVB Loan, (b) 2.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made by the second anniversary of the effective date of the SVB Loan or (c) 1.0% of the outstanding principal balance of the applicable Growth Capital Advances if prepayment was made after the second anniversary of the effective date of the SVB Loan.

The Company repaid the outstanding principal balance and accrued portion of the final payment under the SVB Loan in full using the first tranche from the new term loan entered into in March 2019 ("the 2019 Loan").

March 2019 Loan Agreement with Silicon Valley Bank and WestRiver Innovation Lending Fund VIII, L.P.

In March 2019, the Company entered into the 2019 Loan with SVB and WestRiver Innovation Lending Fund VIII, L.P. ("WestRiver"), pursuant to which the Company could borrow up to $15.0 million, issuable in three separate tranches ("Advances"), of $7.5 million ("Tranche 1"), which was issued upon execution of the 2019 Loan, $2.5 million, which was issued in May 2019 ("Tranche 2") and $5.0 million, which was issued in October 2019 ("Tranche 3"), which the Company was required to draw upon the achievement of certain regulatory milestones (the "Tranche 3 Milestones").

The maturity date of the 2019 Loan is March 1, 2023. Under the terms of the 2019 Loan, the Company is to make interest-only payments through June 30, 2020 with respect to Tranche 1, Tranche 2 and Tranche 3 at a rate equal to the greater of the Prime Rate plus 1.00%, as defined in the 2019 Loan, or 6.5%, followed by an amortization period of 33 months of equal monthly payments of principal plus interest until paid in full. In addition to and not in substitution for the Company's regular monthly payments of principal plus accrued interest, the Company is required to make a final payment equal to 6% of the aggregate principal amount of the advances ("Final Payment") on the maturity date.

Upon execution of the 2019 Loan and the draw of Tranche 1, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 37,606 shares of common stock with an exercise price of $4.73 per share. In May 2019, upon the draw of Tranche 2, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 12,130 shares of common stock with an exercise price of $10.86 per share. In October 2019, upon the draw of Tranche 3, the Company issued to SVB and WestRiver warrants to purchase an aggregate of 24,262 shares of common stock with an exercise price of $3.88 per share. All warrants are immediately exercisable and expire ten years from the date of issuance.

Upon execution of the 2019 Loan, the Company drew $7.5 million from Tranche 1 and repaid the outstanding principal balance and the accrued portion of the Final Payment of the SVB Loan.

The Company's obligations under the 2019 Loan are secured by a first-priority security interest in substantially all of the Company's current and future assets. The Company is also obligated to comply with various other customary covenants, including restrictions on the Company's ability to encumber its intellectual property assets.

The Company recorded a debt discount of $0.4 million for the estimated fair value of warrants and debt issuance costs upon the borrowings of Tranches 1, 2 and 3, which is being amortized to interest expense over the term of the 2019 Loan using the effective-interest method. Interest expense under the SVB Loan and the 2019 Loan, including amortization of the debt discount related to the term debt, totaled $0.4 million and $0.2 million for the three months ended June 30, 2020 and 2019, respectively, and $0.8 million and $0.4 million for the six months ended June 30, 2020 and 2019, respectively. The balance of the

Final Payment liability was $0.4 million as of June 30, 2020 and is included in other long-term liabilities on the condensed balance sheet. The Company is in compliance with all covenants under the 2019 Loan as of June 30, 2020.

Based on a 39-month amortization of the outstanding principal amounts for the 2019 Loan, the following table sets forth by year the Company's required future principal payments as of June 30, 2020 (in thousands):

Years Ending December 31,	
2020 (remaining six months)	$ 2,528
2021	5,316
2022	5,677
2023	1,479
Thereafter	—
Total principal payments	15,000
Less unamortized loan fees	(217)
Total term loan borrowings	$ 14,783

7. Development Derivative Liability

In January 2020, the Company entered into the SFJ Agreement, pursuant to which SFJ has agreed to provide up to $120.0 million in funding and project management services in connection with the global Phase 3 clinical trial of PB2452. During the term of the SFJ Agreement, the Company will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union.

From the inception of the SFJ Agreement through June 30, 2020, SFJ has provided funding and paid for amounts on the Company's behalf in the aggregate amount of $18.4 million under the SFJ Agreement. SFJ will pay the Company an additional $71.6 million in six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, less certain services to be provided or amounts to be paid in clinical trial cost reimbursements. SFJ will also provide up to an additional $30.0 million upon the achievement of specified milestones with respect to the Company's clinical development of PB2452.

If the United States Food and Drug Administration ("FDA") approves a Biologics License Application for PB2452, the Company has agreed to pay to SFJ an initial payment of $5.0 million and an additional $325.0 million in the aggregate in seven additional annual payments (the "U.S. Approval Payments"). If the European Medicines Agency ("EMA") or the national regulatory authorities in certain European countries provide marketing approval of PB2452, the Company will pay SFJ an initial payment of $5.0 million and an additional $205.0 million in the aggregate in seven additional annual payments (the "EU Approval Payments"). The majority of the U.S. Approval Payments and the EU Approval Payments will be made from the third anniversary to the seventh anniversary of marketing approval in the applicable jurisdiction. If either the Pharmaceuticals and Medical Devices Agency (the "PMDA") of Japan or the National Medical Products Administration (the "NMPA") of China provides marketing approval of PB2452, the Company will pay SFJ an initial payment of $1.0 million and then an additional $59.0 million in the aggregate in eight additional annual payments (the "Japan/China Approval Payments"), with the majority of the payments to be made from the fifth anniversary to the eighth anniversary of marketing approval. The Japan/China Approval Payments will only be paid once regardless of receipt of marketing approval in both Japan and China. The U.S. Approval Payments, EU Approval Payments and Japan/China Approval Payments will be proportionately adjusted in the event that the actual funding from SFJ is lower or greater than $120.0 million. The Company will not be obligated to make the U.S. Approval Payments if it does not receive marketing approval for PB2452 from the FDA, the EU Approval Payments if it does not receive marketing approval for PB2452 from the EMA or the national regulatory authority in certain European countries or the Japan/China Approval Payments if it does not receive marketing approval for PB2452 from either the PMDA or the NMPA.

Upon execution of the SFJ Agreement, the Company issued to SFJ 2,200,000 common stock warrants at an exercise price of $6.50 per share and a contractual term of ten years. The warrants were issued in two tranches: Tranche A and Tranche B. Tranche A represents 1,100,000 warrants that are immediately exercisable by SFJ, provided that SFJ may not sell such exercised shares until one year from the original warrant issuance date. Tranche B represents 1,100,000 warrants that are exercisable at the earlier of (i) the achievement of certain development milestones or (ii) the consummation of an Acquisition, as defined in the SFJ

Agreement. The warrants are equity-classified and were valued at $7.9 million at issuance using a probability adjusted Black-Scholes valuation technique.

The Company accounts for the SFJ Agreement as a derivative instrument that increases and decreases as consideration is received and repayments are made, respectively. The derivative is further adjusted at each reporting period to its estimated fair value. At June 30, 2020, the derivative is presented as a liability in the Company's condensed balance sheet. Any changes in fair value are recorded within the Company's condensed statements of operations. The liability was initially recorded at a value of $2.1 million, which incorporates the $10.0 million upfront payment from SFJ and the issuance of the Company's common stock warrants to SFJ. During the six months ended June 30, 2020, SFJ provided additional funding and paid for amounts on the Company's behalf in the aggregate amount of $8.4 million, and the development derivative liability was subsequently remeasured at June 30, 2020, as a Level 3 derivative. The change of fair value resulted in a $4.2 million loss from remeasurement of development derivative liability on the condensed statements of operations.

The derivative is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The valuation method incorporates certain unobservable Level 3 key inputs including (i) the probability and timing of funding, (ii) the probability and timing of achieving regulatory approvals, (iii) the Company's cost of borrowing (16.00% plus the risk free borrowing rate) and (iv) SFJ's cost of borrowing (2.50% plus the risk free borrowing rate).

The following table presents activity for the development derivative liability during the six months ended June 30, 2020 (in thousands):

	Development Derivative Liability
Balance at December 31, 2019	$ —
Initial payment, net of common stock warrants	2,075
Funding during the period	8,449
Change in fair value	4,162
Balance at June 30, 2020	$ 14,686

8. Commitments and Contingencies

Legal Proceedings

The Company is not currently a party to any litigation, nor is management aware of any pending or threatened litigation against the Company, that it believes would materially affect the Company’s business, operating results, financial condition or cash flows.

9. Leases

The Company leases office and research and development facilities and equipment under various non-cancellable operating lease agreements.

In January 2010, the Company entered into a lease for office and laboratory space in Malvern, Pennsylvania (the “Malvern Lease”). The Malvern Lease commenced in March 2010 and was amended to extend its term to July 2018 and again to September 2023, with an option to extend the lease for an additional three years. This lease contains escalating rent payments. In December 2019, the Company entered into a lease for office space in San Diego, California, which expires in October 2022. In June 2020, the Company entered into a lease for additional office space in Malvern, Pennsylvania, which expires in September 2023. As of June 30, 2020, the weighted average remaining lease term for the Company’s leases was 5.0 years, and the weighted average discount rate used to determine the right-of-use assets and corresponding operating lease liabilities was 5.7%.

Maturities of operating lease liabilities as of June 30, 2020 are as follows (in thousands):

Year Ending December 31,	
2020 (remaining six months)	$ 262
2021	561
2022	552
2023	416
2024	278
Thereafter	498
Total future minimum lease payments	2,567
Less: Present value adjustment	(369)
Operating lease liabilities	$ 2,198

The Company recognizes rent expense for the operating leases on a straight-line basis. Rent expense was $0.1 million for the three months ended June 30, 2020 and 2019, and $0.2 million for the six months ended June 30, 2020 and 2019.

10. Stockholders' Equity

April 2019 Offering

In April 2019, the Company completed an underwritten public offering of its common stock, which resulted in the issuance and sale of an aggregate of 4,124,475 shares of common stock at a public offering price of $12.00 per share, generating net proceeds of $46.3 million after deducting underwriting discounts and commissions and other offering costs.

Shelf Registration Statement

In December 2019, the Company filed the 2019 Shelf Registration Statement on Form S-3, which became effective in January 2020. The 2019 Shelf Registration Statement permits: (i) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination; and (ii) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $60.0 million of the Company's common stock that may be issued and sold in "at-the-market" sales under the ATM Program. During the six months ended June 30, 2020, the Company sold 80,523 shares of common stock pursuant to the ATM Program for gross proceeds of $0.5 million.

11. Stock-Based Compensation

Stock-based compensation expense has been reported in the Company's condensed statements of operations for the three and six months ended June 30, 2020 and 2019 as follows (in thousands):

	Three Months Ended June 30,		**Six Months Ended June 30,**	
	2020	**2019**	**2020**	**2019**
General and administrative	$ 402	$ 205	$ 742	$ 397
Research and development	173	65	304	111
Total stock-based compensation	$ 575	$ 270	$ 1,046	$ 508

As of June 30, 2020, the total unrecognized compensation expense related to unvested employee and non-employee stock option awards was $6.0 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.9 years.

In October 2018, the Company's board of directors and stockholders approved the 2018 Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective on October 17, 2018, and is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code.

Under the ESPP, eligible employees are granted rights to purchase shares of common stock, which are funded through payroll deductions that cannot exceed 15% of each employee's compensation. The ESPP generally provides for a 24-month offering period, which includes four six-month purchase periods. At the end of each purchase period, eligible employees are permitted to purchase shares of common stock at 85% of the lower of fair market value at the beginning of the offering period or fair market value at the end of the purchase period. The ESPP is considered a compensatory plan, and the Company recorded stock-based compensation expense of $21,000 for the three and six months ended June 30, 2020. As of June 30, 2020, no shares of common stock had been issued under the ESPP.

As of June 30, 2020, the total unrecognized compensation expense related to the ESPP was $0.4 million, which is expected to be recognized over a weighted-average period of approximately 1.4 years.

12. License and Other Agreements

MedImmune Limited License Agreement

In November 2017, the Company entered into a license agreement ("MedImmune License") with MedImmune Limited ("MedImmune"). MedImmune is a wholly-owned subsidiary of AstraZeneca plc ("AstraZeneca"). Pursuant to the terms of the MedImmune License, MedImmune granted the Company exclusive global rights for the purpose of developing and commercializing products under the MedImmune License ("MedImmune licensed product"). The Company is obligated to make a series of contingent milestone payments totaling up to an aggregate of $18.0 million upon the achievement of clinical development and regulatory milestones. In addition, the Company will pay MedImmune tiered royalties ranging from mid-single-digit to low-teen percentages of net sales of any MedImmune licensed products and additional payments of up to $50.0 million in aggregate commercial milestones. The Company incurred no costs under the MedImmune License in the three and six months ended June 30, 2020 and 2019.

The Company also must pay quarterly fees relating to technical services provided by MedImmune. The MedImmune License requires the Company to cooperate with MedImmune on commercial messaging of PB2452 and provides MedImmune with the return of rights to PB2452 if certain commercial diligence requirements are not achieved by the Company. In addition, the MedImmune License offers an option for third-party product storage costs. The Company incurred no third-party product storage costs in the three and six months ended June 30, 2020 and 2019. AstraZeneca is a stockholder of the Company.

Duke License Agreement

In October 2006, the Company entered into a license agreement with Duke University ("Duke") (as amended, the "Duke License"). Pursuant to the Duke License, Duke granted to the Company an exclusive, worldwide license under certain patent rights and a non-exclusive license to know-how owned or controlled by Duke to develop and commercialize any products or processes covered under the Duke License (the "Duke licensed products"). The Duke License was amended in February 2016 to allow Duke to use the Company's technology in the area of small-molecule oncologics. The Duke License is a worldwide, sublicensable agreement and remains in full effect for the life of the last-to-expire patents included in the patent rights, which is estimated to be 2029. The Company is required to apply for, prosecute and maintain all United States and foreign patent rights under the Duke License.

The Company is obligated to pay up to $2.2 million upon the achievement of clinical development and regulatory milestones and up to $0.4 million upon the achievement of commercial milestones. The Duke License may be terminated by Duke if the Company fails to meet certain clinical development and regulatory milestones within specified timeframes. As of June 30, 2020, the Company was in compliance with its development obligations.

The Company is required to use commercially reasonable efforts to develop one or more products or processes and introduce them into commercial markets. Duke will receive low single-digit royalty percentages on net sales of Duke licensed products by the Company or its sublicensee, with minimum aggregate royalties of $0.2 million payable following the Company's achievement of certain commercial milestones. No sales of Duke licensed products or services have occurred since the effective date through June 30, 2020.

Certain alliance fee payments up to the greater of $0.3 million or a low double-digit percentage of the fees the Company receives from a third party in consideration of forming a strategic alliance may be required depending upon how the patent rights are commercialized. The Company must pay Duke the first $1.0 million of non-royalty payments it receives from a sublicensee, and thereafter a specified percentage of any additional nonroyalty payments it receives, subject to certain conditions. If Duke receives revenue as a result of a license or sublicense to a third-party in the field of small-molecule oncologics, it will pay the Company a specified percentage of the amount of such revenue in excess of $1.0 million. The Company incurred no costs under the Duke License in the three and six months ended June 30, 2020 and incurred $0.3 million in costs in the three and six months ended June 30, 2019.

Wacker License Agreement

In April 2019, the Company entered into a license agreement (“Wacker License Agreement”), with Wacker Biotech GmbH (“Wacker”), pursuant to which Wacker granted the Company an exclusive license under certain of Wacker’s intellectual property rights to use Wacker’s proprietary *E. coli* strain for the manufacture of PB2452 worldwide outside of specified Asian countries, and to commercialize PB2452, if approved, manufactured by the Company or on the Company’s behalf using Wacker’s proprietary *E. coli* strain throughout the world. The Company has the right to grant sublicenses under the license, subject to certain conditions as specified in the Wacker License Agreement. Under the terms of the agreement, the Company is required to pay a fixed, nominal per-unit royalty, which is subject to adjustment, and an annual license fee in a fixed Euro amount in the low to mid six digits. The agreement will be in force for an indefinite period of time, and upon the expiration of the Company’s royalty obligations, the license will be considered fully paid and will convert to a non-exclusive license. Either party may terminate the Wacker License Agreement for breach if such breach is not cured within a specified number of days. The Company incurred $0.1 million and $0.2 million under the Wacker License Agreement for the three and six months ended June 30, 2020, respectively, and no costs for the three and six months ended June 30, 2019.

Viamet Asset Purchase Agreement

In January 2020, the Company entered into a purchase agreement ("PB6440 Agreement") with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Therapeutics (Bermuda), Ltd., (the "Sellers"), pursuant to which the Company acquired all of the assets and intellectual property rights related to the Sellers’ proprietary CYP11B2 inhibitor compound, formerly known as SE-6440 or VT-6440, and certain other CYP11B2 inhibitor compounds that are covered by the patent rights acquired by the Company under the PB6440 Agreement, (together, "Compounds"). Under the terms of the PB6440 Agreement, the Company paid the Sellers an upfront fee of $0.1 million upon the closing of the transaction, and are required to pay the Sellers up to $5.1 million upon the achievement of certain development and intellectual property milestones with respect to certain product candidates that contain a Compound, up to $142.5 million upon the achievement of certain commercial milestones with respect to any approved product that contains a Compound and low- to mid-single digit royalty percentages on the net sales of approved products that contain a Compound, subject to customary reductions and offsets in specified circumstances. The Company incurred zero and $0.1 million in costs under the PB6440 Agreement for the three and six months ended June 30, 2020, respectively.

13. Revenue

Grant revenue

In February 2018, the Company received Small Business Innovation Research (“SBIR”) grants from the National Institutes of Health in an aggregate amount of $2.8 million to support the clinical development of PB1046 for the treatment of pulmonary arterial hypertension for the period from February 17, 2018 to July 31, 2020. In connection with the SBIR grants, the United States government will receive a non-exclusive, royalty-free license to use any technology the Company develops under such grants. The Company recognized zero and $0.2 million of revenue under the SBIR grants in the three months ended June 30, 2020 and 2019, respectively and $0.3 million and $0.9 million in the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, the Company has received all $2.8 million in funding available under the SBIR grant.

Revenue Under Collaborative Agreement

In April 2019, the Company entered into an agreement with ImmunoForge Co., Ltd. (“ImmunoForge”) for the exclusive, worldwide license of PB1023, a long-acting, recombinant glucagon-like peptide-1 analogue, for the treatment of certain diseases, including conditions related to sarcopenia.

In addition to upfront payments already received, the Company is eligible to receive milestone-based payments and mid-single digit royalty payments on net sales of licensed products, a percentage of which Duke University is entitled to receive pursuant to the Duke License. The Company recognized no revenue for the three and six months ended June 30, 2020 and $0.5 million for the three and six months ended June 30, 2019 related to the ImmunoForge agreement.

14. Related Party Transactions

As described above in Note 12, the Company is party to the MedImmune License. AstraZeneca, the parent company of MedImmune, is a related party of the Company.

15. Subsequent Events

In July 2020, the Company raised gross proceeds of $2.4 million pursuant to the ATM Program, selling 481,325 shares of common stock. The Company has $197.1 million of common stock remaining that can be sold under the 2019 Shelf Registration Statement, of which $57.1 million may be sold under the ATM Program.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the periods ended December 31, 2019 and 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K filed with the SEC on March 30, 2020. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to PhaseBio Pharmaceuticals, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its potential impact on our business and the global economy. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. Our lead product candidate, PB2452, is a novel reversal agent for the antiplatelet drug ticagrelor, which we are developing for the reversal of the antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Based on feedback from the United States Food and Drug Administration, or FDA, we intend to seek approval of PB2452 in the United States through an accelerated approval process. In our completed Phase 2a clinical trial of PB2452, we observed immediate and complete reversal of ticagrelor's antiplatelet activity within five minutes following initiation of infusion and sustained reversal for over 20 hours. Our second product candidate, PB1046, is a once-weekly fusion protein currently in a Phase 2b clinical trial for the treatment of pulmonary arterial hypertension, or PAH. In May 2020, we received FDA authorization to proceed with VANGARD, a Phase 2 clinical trial to evaluate PB1046 as a treatment for hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and acute respiratory distress syndrome, or ARDS. PB1046 utilizes our proprietary half-life extending elastin-like polypeptide, or ELP, technology, which also serves as an engine for our preclinical pipeline. We are also developing our preclinical product candidate, PB6440, for treatment-resistant hypertension. We retain worldwide commercial rights to all of our product candidates.

As we advance our clinical programs for PB2452 and PB1046 with site activations and patient enrollment, we remain in close contact with our clinical research organizations, clinical sites and suppliers to attempt to assess the impacts that COVID-19 may have on our clinical trials and current timelines and to consider whether we can implement appropriate mitigating measures to help lessen such impacts. At this time, however, we cannot fully forecast the scope of impacts that COVID-19 may have on our ability to initiate trial sites, enroll and assess patients, supply study drug and report trial results.

We are developing PB2452 pursuant to a co-development agreement, or the SFJ Agreement, with SFJ Pharmaceuticals X, Ltd., an SFJ Pharmaceuticals Group company, or SFJ. Under the SFJ Agreement, SFJ has agreed to pay us up to $120.0 million to support the clinical development of PB2452. During the term of the SFJ Agreement, we will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operations support in the European Union.

The FDA granted Breakthrough Therapy designation for PB2452 in April 2019. The European Medicines Agency, or EMA, granted PB2452 Priority Medicines, or PRIME, designation in February 2020. Based on feedback from the FDA, we intend to submit a Biologics License Application, or BLA, for potential accelerated approval based on an interim analysis of the first approximately 100 patients treated in our Phase 3 trial, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure. We have commenced our pivotal Phase 3 clinical trial and are currently working to identify and initiate additional clinical sites for this study, although the COVID-19 pandemic has temporarily impacted the pace of site initiation and patient enrollment. Based on an 18-month estimated enrollment timeline for the first 100 patients in the Phase 3 trial, we are targeting to submit our BLA for PB2452 in the second half of 2022, although that timeline could be impacted by the continued scope and duration of the COVID-19 pandemic. To support full approval for patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure, the FDA recommended enrollment of 200 total patients in the Phase 3 trial. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA

requirements. The Committee for Medicinal Products for Human Use, or CHMP, of the EMA has also generally agreed with our proposed development plan for PB2452.

With respect to our PB1046 program, we temporarily paused enrollment of new patients in our Phase 2b clinical trial for the treatment of PAH as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, we also informed investigators that they could continue dosing PB1046 and performing assessments for current trial participants if they deemed it appropriate and such activities were permitted by their respective institutions. Certain sites have resumed screening patients on a limited basis and we continue to work with trial sites to help design plans to enable them to resume new patient enrollment, once appropriate and permitted. Additionally, we continue to identify new trial sites for future initiation. We currently expect to report the top-line results of this trial in 2021.

The VANGARD trial will evaluate PB1046 as a treatment for hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS. The trial is a multi-center, randomized, double-blind, parallel-group trial that will assess the efficacy and safety of once-weekly subcutaneous injections of PB1046 in hospitalized COVID-19 patients. Approximately 210 patients are targeted to be enrolled at approximately 20 sites nationwide. The primary endpoint will measure days alive and free of respiratory failure. We enrolled the first patient in the trial in July 2020. Subject to the pace of enrollment and any further impacts of the COVID-19 pandemic, we are targeting to report top-line results of this trial late in the fourth quarter of 2020. The FDA has informed us that positive, clearly interpretable and clinically meaningful trial results would enable us to submit a BLA for PB1046 in this indication.

We have a limited operating history. Since our inception in 2002, our operations have focused on developing our clinical and preclinical product candidates and our proprietary ELP technology, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials and preclinical studies. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since inception, we have financed our operations primarily through the sale of equity and debt securities and our term loans with Silicon Valley Bank, or SVB, and WestRiver Innovation Lending Fund VIII, L.P., or WestRiver.

In April 2019, we received $46.3 million in net proceeds from an underwritten public offering of our common stock. In May 2019, we received an additional $2.5 million under our term loan with SVB and WestRiver, or our 2019 Loan, and in October 2019, we received an additional $5.0 million under our 2019 Loan. In January 2020, we entered into the SFJ Agreement pursuant to which SFJ has agreed to provide us up to $120.0 million of funding to support the clinical development of PB2452. In March 2020, SFJ paid us an initial $10.0 million. SFJ will pay us an additional $71.6 million in six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, less certain services to be provided or amounts to be paid in clinical trial cost reimbursements, and up to an additional $30.0 million upon the achievement of specified clinical development milestones with respect to our ongoing Phase 3 clinical trial of PB2452.

Since our inception, we have incurred significant operating losses. Our net loss was $43.0 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $205.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our ongoing clinical trials of PB2452 and PB1046, as well as initiate and complete additional clinical trials, as needed;
- seek to expand our geographical reach through the SFJ Agreement and the corresponding clinical development support fees that we will incur;
- pursue regulatory approvals for PB2452 as a reversal agent for the antiplatelet drug ticagrelor and PB1046 for the treatment of PAH and for the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS;
- develop PB6440 for treatment-resistant hypertension;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical and regulatory capabilities;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including PB2452 and PB1046;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and possible future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

FINANCIAL OVERVIEW

Components of Operating Results

Revenue

Grant Revenue

Grant revenue is derived from government grants that support our efforts on specific research projects. We recognize grant revenue when there is reasonable assurance of compliance with the conditions of the grant and reasonable assurance that the grant revenue will be received.

Research and Development Expense

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply and potential commercial supply, including manufacturing validation batches;
- clinical development support fees that we incur related to the SFJ Agreement;
- outsourced professional scientific development services;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- licensing costs payable to third parties for use of their intellectual property;
- expenses relating to regulatory activities; and
- facilities, laboratory materials and supplies used to support our research activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expense to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct our later-stage clinical trials for PB2452 and PB1046, develop PB6440, conduct other preclinical studies and clinical trials and prepare regulatory filings and, if we receive regulatory approval for one or more product candidates, prepare for commercialization efforts.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our product candidates, or when, if ever, material net cash inflows may commence from those candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- delays caused by the COVID-19 pandemic;
- delays in regulators or institutional review boards authorizing us or our investigators to commence our clinical trials or in our ability to negotiate agreements with clinical trial sites or contract research organizations;
- our ability to secure adequate supply of our product candidates for our trials;
- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;

- the number of patients that ultimately participate in the trials;
- the number of doses that patients receive;
- any side effects associated with our product candidates;
- the duration of patient follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

General and Administrative Expense

General and administrative expense consists principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expense includes professional fees for legal, accounting and tax-related services and insurance costs.

We anticipate that our general and administrative expense will increase as we continue to operate as a public reporting company and continue to develop PB2452, PB1046, PB6440 and our future product candidates. We believe that these increases likely will include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public reporting companies.

Loss From Remeasurement of Development Derivative Liability

Loss from remeasurement of development derivative liability reflects the revaluation at each reporting date of our development derivative liability based on the present value of the estimated consideration to be received and the estimated consideration to be paid pursuant to the contractual terms under the SFJ Agreement, which is determined to be fair value. The liability is remeasured at the end of each quarter as a Level 3 derivative, with the change in fair value recorded in the condensed statements of operations.

Interest Expense

Interest expense consists of interest expense on our convertible promissory notes and term loan. Following the conversion of the convertible promissory notes into shares of redeemable convertible Series D preferred stock in August 2018, we no longer recognize interest on the convertible promissory notes. We recognize interest on our term loan with SVB and WestRiver.

License, Co-Development and Other Agreements

MedImmune Limited License Agreement

In November 2017, we entered into an exclusive license agreement, or the MedImmune License, with MedImmune Limited, or MedImmune, a wholly owned subsidiary of AstraZeneca plc. Pursuant to the MedImmune License, MedImmune granted us an exclusive, worldwide license under certain patent rights owned or controlled by MedImmune to develop and commercialize any products covered by the MedImmune License, or the MedImmune Licensed Products, for the treatment, palliation, diagnosis or prevention of any human disorder or condition. Under the MedImmune License, we paid MedImmune an upfront fee of $0.1 million. We are also required to pay MedImmune: quarterly fees relating to technical services provided by MedImmune; up to $18.0 million in clinical and regulatory milestone fees, $1.0 million of which was incurred in the second quarter of 2019; up to $50.0 million in commercial milestone fees; and mid-single digit to low-teen royalty percentages on net

sales of MedImmune Licensed Products, subject to reduction in specified circumstances. In addition, the MedImmune License offers an option for third-party product storage costs. From the inception of the MedImmune License through June 30, 2020, we have incurred costs of $1.6 million under the MedImmune License.

Co-Development Agreement with SFJ Pharmaceuticals

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ will provide us funding to support the global development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. In March 2020, we obtained the consent of Silicon Valley Bank, or SVB, to grant SFJ a security interest in all of the assets owned or controlled by us that are necessary for the manufacture, use or sale of PB2452. Under the SFJ Agreement, SFJ has agreed to pay us up to $120.0 million to support the clinical development of PB2452. From the inception of the SFJ Agreement through June 30, 2020, SFJ has provided funding and paid for amounts on our behalf in the aggregate amount of $18.4 million in PB2452 clinical development costs under the SFJ Agreement. SFJ will pay us an additional $71.6 million in six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, less certain services to be provided or amounts to be paid in clinical trial reimbursements. SFJ will also provide up to an additional $30.0 million upon the achievement of specified milestones with respect to our clinical development of PB2452. During the term of the SFJ Agreement, we will have primary responsibility for clinical development and regulatory activities for PB2452 in the United States and the European Union, while SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union.

Under the terms of the SFJ Agreement, following the FDA approval of a BLA for PB2452, we will pay SFJ an initial payment of $5.0 million and an additional $325.0 million in the aggregate in seven additional annual payments. If the EMA or the national regulatory authority in certain European countries approve a BLA for PB2452, we will pay SFJ an initial payment of $5.0 million and an additional $205.0 million in the aggregate in seven additional annual payments. If either the PMDA of Japan or the NMPA of China approves a marketing application for PB2452, we will pay SFJ an initial payment of $1.0 million and then an additional $59.0 million in the aggregate in eight additional annual payments.

Within 120 days following approval of a BLA for PB2452 in one of the jurisdictions described above, we have the right, at our option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments for such jurisdiction (i.e., the U.S. Approval Payments, EU Approval Payments or Japan/China Approval Payments, as applicable) for a price reflecting a mid-single-digit discount rate. Within 120 days following a change of control of our company, we or our successor have the right, at its option, to make a one-time cash payment to SFJ to buy out all or a portion of the future unpaid approval payments in any of the jurisdictions in which a BLA for PB2452 was approved prior to the change of control for a price reflecting a mid-single-digit discount rate, provided that SFJ has not previously assigned the right to receive such payments to a third party (in which event we or our successor shall not have such right).

If following termination of the SFJ Agreement we continue to develop PB2452 and obtain BLA approval in the United States, the European Union, Japan or China, we will make the applicable approval payments for such jurisdiction to SFJ as if the SFJ Agreement had not been terminated, less any payments made upon termination, except that if we terminate the SFJ Agreement for SFJ's failure to make any payment to us when due, or SFJ terminates the SFJ Agreement due to a material adverse event, as defined in the SFJ Agreement, then our obligation to make such approval payments would be reduced by 50%.

Duke License Agreement

In October 2006, we entered into an exclusive license agreement, or the Duke License, with Duke University, or Duke, which we most recently amended in April 2019. Pursuant to the Duke License, Duke granted us an exclusive, worldwide license under certain patent rights owned or controlled by Duke, and a non-exclusive, worldwide license under certain know-how of Duke, to develop and commercialize any products covered by the Duke License, or Duke licensed products, relating to ELPs. Under the Duke License, we paid Duke an upfront fee of $37,000, additional fees in connection with amendments to the Duke License of $0.2 million and other additional licensing fees of $0.2 million. In consideration for license rights granted to us, we initially issued Duke 24,493 shares of our common stock. Until we reached a certain stipulated equity milestone, which we reached in October 2007, we were obligated to issue additional shares of common stock to Duke from time to time so that its aggregate ownership represented 7.5% of our issued and outstanding capital stock. We are also required to pay Duke: up to $2.2 million in regulatory and clinical milestone fees; up to $0.4 million in commercial milestone fees; low single-digit royalty percentages on net sales of Duke licensed products, with minimum aggregate royalty payments of $0.2 million payable following our achievement of certain commercial milestones; and up to the greater of $0.3 million or a low double-digit percentage of the fees we receive from a third party in consideration of forming a strategic alliance with respect to certain patent rights covered under the Duke License. We also must pay Duke the first $1.0 million of non-royalty payments we receive from a sublicensee, and thereafter a low double-digit percentage of any additional nonroyalty payments we receive, subject to certain conditions.

From the inception of the Duke License through June 30, 2020, we have incurred royalty costs of $0.3 million under the Duke License. We are also required to apply for, prosecute and maintain all U.S. and foreign patent rights under the Duke License.

Wacker License Agreement

In April 2019, we entered into a license agreement, or the Wacker License Agreement, with Wacker Biotech GmbH, or Wacker, pursuant to which Wacker granted us an exclusive license under certain of Wacker's intellectual property rights to use Wacker's proprietary *E. coli* strain for the manufacture of PB2452 worldwide outside of specified Asian countries and to commercialize PB2452, if approved, manufactured by us or on our behalf using Wacker's proprietary *E. coli* strain throughout the world. We have the right to grant sublicenses under the license, subject to certain conditions as specified in the Wacker License Agreement. Under the terms of the agreement, we are required to pay a fixed, nominal per-unit royalty, which is subject to adjustment, and an annual license fee in a fixed Euro amount in the low to mid six digits. The agreement will be in force for an indefinite period of time, and upon the expiration of our royalty obligations, the license will be considered fully paid and will convert to a non-exclusive license. Either party may terminate the Wacker License Agreement for breach if such breach is not cured within a specified number of days. We incurred $0.1 million and $0.2 million in costs under the Wacker License Agreement for the three and six months ended June 30, 2020, respectively.

Viamet Asset Purchase Agreement

In January 2020, we entered into the PB6440 Agreement with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Therapeutics (Bermuda), Ltd., or the Sellers, pursuant to which we acquired all of the assets and intellectual property rights related to the Sellers' proprietary CYP11B2 inhibitor compound, formerly known as SE-6440 or VT-6440, and certain other CYP11B2 inhibitor compounds that are covered by the patent rights acquired by us under the PB6440 Agreement, or together, Compounds. Under the terms of the PB6440 Agreement, we paid the Sellers an upfront fee of $0.1 million upon the closing of the transaction, and we are required to pay the Sellers up to $5.1 million upon the achievement of certain development and intellectual property milestones with respect to certain product candidates that contain a Compound, up to $142.5 million upon the achievement of certain commercial milestones with respect to any approved product that contains a Compound and low- to mid-single digit royalty percentages on the net sales of approved products that contain a Compound, subject to customary reductions and offsets in specified circumstances. We incurred zero and $0.1 million in costs under the PB6440 Agreement for the three and six months ended June 30, 2020, respectively.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		
	2020	2019	Change
Revenue:			
Grant revenue	$ —	$ 203	$ (203)
Revenue under collaborative agreement	—	500	(500)
Total revenue	—	703	(703)
Operating expenses:			
Research and development	20,856	7,781	13,075
General and administrative	3,242	2,404	838
Total operating expenses	24,098	10,185	13,913
Loss from operations	(24,098)	(9,482)	(14,616)
Other income (expense):			
Loss from remeasurement of development derivative liability	(3,708)	—	(3,708)
Interest income	21	491	(470)
Interest expense	(379)	(219)	(160)
Foreign exchange gain (loss)	22	(22)	44
Total other income (expense)	(4,044)	250	(4,294)
Net loss	$ (28,142)	$ (9,232)	$ (18,910)

Grant Revenue

Grant revenue was zero for the three months ended June 30, 2020, compared to $0.2 million for the three months ended June 30, 2019. We did not incur any costs that qualified for grant reimbursement under our government grants during the three months ended June 30, 2020. As of June 30, 2020, we have received all $2.8 million in funding available under the SBIR grant. Revenue under collaborative agreement was zero for the three months ended June 30, 2020, compared to $0.5 million for the three months ended June 30, 2019, which reflected the receipt of an upfront payment in April 2019 under our agreement with ImmunoForge.

Research and Development Expense

Research and development expense was $20.9 million for the three months ended June 30, 2020, compared to $7.8 million for the three months ended June 30, 2019. The increase of $13.1 million was primarily attributable to increased drug manufacturing and clinical development activities related to PB2452 and PB1046 and increased personnel costs due to additional headcount.

The following table summarizes our research and development expenses by functional area for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		
	2020	2019	Change
Preclinical and clinical development	$ 18,523	$ 6,290	$ 12,233
Compensation and related benefits	1,790	1,036	754
Stock-based compensation	173	65	108
Facilities expense	180	229	(49)
Other	190	161	29
Total research and development expenses	$ 20,856	$ 7,781	$ 13,075

We track our external research and development expenses on a program-by-program basis. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, early research and consumable costs, which are deployed across multiple projects under development. The following table summarizes our research and development expenses by product candidate for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		
	2020	2019	Change
External research and development expense by program:			
PB2452	$ 13,036	$ 4,609	$ 8,427
PB1046	5,220	1,185	4,035
Unallocated research and development expense:			
Compensation and stock-based compensation	1,963	1,101	862
Other research and development	637	886	(249)
Total research and development expenses	$ 20,856	$ 7,781	$ 13,075

General and Administrative Expense

General and administrative expense was $3.2 million for the three months ended June 30, 2020, compared to $2.4 million for the three months ended June 30, 2019. The increase of $0.8 million was primarily attributable to an increase in professional services related to legal and consulting services and personnel expense due to additional headcount.

Loss From Remeasurement of Derivative Liability

Loss from remeasurement of derivative liability was $3.7 million for the three months ended June 30, 2020. The liability was initially recorded at the present value of the estimated consideration to be received and the estimated consideration to be paid pursuant to the contractual terms of the SFJ Agreement, which was determined to have been fair value. The derivative liability was subsequently remeasured at the end of the quarter as a Level 3 derivative.

Interest Income

Interest income was $21,000 for the three months ended June 30, 2020, compared to $0.5 million for the three months ended June 30, 2019. The decrease of $0.5 million was attributable to lower balances of cash and cash equivalents and lower interest rates during 2020.

Interest Expense

Interest expense was $0.4 million for the three months ended June 30, 2020, compared to $0.2 million for the three months ended June 30, 2019. The increase of $0.2 million was attributable to increased borrowings on the 2019 Loan.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019 (in thousands):

	Six Months Ended June 30,		
	2020	2019	Change
Revenue:			
Grant revenue	$ 320	$ 856	$ (536)
Revenue under collaborative agreement	—	500	(500)
Total revenue	320	1,356	(1,036)
Operating expenses:			
Research and development	32,305	13,502	18,803
General and administrative	6,401	4,720	1,681
Total operating expenses	38,706	18,222	20,484
Loss from operations	(38,386)	(16,866)	(21,520)
Other income (expense):			
Loss from remeasurement of development derivative liability	(4,162)	—	(4,162)
Interest income	232	808	(576)
Interest expense	(757)	(445)	(312)
Foreign exchange gain (loss)	26	(22)	48
Total other income (expense)	(4,661)	341	(5,002)
Net loss	$ (43,047)	$ (16,525)	$ (26,522)

Revenue

Grant revenue was $0.3 million for the six months ended June 30, 2020, compared to $0.9 million for the six months ended June 30, 2019. We incurred fewer costs that qualified for grant reimbursement under our government grants during the six months ended June 30, 2020. Revenue under collaborative agreement was zero for the six months ended June 30, 2020, compared to $0.5 million for the six months ended June 30, 2019, which reflected the receipt of an upfront payment in April 2019 under our agreement with ImmunoForge.

Research and Development Expense

Research and development expense was $32.3 million for the six months ended June 30, 2020, compared to $13.5 million for the six months ended June 30, 2019. The increase of $18.8 million was primarily attributable to increased costs associated with drug manufacturing and clinical development activities largely related to PB2452 and PB1046, general research activities and increased personnel costs due to additional headcount.

The following table summarizes our research and development expenses by functional area for the six months ended June 30, 2020 and 2019 (in thousands):

	Six Months Ended June 30,		
	2020	2019	Change
Preclinical and clinical development	$ 27,701	$ 10,604	$ 17,097
Compensation and related benefits	3,377	2,121	1,256
Stock-based compensation	304	111	193
Facilities expense	445	387	58
Other	478	279	199
Total research and development expenses	$ 32,305	$ 13,502	$ 18,803

We track our external research and development expenses on a program-by-program basis. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation,

early research and consumable costs, which are deployed across multiple projects under development. The following table summarizes our research and development expenses by product candidate for the six months ended June 30, 2020 and 2019 (in thousands):

	Six Months Ended June 30,		
	2020	2019	Change
External research and development expense by program:			
PB2452	$ 19,904	$ 7,926	$ 11,978
PB1046	6,946	2,086	4,860
Unallocated research and development expense:			
Compensation and stock-based compensation	3,681	2,232	1,449
Other research and development	1,774	1,258	516
Total research and development expenses	$ 32,305	$ 13,502	$ 18,803

General and Administrative Expense

General and administrative expense was $6.4 million for the six months ended June 30, 2020, compared to $4.7 million for the six months ended June 30, 2019. The increase of $1.7 million was primarily attributable to increases in professional services including legal, accounting and other consulting services and personnel expense due to additional headcount.

Loss From Remeasurement of Derivative Liability

Loss from remeasurement of derivative liability was $4.2 million for the six months ended June 30, 2020. The liability was initially recorded at the present value of the estimated consideration to be received and the estimated consideration to be paid pursuant to the contractual terms of the SFJ Agreement, which was determined to have been fair value. The derivative liability was subsequently remeasured at the end of the quarter as a Level 3 derivative.

Interest Income

Interest income was $0.2 million for the six months ended June 30, 2020, compared to $0.8 million for the six months ended June 30, 2019. The decrease of $0.6 million was attributable to lower balances of cash and cash equivalents and lower interest rates during 2020.

Interest Expense

Interest expense was $0.8 million for the six months ended June 30, 2020, compared to $0.4 million for the six months ended June 30, 2019, reflecting a decrease of $0.3 million. The increase was attributable to increased borrowings on the 2019 Loan.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales and have incurred net losses and negative cash flows from our operations. We have financed our operations primarily through public offerings of our common stock, private placements of convertible debt and convertible preferred stock and borrowings under our term loans. In future periods, we expect to receive up to an additional $101.6 million from the SFJ Agreement, $30.0 million of which we are eligible to receive upon the achievement of specified milestones with respect to our clinical development of PB2452. As of June 30, 2020, we had cash and cash equivalents of $53.0 million.

In March 2019, we entered into the 2019 Loan with SVB and WestRiver, pursuant to which we could borrow up to $15.0 million, issuable in three separate tranches. As of June 30, 2020, we had drawn on all three tranches under the 2019 Loan in the amounts of $7.5 million, $2.5 million and $5.0 million.

In April 2019, we completed an underwritten public offering of our common stock, which resulted in the issuance and sale of an aggregate of 4,124,475 shares of common stock at a public offering price of $12.00 per share, generating net proceeds of $46.3 million after deducting underwriting discounts and commissions and other offering costs.

In December 2019, we filed a shelf registration statement on Form S-3, or the 2019 Shelf Registration Statement, which became effective in January 2020. The 2019 Shelf Registration Statement permits: (i) the offering, issuance and sale by us of up to a maximum aggregate offering price of $200.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination; and (ii) the offering, issuance and sale by us of up to a maximum aggregate offering price of $60.0 million of our common stock that may be issued and sold under an "at-the-market" sales agreement, or ATM Program, with Citigroup Global Markets Inc. and William Blair & Company, L.L.C. We have raised gross proceeds of $2.9 million pursuant to the ATM Program selling 561,848 shares of our common stock at a weighted average price of $5.41 per share. After these sales we have $197.1 million of common stock remaining that can be sold under the 2019 Shelf Registration Statement, of which $57.1 million may be sold under the ATM Program.

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ agreed to provide funding to support the development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor. Under the SFJ Agreement, SFJ has agreed to pay us up to $120.0 million to support the clinical development of PB2452. From the inception of the SFJ Agreement through June 30, 2020, SFJ has provided funding and paid for amounts on our behalf in the aggregate amount of $18.4 million in PB2452 clinical trial costs. SFJ will pay us an additional $71.6 million in six equal quarterly payments beginning with the quarter ending September 30, 2020 through the quarter ending December 31, 2021, less certain services to be provided or amounts to be paid in clinical trial cost reimbursements. We are eligible to receive up to an additional $30.0 million upon the achievement of specific clinical development milestones with respect to our ongoing Phase 3 clinical trial of PB2452.

The following table summarizes our cash flows for each of the periods set forth below (in thousands):

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (32,785)	$ (18,865)
Net cash used in investing activities	(1,179)	(429)
Net cash provided by financing activities	12,964	48,585
Net decrease in cash and cash equivalents	$ (21,000)	$ 29,291

Operating Activities

Net cash used in operating activities was $32.8 million during the six months ended June 30, 2020. The use of cash primarily related to our net loss of $43.0 million, in addition to a $1.2 million change in our operating assets and liabilities. The use of cash was partially offset by non-cash expenses, primarily $5.7 million in research and development expenses paid for on our behalf by SFJ, $4.2 million loss from remeasurement of development derivative liability and $1.0 million in stock-based compensation. The change in our operating assets and liabilities was principally due to a $7.1 million increase in prepaid expenses as a result of drug manufacturing payments related to PB2452, partially offset by a $4.3 million increase in accounts payable in the first half of 2020.

Net cash used in operating activities was $18.9 million during the six months ended June 30, 2019. The use of cash primarily related to our net loss of $16.5 million, in addition to a $3.2 million change in our operating assets and liabilities.

Investing Activities

Net cash used in investing activities was $1.2 million for the purchase of property and equipment and the acquisition of intellectual property rights during the six months ended June 30, 2020. Net cash used in investing activities was $0.4 million for the purchase of property and equipment during the six months ended June 30, 2019.

Financing Activities

Net cash provided by financing activities was $13.0 million during the six months ended June 30, 2020, due primarily to the receipt of $12.6 million under the SFJ Agreement and $0.5 million in net proceeds from sales under the ATM Program, partially offset by $0.2 million in payments of stock offering costs. Net cash provided by financing activities was $48.6 million during the six months ended June 30, 2019, due primarily to the receipt of $46.3 million in net proceeds from the April 2019 underwritten public offering and borrowings of $3.1 million on the 2019 Loan, partially offset by $0.9 million in repayments of the SVB Loan.

Funding Requirements

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next several years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents as of June 30, 2020, in addition to the $2.4 million received in July 2020 through the issuance of common stock under the ATM Program and the $71.6 million in anticipated proceeds that we will receive pursuant to the SFJ Agreement, will be sufficient to fund our operating expenses and capital requirements into the second half of 2021. We intend to devote our existing cash to advance PB2452 and PB1046, fund the development of our ELP technology and preclinical programs and for general working capital and other general corporate purposes. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of product candidates.

Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing and planned future clinical trials of PB2452, PB1046, PB6440 and our other preclinical programs;
- the timing and amount of payments we receive under the SFJ Agreement;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize PB1046 in the United States;
- our ability to establish collaborations to commercialize PB2452, PB1046 or any of our other product candidates outside of the United States; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

Our future commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the terms of these equity securities or this debt may restrict our ability to operate. Any future debt financing and equity financing, if available, may involve agreements that include covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital

expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through government or private grants, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

We are continuing to assess the effect that the COVID-19 pandemic may have on our business and operations. The extent to which COVID-19 may impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic distribution of the disease over time, the continued duration of the outbreak, the efficacy and availability of vaccines and antiviral agents against the disease, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the continued duration of, COVID-19 may be difficult to assess or predict, a continued and growing pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

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 in the SEC rules and regulations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with United States generally accepted accounting policies, or GAAP. The preparation of these condensed financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis.

Significant estimates include assumptions we have used in the determination of accrued research and development costs and those used for the inputs in our valuation of the development derivative liability. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As disclosed in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operation" of our 2019 Annual Report on Form 10-K, we believe that our critical accounting policy for accrued research and development expense is critical to the judgments and estimates used in the preparation of our financial statements.

In addition, we identified the following policy as a new critical policy that reflects significant judgments or uncertainties, and potentially may result in materially different results under different assumptions and conditions.

Development Derivative Liability

In January 2020, we entered into the SFJ Agreement, pursuant to which SFJ will provide funding to support the global development of PB2452 as a reversal agent for the antiplatelet drug ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. Under the SFJ Agreement, SFJ has agreed to pay us up to $120.0 million to support the clinical development of PB2452.

If the FDA approves a BLA for PB2452, we have agreed to pay to SFJ an initial payment of $5.0 million and an additional $325.0 million in the aggregate in seven additional annual payments, or the U.S. Approval Payments. If the EMA or the national regulatory authorities in certain European countries provide marketing approval of PB2452, we will pay SFJ an initial payment of $5.0 million and an additional $205.0 million in the aggregate in seven additional annual payments, or the EU Approval Payments. The majority of the U.S. Approval Payments and the EU Approval Payments will be made from the third anniversary to the seventh anniversary of marketing approval in the applicable jurisdiction. If either the Pharmaceuticals and Medical Devices Agency, or the PMDA, of Japan or the National Medical Products Administration, or the NMPA, of China provides marketing approval of PB2452, we will pay SFJ an initial payment of $1.0 million and then an additional $59.0 million

in the aggregate in eight additional annual payments, or the Japan/China Approval Payments, with the majority of the payments to be made from the fifth anniversary to the eighth anniversary of marketing approval. The Japan/China Approval Payments will only be paid once regardless of receipt of marketing approval in both Japan and China. The U.S. Approval Payments, EU Approval Payments and Japan/China Approval Payments will be proportionately adjusted in the event that the actual funding from SFJ is lower or greater than $120.0 million. We will not be obligated to make the U.S. Approval Payments if we do not receive marketing approval for PB2452 from the FDA, the EU Approval Payments if we do not receive marketing approval for PB2452 from the EMA or the national regulatory authority in certain European countries or the Japan/China Approval Payments if we do not receive marketing approval for PB2452 from either the PMDA or the NMPA.

We account for the SFJ Agreement as a derivative instrument that increases and decreases as consideration is received and repayments are made, respectively. The derivative is further adjusted at each reporting period to its estimated fair value. The derivative is valued using a scenario-based discounted cash flow method, whereby each scenario makes assumptions about the probability and timing of cash flows, and such cash flows are present valued using a risk-adjusted discount rate. The valuation method incorporates certain unobservable Level 3 key inputs including (i) the probability and timing of funding, (ii) the probability and timing of achieving regulatory approvals, (iii) our cost of borrowing (16.00% plus the risk free borrowing rate) and (iv) SFJ's cost of borrowing (2.50% plus the risk free borrowing rate). The derivative is presented as a liability in our condensed balance sheet. Any changes in fair value are recorded as a loss from remeasurement of development derivative liability on the condensed statements of operations.

If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Recent Accounting Pronouncements

See “Note 2. Significant Accounting Policies” in “Notes to Condensed Financial Statements” located in “Part I – Financial Information, Item 1. Financial Statements” in this Quarterly Report on Form 10-Q for information concerning recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risks

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

With respect to the quarter ended June 30, 2020, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2020 that have 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 subject to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Quarterly Report on Form 10-Q and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

The ongoing COVID-19 pandemic is likely to adversely impact our business and operations, including our clinical trials.

Our business operations are likely to be adversely affected by the effects of the ongoing COVID-19 pandemic, which was declared by the World Health Organization as a global pandemic. The U.S., state and local governments have imposed travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States that, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings and events and order cessation of non-essential travel. In response to public health directives and orders, we have implemented work-from-home policies for all employees.

We may experience disruptions due to the COVID-19 pandemic that could severely impact our business and clinical trials, including:

- delays, difficulties or a suspension in enrolling patients in our ongoing and planned clinical trials;
- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others; and
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

For our clinical trials that are planned to be conducted at sites in countries that are experiencing heightened impact from COVID-19, in addition to the risks listed above, we may also experience the following adverse impacts:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;

- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in these affected geographies.

As we advance our clinical programs for PB2452 and PB1046 with site activations and patient enrollment, we remain in close contact with our CROs, clinical sites and suppliers to attempt to assess the impacts that COVID-19 may have on our clinical trials and current timelines and to consider whether we can implement appropriate mitigating measures to help to lessen such impacts. At this time, however, we cannot currently fully forecast the scope of impacts that COVID-19 may have on our ability to initiate trial sites, enroll and assess patients, supply study drug and report trial results.

We have commenced our pivotal Phase 3 clinical trial for PB2452 and are currently working to identify and initiate additional clinical sites for this study, although the COVID-19 pandemic has temporarily impacted the pace of site initiation and patient enrollment. Based on an 18-month estimated enrollment timeline for the first 100 patients in the Phase 3 trial, we are targeting to submit our BLA for PB2452 in the second half of 2022, although that timeline could be impacted by the continued scope and duration of the COVID-19 pandemic.

With respect to our PB1046 program, we temporarily paused enrollment of new patients in our Phase 2b clinical trial for the treatment of PAH as a precaution to minimize potential exposure of this patient population at high risk of serious illness from COVID-19. However, we also informed investigators that they could continue dosing PB1046 and performing assessments for current trial participants if they deemed it appropriate and such activities were permitted by their respective institutions. Certain sites have resumed screening patients on a limited basis and we continue to work with trial sites to help design plans to enable them to resume new patient enrollment, once appropriate and permitted. Additionally, we continue to identify new trial sites for future initiation. We currently expect to report the top-line results of this trial in 2021.

In addition, we recently launched our VANGARD study, which is a Phase 2 clinical trial to assess the efficacy and safety of PB1046 in hospitalized COVID-19 patients at high risk for rapid clinical deterioration and ARDS. Subject to the pace of enrollment, we are targeting to report top-line results of this trial late in the fourth quarter of 2020, although that timeline could be impacted by the continued scope and duration of the COVID-19 pandemic.

In addition, remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic could negatively impact productivity, disrupt our ongoing research and development activities and impact our operations, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations and their effect on our ability to conduct our business in the ordinary course. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements could potentially result in control deficiencies in the preparation of our financial reports, which could be significant.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the continued duration of, COVID-19 may be difficult to assess or predict, a continued and growing pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 may impact our business and clinical trials will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic distribution of the disease over time, the continued duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the efficacy and availability of vaccines and antiviral agents against the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this “Risk Factors” section.

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history.

Since our inception, we have incurred significant net losses. Our net loss was $43.0 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $205.2 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Since inception, we have financed our operations primarily with proceeds raised in our initial public offering, private placements of convertible debt and convertible preferred stock and borrowings under our term loan. In future periods we expect to receive up to $101.6 million from the SFJ Agreement, $30.0 million of which we are eligible to receive upon the achievement of specified milestones with respect to our clinical development of PB2452. We have no products approved for commercialization and have never generated any revenue from product sales.

We have devoted substantially all of our financial resources and efforts to the development of our clinical and preclinical product candidates and our proprietary half-life extending elastin-like polypeptide, or ELP, technology, including conducting preclinical studies and clinical trials. We expect to continue to incur significant expenses and operating losses over the next several years. We expect that it could be several years, if ever, before we have a commercialized product. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our ongoing clinical trials of PB2452 and PB1046, as well as initiate and complete additional clinical trials, as needed;
- seek to expand our geographical reach through the SFJ Agreement and the corresponding clinical development support fees that we will incur;
- pursue regulatory approvals for PB2452 as a reversal agent for the antiplatelet drug ticagrelor and PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS;
- develop PB6440 for treatment-resistant hypertension;
- seek to discover and develop additional clinical and preclinical product candidates;
- scale up our clinical and regulatory capabilities;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval, including PB2452 and PB1046;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2002, and our operations to date have been largely focused on raising capital and developing our clinical and preclinical product candidates and our proprietary ELP half-life extending technology, including undertaking preclinical studies and conducting clinical trials. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we complete our ongoing clinical trials of our product candidates, initiate future clinical trials of our product candidates, seek marketing approval for PB2452 as a ticagrelor reversal agent and PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS, develop PB6440 for treatment-resistant hypertension and advance any of our other product candidates we may develop or otherwise acquire. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for PB2452, PB1046, PB6440 or any other product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of June 30, 2020, we had cash and cash equivalents of $53.0 million. We believe that our existing cash and cash equivalents as of June 30, 2020, in addition to the $2.4 million received in July 2020 through the issuance of common stock under the ATM Program and the $71.6 million in anticipated proceeds that we will receive pursuant to the SFJ Agreement, will be sufficient to fund our operating expenses and capital requirements into the second half of 2021. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the progress and results of our ongoing and planned future clinical trials of PB2452 and PB1046 and our development of PB6440 and other preclinical programs;
- the timing and amount of any payments we receive under the SFJ Agreement;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for any future product candidates we may decide to pursue;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish collaborations to commercialize PB1046 in the United States;
- our ability to establish collaborations to commercialize PB2452, PB1046, PB6440 or any of our other product candidates outside the United States; and

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

We will require additional capital to commercialize PB2452, PB1046 and PB6440. If we receive regulatory approval for any of these product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private party grants, debt financings and license and collaboration agreements. Except with respect to the funding obligations pursuant to the SFJ Agreement, we do not currently have any other committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, under the SFJ Agreement, we granted SFJ a first-priority security interest in all of our assets related to PB2452, subject only to the lien of SVB and WestRiver, or the Lenders, for existing indebtedness to the Lenders. In connection with the grant of the security interest, we agreed to certain affirmative and negative covenants, including restrictions on our ability to pay dividends, incur additional debt or enter into licensing transactions with respect to intellectual property related to PB2452. Similarly, our loan and security agreement with the Lenders is secured by a security interest in substantially all of our current and future assets. We are also obligated to comply with various other customary covenants, including restrictions on our ability to encumber our intellectual property assets. The security interests granted to SFJ and the Lenders may preclude future debt financing or make the terms of such financings less favorable.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. 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.

If we receive regulatory approval for PB2452, or if the SFJ Agreement is terminated, we will be required to make substantial payments to SFJ pursuant to the SFJ Agreement. If we do not have sufficient funding or cash flow from our business to meet our payment obligations under the SFJ Agreement, SFJ could exercise its remedies as a holder of a first-priority security interest in our assets and our business could be materially harmed.

On January 9, 2020, we entered into the SFJ Agreement, pursuant to which SFJ is to provide up to $120.0 million to support the global development of PB2452. If we receive regulatory approval for PB2452 as a reversal agent for the antiplatelet drug ticagrelor, we will be required to make substantial payments to SFJ pursuant to the SFJ Agreement. Our ability to make these required payments depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to meet our obligations under the SFJ Agreement. If we are unable to generate such cash flow or to obtain additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources on acceptable terms or at all, we could default on our payment obligations to SFJ. We have granted SFJ a first-priority security interest in all of our assets related to PB2452, subject only to the lien of the Lenders for existing indebtedness to the Lenders. If we are unable to meet our payment obligations to SFJ, SFJ may exercise its remedies as a holder of a first-priority security interest, which would result in a loss of our assets and our business would be materially harmed.

In addition, in the event that (i) we fail to pay any amounts payable to SFJ under the SFJ Agreement within a specified time period, (ii) we are in default of our obligations (subject to certain exclusions) under the MedImmune License or (iii) either (a) we determine it is probable that we will be unable to meet our obligations as they become due within one year after

the date that our financial statements for the then-current quarter are issued, or available to be issued or (b) a "going concern" footnote is included in any of our financial statements, and, in either case ((a) or (b)), we fail to remedy such going concern condition as specified in the agreement, SFJ may elect to have our business related to PB2452 transferred to SFJ. If our business related to PB2452 is transferred to SFJ, we will not share in any revenues from the commercialization of PB2452 until SFJ has received a 300% return on its investment in PB2452, after which we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the United States and certain European countries, and after SFJ has received an aggregate 500% return on its investment in PB2452, we will be entitled to a mid-single-digit royalty on net sales of PB2452 in the rest of the world.

In the event that the SFJ Agreement is terminated, we will be obligated to make substantial payments to SFJ. If following termination of the SFJ Agreement we continue to develop PB2452 and obtain BLA approval in the United States, the European Union, Japan or China, we will be obligated to pay applicable approval payments for any such jurisdiction to SFJ as if the SFJ Agreement had not been terminated, less any payments made upon termination, except in limited circumstances. Further, if our business related to SFJ is transferred to SFJ in the event that we breach certain provisions of the SFJ Agreement, we will not share in any revenues from the commercialization of PB2452 until SFJ has received an at least 300% return on its investment in PB2452. See "Business - License, Co-Development and Other Agreements - Co-Development Agreement for PB2452 with SFJ Pharmaceuticals." Such payment obligations could have significant consequences for our stockholders and our business, results of operations and financial condition and could force us to delay or terminate development of PB2452 or other product candidates.

Risks Related to the Development of Our Product Candidates

We currently have only two clinical-stage product candidates, PB2452, a ticagrelor reversal agent, and PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS. If we are unable to successfully develop, receive regulatory approval for and commercialize our product candidates for these or any other indications, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

We currently have no products that are approved for commercial sale. We currently have only two clinical-stage product candidates, PB2452 and PB1046. To date, we have not yet conducted any pivotal clinical trials. We have not completed the development of any product candidates, and we may never be able to develop marketable products.

We have invested substantially all of our efforts and financial resources in the development of our clinical and preclinical product candidates and our proprietary ELP technology. Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of PB2452, PB1046, PB6440 or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment and completion of clinical trials;
- with respect to PB2452, the success of our collaboration with SFJ;
- successful development of, or making arrangements with third-party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- receipt of timely marketing approvals from applicable regulatory authorities;
- launching commercial sales of products, if approved;
- acceptance of our products, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with PB2452, PB1046, PB6440 or any other product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we develop, specifically, alternative reversal agents or antiplatelet therapies to ticagrelor (including therapies that may be developed with a reversal agent), alternative treatments for PAH or treatment-resistant hypertension or alternative treatments for COVID-19 patients at risk for rapid clinical deterioration and ARDS;

- with respect to PB1046 for the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS, the timing, availability and efficacy of potential vaccines or potential antiviral agents for COVID-19;
- our ability to produce PB2452, PB1046, PB6440 or any other product candidates we develop on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs, and complying effectively with other procedures; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for PB2452, PB1046, PB6440 or any other product candidate we develop, we may not be able to continue our operations.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. PB2452 and PB1046 are currently our only clinical-stage product candidates. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for PB2452, PB1046, PB6440 or any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of a BLA, or a new drug application, or NDA, from the FDA. To date, we have only had limited discussions with the EMA and other comparable foreign authorities regarding regulatory approval for PB2452, PB1046 or any other product candidate outside of the United States.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our clinical and preclinical product candidates, including PB2452, PB1046 and PB6440. Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize PB2452, PB1046, PB6440 and any future product candidates in a timely manner.

Even if we eventually complete clinical testing and receive approval of a BLA, NDA or foreign marketing application for PB2452, PB1046, PB6440 or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a

product candidate for a more limited indication or patient population than we originally request, and the FDA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Based on feedback from the FDA, we intend to seek regulatory approval of PB2452 in the United States through an accelerated approval process. If we are not successful with this process, the development and commercialization of PB2452 could be delayed, abandoned or significantly more costly.

The FDA's accelerated approval regulations allow drugs that are being developed to treat an unmet medical need to be approved substantially based on evidence of an effect on a surrogate biomarker endpoint that is considered reasonably likely to predict clinical benefit, rather than a clinical endpoint such as survival or irreversible morbidity. Based on feedback from the FDA, our strategy is to use an accelerated approval pathway that may require that our Phase 3 clinical trial of PB2452 be ongoing at the time of BLA approval. To support our BLA submission for accelerated approval, the FDA recommended an interim analysis of biomarker data from an initial subset of 100 patients, with approximately 50 patients with uncontrolled major or life-threatening bleeding and approximately 50 patients requiring urgent surgery or an invasive procedure, in our Phase 3 trial, together with safety data from our Phase 2 clinical trials. After we submit our BLA with data from the first 100 patients, we intend to complete the Phase 3 trial and establish a post-approval registry in accordance with FDA requirements. If the FDA requires the completion of the Phase 3 trial prior to the submission of a BLA, the development and commercialization timeline of PB2452 will be delayed. Further, the FDA may determine that the trials conducted by us were insufficient to support approval for all or some of the proposed indications, require us to conduct extensive post-approval studies or require us to make modifications to our ongoing Phase 3 clinical trial after approval and marketing.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs and experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

In order to obtain FDA approval to market a new biological or drug product we must demonstrate proof of safety, purity and efficacy in humans. The risk of failure for product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety, purity, potency, and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We have not completed all clinical trials required for the approval of any of our product candidates. We cannot assure you that any clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

We may incur additional costs and experience delays in ongoing clinical trials for our product candidates, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we experience delays in the completion of any clinical trial of our product candidates or if any such trial is terminated, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy

during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication.

If our product candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labels;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

As an organization, we have never completed pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or other regulatory agencies to market PB2452, PB1046, PB6440 or any future product candidate. Carrying out pivotal clinical trials is a complicated process. As an organization, we have not previously completed any later stage or pivotal clinical trials. In order to do so, we have needed to and will need to further expand our clinical development and regulatory capabilities, and we may be unable to recruit and train additional qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. See "— Risks Related to our Dependence on Third Parties —We rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials." In particular, pursuant to the SFJ Agreement, SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA or NDA submission and approval of PB2452, PB1046, PB6440 or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- the perceived risks and benefits of the product candidate in the trial;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on and expect to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk

that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Our clinical development of PB2452 depends on the continued use of ticagrelor as an antiplatelet therapy.

We are developing PB2452 as a ticagrelor reversal agent for the treatment of patients on ticagrelor with uncontrolled major or life-threatening bleeding or requiring urgent surgery or an invasive procedure. If previously unknown safety risks related to ticagrelor are discovered that would affect its use as an antiplatelet therapy, or if market acceptance of ticagrelor significantly changes, we may pause or stop development of PB2452, which would significantly and adversely affect our business prospects.

ELP is a novel technology, which makes it difficult to predict the time, risks and cost of development and of subsequently obtaining regulatory approval of our ELP product candidates.

PB1046 and certain other preclinical product candidates are based on our proprietary ELP technology. Some of our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel ELP technology. We may never receive approval to market and commercialize any product candidate that utilizes ELP.

If we uncover any previously unknown risks related to our ELP technology, or if we experience unanticipated problems or delays in developing our ELP product candidates, we may be unable to complete our clinical trials and preclinical studies, meet the obligations of our license agreements or commercialize our product candidates on a timely or profitable basis. If serious adverse events or unacceptable side effects are observed in clinical trials or preclinical studies of a product candidate based on our ELP technology, our ability to develop other product candidates based on our ELP technology would be adversely affected.

We may be unable to obtain or maintain orphan drug designations or exclusivity for PB1046 or other product candidates, which could limit the potential profitability of such product candidates.

Regulatory authorities in some jurisdictions, including the United States, designate drugs intended for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Generally, a product that has orphan drug designation and subsequently receives the first FDA approval for the disease for which it has such designation is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

The FDA has granted two orphan drug designations for PB1046: one for the treatment of PAH and a second for cardiomyopathy associated with DMD. We may seek orphan drug designation for future indications for PB1046 or for other product candidates. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer or more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition.

Breakthrough Therapy designation by the FDA and PRIME designation by the EMA for PB2452, or any other product candidate, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.

We have received a Breakthrough Therapy designation for PB2452 for the reversal of ticagrelor's antiplatelet activity and may, in the future, apply for Breakthrough Therapy designation for other product candidates. A Breakthrough Therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

Access to the PRIME initiative is granted by the EMA to support the development and accelerate the review of new therapies to treat patients with unmet medical need. The receipt of this access for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional EMA procedures and, in any event, does not assure ultimate approval by the EMA. In addition, even though PB2452 has been granted access to PRIME, the EMA may later decide that it no longer meets the conditions for such access.

We may not be successful in our efforts to increase our pipeline of product candidates, including by pursuing additional indications for our current product candidates or in-licensing or acquiring additional product candidates for other diseases.

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing PB1046 for the treatment of other orphan conditions and PB6440 for treatment-resistant hypertension and by identifying other product candidates using our ELP technology. In addition, we may in-license or acquire additional product candidates for other diseases. We may not be able to identify or develop product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS, and PB6440 for treatment-resistant hypertension. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for PB1046 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The United Kingdom’s withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following the result of a referendum in 2016, the United Kingdom, or UK, left the European Union, or EU, on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the UK and the EU, the UK will be subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules will continue to apply. Negotiations between the UK and the EU are expected to continue in relation to the customs and trading relationship between the UK and the EU following the expiry of the Transition Period.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the UK will no longer be covered by the centralized procedures for obtaining EU-wide marketing and manufacturing authorizations from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products will be required in the UK, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and limit our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Risks Related to the Commercialization of Our Product Candidates

Market acceptance of PB2452, if approved, will depend heavily on the continued market acceptance and use of ticagrelor.

The commercial success of PB2452 as a ticagrelor reversal agent, if approved, is dependent on the continued market acceptance and use of ticagrelor as an antiplatelet therapy. Ticagrelor competes against other commercially available antiplatelet therapies, including other $P2Y_{12}$ receptor antagonists, many of which are available as generic drugs and therefore significantly less expensive than ticagrelor. New antiplatelet therapies may also be developed in the future, including other $P2Y_{12}$ receptor antagonists and other antiplatelet therapies which could also have reversal agents, that could displace ticagrelor as the American College of Cardiology, American Heart Association and European Society of Cardiology's preferred antiplatelet agent for acute coronary syndrome or otherwise reduce ticagrelor's market position. Any such changes in the market acceptance and use of ticagrelor would significantly harm our business, results of operations and prospects for PB2452.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;

- the availability of third-party coverage and adequate reimbursement for PB2452, PB1046, PB6440 and any other product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish sales, marketing and distribution capabilities for PB2452, PB1046, PB6440 or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for PB2452, PB1046, PB6440 or any other product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in a smaller than expected commercial opportunity and/or others discovering, developing or commercializing products before or more successfully than we do.

The life sciences industry is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, compounding facilities, academic institutions and governmental agencies and public and private research institutions.

There are currently no other known reversal agents approved or in clinical development for ticagrelor or any other antiplatelet drugs. In the European Union, an extracorporeal whole blood purification adsorber device is available that may be useful for non-specific removal of ticagrelor during some cardiac procedures when used in conjunction with cardiopulmonary bypass. Upon approval, PB2452 would be the only therapeutic agent available for specific reversal of ticagrelor. There can be no assurance that competitors will not seek to develop a competing product. Moreover, the success of PB2452, if approved, will be dependent on the continued success of ticagrelor. See "—Market acceptance of PB2452, if approved, will depend heavily on the continued market acceptance and use of ticagrelor."

We are aware of several other products and product candidates as potential treatments for PAH that would compete with PB1046. Although we anticipate that PB1046 may be used as a complement to patients' existing therapies, we expect to compete with existing treatments for PAH patients with Class II-IV symptoms that target the endothelin, nitric oxide and prostacyclin pathways, as well as any generic equivalents that may be developed. In addition to currently approved drugs within

these classes, we are also aware of a number of PAH therapies in clinical development with which PB1046 would compete if approved.

We are also aware of several other classes of products and product candidates that are potential treatments for COVID-19 patients at high risk for rapid clinical deterioration and ARDS that could potentially compete with PB1046, if approved. Potential competitors include RLF-100, a formulation of vasoactive intestinal peptide for continuous IV infusion or inhalation, as well as antibody therapies, anti-inflammatory therapies, antiviral therapies, RNA-based treatments, vaccines and others. Although we anticipate that PB1046 may be used in conjunction with multiple other interventions, the launch of effective anti-viral therapies or successful implementation of vaccination strategies could markedly reduce the need for treatments for patients at high risk for rapid clinical deterioration and ARDS.

In addition, we are aware of several other products and product candidates as potential treatments for treatment-resistant hypertension that could compete with PB6440. Although we anticipate that PB6440 may be used as a complement to patients' existing antihypertensive therapies, we expect to compete with existing generic treatments for hypertension that target the mineralocorticoid receptor. In addition to the currently approved mineralocorticoid receptor antagonists, eplerenone and spironolactone, we are also aware of a number of therapies in clinical development for the treatment of resistant hypertension with which PB6440 would compete if approved.

In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, are more convenient or are less expensive than PB2452, PB1046, PB6440 or any other product that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

The success of PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS, PB6440 for treatment-resistant hypertension or any future product candidate will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these procedures.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for PB2452 as a ticagrelor reversal agent, PB1046 for the treatment of PAH and the treatment of hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and ARDS, PB6440 for treatment-resistant hypertension and/or procedures utilizing PB2452, PB1046, PB6440 or any other product candidate, and the extent to which patients will be willing to pay out-of-pocket for such products and procedures, in the absence of reimbursement for all or part of the cost. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Separate reimbursement for the product itself or the treatment or procedure in which our product is used may not be available. Even if the procedure using our product is covered, third-party payors, such as Medicare, Medicaid, managed care organizations, and private health insurers, may package the cost of the drug into the procedure payment and not separately reimburse the physician for the costs associated with our product. A decision by a third-party payor not to cover or separately reimburse for our products could reduce physician utilization of our products once approved. Additionally, in the United States, there is no uniform policy of coverage and reimbursement among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of

the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational.

Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. An example of payment rate updates occurs in the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and introduced a merit-based incentive bonus program for Medicare physicians, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models and the Merit-based Incentive Payment System. In November 2019, CMS issued a rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Any resulting decrease in payment under the merit-based reimbursement system may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that PB2452, PB1046, PB6440 or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

The market for PB2452, PB1046, PB6440 or any other product candidates may be smaller than we expect.

Our estimates of the potential market opportunity for PB2452, PB1046, PB6440 or any other product candidates include several key assumptions based on our industry knowledge, industry publications and third-party research reports. These assumptions include, for PB2452, the number of patients on ticagrelor who will experience uncontrolled major or life-threatening bleeding or who will require urgent surgery or an invasive procedure; for PB1046, the number of patients with PAH or that are hospitalized with COVID-19 at high risk for rapid clinical deterioration and ARDS; and for PB6440, the number of patients with treatment-resistant hypertension, as well as the estimated reimbursement levels for each product candidate if approved. However, there can be no assurance that any of these assumptions are, or will remain, accurate. If the actual market for PB2452, PB1046, PB6440 or for any other product candidates we may develop is smaller than we expect, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;

- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $10,000,000 in product liability insurance coverage in the aggregate, with a per incident limit of $10,000,000, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. 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.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct a significant portion of our existing clinical trials and potential future clinical trials for product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

To date, we have generally engaged CROs to conduct or assist in our ongoing clinical trials of PB2452 and PB1046. We expect to engage CROs for future clinical trials for PB2452, PB1046, PB6440 or other product candidates that we may progress to clinical development. In addition, pursuant to the SFJ Agreement, SFJ will have primary responsibility for clinical development and regulatory activities for PB2452 in China and Japan and will provide clinical trials operational support in the European Union. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct these clinical trials. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our

product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of PB2452, PB1046, PB6440 or any other product candidates.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We contract with third parties for the manufacture of PB2452 and PB1046 for clinical drug supply and expect to continue to do so for commercialization, if approved. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any cGMP manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the cGMP manufacture of PB2452, PB1046, PB6440 and any other product candidates that we may pursue, for clinical development as well as for commercial manufacture of PB2452, PB1046, PB6440 and any other product candidates which we may pursue, if we receive marketing approval. We also rely on a proprietary *E. coli* strain owned by Wacker Biotech GmbH, or Wacker, which we have licensed for the production of PB2452. Our reliance on Wacker's *E. coli* strain increases the risk that we will not have sufficient quantities of PB2452 or be able to obtain quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts. We will continue to rely on Wacker to manufacture our clinical supply of PB2452 for our ongoing clinical trials.

With respect to PB2452, to date we have only relied upon Wacker for manufacture of drug substance for use in our initial clinical trials. As we scale our manufacturing of PB2452 to meet potential commercial demand, if PB2452 is approved, we have initiated a technology transfer of our current manufacturing process for PB2452 to BioVectra, another cGMP contract manufacturer. We have engaged BioVectra to manufacture drug substance for our ongoing clinical trials and intend to engage BioVectra to manufacture commercial supply of PB2452, if approved. We will need to perform analytical and other tests to demonstrate that the new materials produced by Wacker, BioVectra, or any other future third-party manufacturer that we engage, are comparable in all respects to the product utilized in our previous clinical trials. There is no assurance that any such product will pass the required comparability testing, that any other future third-party manufacturer that we engage will be successful in producing PB2452 or that any materials produced by Wacker, BioVectra or any other third-party manufacturer that we engage will have the same effect in patients that we have observed to date with respect to materials used in our previous clinical trials. Moreover, if supplies are interrupted or produced in poor yield or quality, it would materially harm our business. BioVectra will be required to scale up the manufacturing process to meet our future needs of PB2452 for later-stage clinical development and, if approved, commercialization. If BioVectra is unable to successfully scale up the manufacturing process, we would need to find

alternative manufacturing facilities or an alternative manufacturing process, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and which could adversely affect the clinical development of PB2452.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of PB2452, PB1046, PB6440 and any other product candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA or other regulatory authorities after we submit our BLA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may be unable to obtain regulatory approval of our marketing applications. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may be unable to enter into any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we enter into such agreements, qualifying and validating such manufacturers may take a significant period of time and reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the incurrence of upfront scale-up costs prior to commercial approval;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible increase in costs for the raw materials for our product candidates; and
- the possible termination or nonrenewal of any agreement by any third party at a time that is costly or inconvenient for us.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supply of our products.

Our product candidates, and any drugs that we may develop, may compete with other product candidates and drugs for access to manufacturing facilities. The performance of our third-party manufacturers may also be interrupted by production shortages or other supply interruptions resulting from the ongoing COVID-19 pandemic. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us in a timely manner. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We are collaborating with SFJ for the development of PB2452, and we may seek additional collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We are collaborating with SFJ for the development of PB2452. We may seek additional third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If SFJ or any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We may seek to establish additional collaborations, and if we are unable to do so, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital. We are collaborating with SFJ for the development of PB2452. For our other product candidates, we may decide to establish additional collaborations with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have

been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and our ELP technology. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

As of the date of this Quarterly Report on Form 10-Q, our patent estate contained at least 21 patent families that we own or in-license that protect various aspects of our product candidates or our ELP technology platform. We own or have rights in 24 United States patents, 16 United States patent applications, over 70 foreign patents and over 55 foreign patent applications. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product that would be competitive with one or more of our product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any of our product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, or that our trade secrets and other confidential proprietary information will not be disclosed. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products, if approved, and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly

available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

If we fail to comply with our obligations in our current and future intellectual property licenses with third parties or the SFJ Agreement, we could lose rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and proprietary technology for the development of PB2452, PB1046 and our ELP technology. These license agreements impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, our licensors may have the right to terminate our licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other penalties. Such an occurrence would materially adversely affect our business prospects.

Licenses to additional third-party technology and materials that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, or at all, which could have a material adverse effect on our business and financial condition. Although we control the prosecution, maintenance and enforcement of the licensed and sublicensed intellectual property relating to PB2452, we may require the cooperation of our licensors and any upstream licensor, which may not be forthcoming. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business. If we or our licensor fail to maintain such patents, or if we or our licensor lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights we may own in the future. Further, if we fail to comply with our development obligations under our license agreements, we may lose our patent rights with respect to such agreement on a territory-by-territory basis, which would affect our patent rights worldwide.

Termination of our current or any future license agreements would reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Any of the foregoing could prevent us from commercializing our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should

our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

Further, we have granted SFJ a security interest in all of our assets related to PB2452, pursuant to the SFJ Agreement. If we are unable to meet our payment obligations to SFJ, SFJ may exercise its remedies as a holder of a first priority security interest, which would result in a loss of our PB2452 intellectual property rights and our business would be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to United States patent law. These included provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe the patents we have applied for. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or

unenforceability of a patent. In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover the technology in question. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We cannot provide any assurance that our current and future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize PB2452, PB1046, PB6440 or any future product candidates. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such United States patent.

Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other

claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture or commercialize PB2452, PB1046, PB6440 or any future product candidates, or if we collaborate with additional third parties for the development of PB2452, PB1046, PB6440 or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents, and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement rights are not as strong as that in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property

rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to make the inventions covered by our issued or future issued patents or our pending patent applications;

- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly

making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the United States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on health plans, healthcare clearinghouses and certain healthcare providers, known as "covered entities", and their respective HIPAA "business associates", which are independent contractors that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (1) payments or other "transfers of value'' made to physicians, as defined by such law, and teaching hospitals, and (2) ownership and investment interests held by physicians and their immediate family members; and
- state and foreign law equivalents of each of the above federal laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state 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 that otherwise restrict payments that may be made to healthcare providers; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the General Data Protection Regulation (EU) 2016/679, or GDPR, which went into effect on May 25, 2018, imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million Euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. In addition, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is

possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving 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 penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state 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, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory approval for PB2452, PB1046, PB6440 or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for PB2452, PB1046, PB6440 or any future product candidates, such product candidates, once approved, will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submitting of safety and other post-market information, among other things. Any regulatory approvals that we receive for PB2452, PB1046, PB6440 or any future product candidates may also be subject to a risk evaluation and mitigation strategy, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing, including Phase 4 trials, and in the event that we receive accelerated approval of PB2452, the completion of a Phase 3 trial, and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of PB2452, PB1046, PB6440 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA, NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize PB2452, PB1046, PB6440 or any future product candidates and harm our business, financial condition, results of operations and prospects.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the United States pharmaceutical industry. The ACA, among other things: (1) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs; (2) expanded the entities eligible for discounts under the 340B drug pricing program; (3) increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP; (4) expanded the eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (5) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (6) introduced a new Medicare Part D coverage gap discount program in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (7) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (8) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including spending on prescription drugs.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a judge for the United States District Court for the Northern District of Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual

mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030, unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration’s budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a plan to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has started soliciting feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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 importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that 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 drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for PB2452, PB1046, PB6440 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;

- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of PB2452, PB1046, PB6440 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore requires significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks Related to Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers, particularly Jonathan P. Mow, our Chief Executive Officer. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of June 30, 2020, we had approximately 50 employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance 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, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government 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, and the curtailment or restructuring of our operations.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Prior to our initial public offering, there was no public market for our common stock, and we cannot assure you that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for you to sell shares at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been, and may continue to be, volatile. Since our initial public offering, or IPO, our common stock has traded at prices ranging from $2.55 to $16.65 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our clinical trials of PB2452, PB1046, PB6440 or any future clinical trials we may conduct, or changes in the development status of our product candidates;

- any delay in our regulatory filings for PB2452, PB1046, PB6440 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from, delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of PB2452, PB1046, PB6440 or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- progress under our collaboration with SFJ for the development of PB2452;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general has, and the Nasdaq Global Market and biotechnology companies in particular have, experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, 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 section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research

analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 registering the issuance of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of approximately 2.2 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plan or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, in the future we may issue common stock or other securities convertible into shares of our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plan or otherwise. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then outstanding shares of our common stock, which could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 66 2⁄3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or the SEC, or other regulatory authorities.

We have broad discretion in the use of our cash and cash equivalents.

We have broad discretion over the use of our cash and cash equivalents, including the net proceeds from our recent public offerings. You may not agree with our decisions, and our use of these cash and cash equivalents may not yield any return on your investment. We expect to use our existing cash and cash equivalents to advance PB2452, PB1046 and PB6440, fund development of our ELP technology and preclinical programs and for working capital and general corporate purposes. In addition, we may use a portion of our cash and cash equivalents to pursue our strategy to in-license or acquire additional product candidates. Our failure to apply our cash and cash equivalents effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these cash and cash equivalents. You will not have the opportunity to influence our decisions on how to use these cash and cash equivalents.

New or future changes to tax laws could materially adversely affect our company.

On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or the Tax Act, which significantly revises the United States Internal Revenue Code of 1986, as amended. Future guidance from the United States Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, on March 27, 2020, President Trump signed into law the CARES Act, which modifies in certain respects the Tax Act. Changes in corporate tax rates, the realization of net deferred tax assets relating to our United States operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future United States tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

At December 31, 2019, we had federal and state net operating loss, or NOL, carryforwards of $149.0 million and $153.4 million, respectively. The federal NOLs generated prior to 2018 may be used to offset up to 100% of future taxable income and will begin to expire in 2022, unless previously utilized. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, as modified by the CARES Act, federal net operating losses incurred in taxable years beginning after December 31, 2017 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses incurred in the taxable year beginning after December 31, 2020 is limited. It is uncertain how various states will respond to the Tax Act and CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of the SFJ Agreement preclude us from paying dividends, and any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

We have begun incurring increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we are incurring significant additional legal, accounting and other costs. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the Nasdaq Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (4) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our

amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Item 2. Recent Sales of Unregistered Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

EXHIBIT INDEX

		Incorporated by Reference			
Exhibit Number	**Exhibit Title**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of PhaseBio Pharmaceuticals, Inc.	8-K	001-38697	3.1	October 22, 2018
3.2	Amended and Restated Bylaws of PhaseBio Pharmaceuticals, Inc.	S-1/A	333-227474	3.4	October 5, 2018
4.1	Form of Warrant to Purchase Shares of Series B Redeemable Convertible Preferred Stock, issued by PhaseBio Pharmaceuticals, Inc. on December 22, 2009.	S-1	333-227474	4.2	September 21, 2018

4.2	Warrant to Purchase Shares of Series C-1 Redeemable Convertible Preferred Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on October 18, 2017.	S-1	333-227474	4.3	September 21, 2018
4.3	Fourth Amended and Restated Investor Rights Agreement, by and among PhaseBio Pharmaceuticals, Inc. and certain of its stockholders, dated August 27, 2018.	S-1	333-227474	4.4	September 21, 2018
4.4	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on March 25, 2019.	10-K	001-38697	4.4	March 26, 2019
4.5	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on March 25, 2019.	10-K	001-38697	4.5	March 26, 2019
4.6	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on July 26, 2019.	10-Q	001-38697	4.6	August 14, 2019
4.7	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on July 26, 2019.	10-Q	001-38697	4.7	August 14, 2019
4.8	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to Silicon Valley Bank on October 2, 2019.	10-Q	001-38697	4.8	November 14, 2019
4.9	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to WestRiver Innovation Lending Fund VIII, L.P. on October 2, 2019.	10-Q	001-38697	4.9	November 14, 2019
4.10	Warrant to Purchase Shares of Common Stock, issued by PhaseBio Pharmaceuticals, Inc. to SFJ Pharmaceuticals X, Ltd. on January 9, 2020	10-K	001-38697	4.10	March 30, 2020
4.11	Description of PhaseBio Pharmaceuticals, Inc. Common Stock	10-K	001-38697	4.11	March 30, 2020
31.1#	Certification of Chief Executive Officer and President (Principal Executive Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

31.2#	Certification of Chief Financial Officer (Principal Financial Officer), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#*	Certification of Chief Executive Officer (Principal 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 (Principal Financial Officer), pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS#	XBRL Instance Document.
101.SCH#	XBRL Taxonomy Extension Schema Document.
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document.

Filed herewith.
+ Indicates management contract or compensatory plan.
† Confidential treatment has been granted for certain portions of this exhibit (indicated by asterisks). Such information has been omitted and was filed separately with the Securities and Exchange Commission.
†† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to PhaseBio Pharmaceuticals, Inc. if publicly disclosed.
* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Signatures

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

PHASEBIO PHARMACEUTICALS INC.

August 11, 2020

By: /s/ John P. Sharp

John P. Sharp
Chief Financial Officer
(*On behalf of the registrant and in his capacity as Principal Financial Officer and Principal Accounting Officer*)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan P. Mow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PhaseBio Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2020

By: /s/ Jonathan P. Mow
Jonathan P. Mow
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Sharp, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PhaseBio Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2020

By: /s/ John P. Sharp
John P. Sharp
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of PhaseBio Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: August 11, 2020

By: /s/ Jonathan P. Mow

Jonathan P. Mow
Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of PhaseBio Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: August 11, 2020

By: /s/ John Sharp
John Sharp
Chief Financial Officer