Filed Pursuant to 424(b)(3)
Registration Statement No. 333-262279

PROSPECTUS SUPPLEMENT NO. 1
(To Prospectus dated March 31, 2022)

Up to 39,688,152 Shares of Common Stock

This prospectus supplement supplements the prospectus dated March 31, 2022 (the "Prospectus"), which forms a part of our registration statement on Form S-1 (File No. 333-262279). This prospectus supplement is being filed to update and supplement the information in the Prospectus with the information contained in our quarterly report on Form 10-Q for the period ended March 31, 2022, filed with the Securities and Exchange Commission on May 10, 2022 (the "Q1 2022 Quarterly Report"). Accordingly, we have attached the Q1 2022 Quarterly Report to this prospectus supplement.

The Prospectus and this prospectus supplement relate to the offering and resale by the selling stockholders identified in the Prospectus of up to 39,688,152 shares of our common stock, par value $0.0001 per share.

This prospectus supplement updates and supplements the information in the Prospectus and is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This prospectus supplement should be read in conjunction with the Prospectus and if there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this prospectus supplement.

Our common stock is listed on Nasdaq Global Market under the symbol "PRDS". On May 9, 2022, the closing price of our common stock was $6.71 per share.

Investing in our securities involves risks that are described in the "*Risk Factors*" section beginning on page 11 of the Prospectus.

The registration statement to which the Prospectus and this prospectus supplement relates registers the resale of a substantial number of shares of our common stock by the selling stockholders. Sales in the public market of a large number of shares, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Neither the SEC nor any state securities commission has approved or disapproved of the securities to be issued under the Prospectus or this prospectus supplement or determined if the Prospectus or this prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is May 10, 2022

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

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 001-40067

PARDES BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-2696306**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2173 Salk Avenue, Suite 250 PMB#052 Carlsbad, CA	**92008**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 649-8758

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.0001 per share	**PRDS**	**The Nasdaq Global Market**

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

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

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

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

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

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

The number of shares of Registrant's common stock outstanding as of May 5, 2022 was 62,320,924.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, including those relating to the success, cost and timing of our product development activities and clinical trials, the potential attributes and benefits of our product candidates, our ability to obtain and maintain regulatory approval for our product candidates and our ability to obtain funding for our operations. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements relating to us in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including due to the pandemic's impact on our research and development activities, clinical trials, and employees;
- the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, including PBI-0451, our lead product candidate, and other positive results;
- the timing, progress and results of clinical trials for PBI-0451 and completion of studies or trials and related preparatory work;
- the period during which the results of the clinical trials will become available;
- the initiation, timing, progress, results and costs of our research and development programs and our current and future preclinical studies, nonclinical studies and clinical trials;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- the timing, scope and likelihood of regulatory filings;
- our ability to obtain emergency use authorization or marketing approval of PBI-0451 and any future product candidates on expected timelines, and to meet existing or future regulatory standards or comply with post-authorization or post-approval requirements;
- our expectations regarding the potential market size, government stockpiling and the size of the patient populations for our product candidates, if approved for commercial use;
- the performance of third parties in connection with the development of our product candidates, including third-party suppliers and manufacturers;
- our intellectual property position and expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expected future growth;
- our estimates regarding expenses, future financial performance and capital requirements;
- the impact of government laws and regulations in the United States and foreign countries;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments and expectations regarding our industry; and
- other risks and uncertainties indicated in this Quarterly Report, including those under "*Risk Factors*" herein, and other filings that have been made or will be made with the SEC.

The forward-looking statements in this Quarterly Report on Form 10-Q are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements.

In addition, statements that we "believe," and similar statements, reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe that such information forms a reasonable basis for such statements, such information may be limited or incomplete, and these statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

The risks and uncertainties include, but are not limited to, those factors described under the headings "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 29, 2022. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic (including declines in SARS-CoV-2 infections) and there may be additional risks that we currently consider immaterial or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. Set forth below is a summary list of the principal risk factors as of the date of filing of this Quarterly Report on Form 10-Q:

- We have a limited operating history and no history of successfully developing or commercializing any approved therapeutic products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability and ability to generate revenue and become profitable in the future.
- We have incurred significant losses since our inception and expect to incur losses for the foreseeable future.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development, manufacturing and commercialization of PBI-0451 or any other product candidates.
- We are heavily dependent on the success of PBI-0451, our lead product candidate. Failure to obtain regulatory approval for PBI-0451 will prevent us from commercializing and marketing PBI-0451.
- PBI-0451 and any other product candidates we may develop must undergo rigorous clinical trials and regulatory approvals, and results from early nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.
- Our subsequent clinical trials may reveal significant adverse events not seen in our earlier clinical trials or preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Interim, "topline" and preliminary data 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. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.
- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including significant competition for recruiting patients with COVID-19 in clinical trials, the availability of other competing therapies and currently declining infection rates.
- We have completed dosing of PBI-0451, our lead product candidate, in our first-in-human Phase 1 clinical trial, but we have not commenced clinical trials on efficacy. Accordingly, there is significant uncertainty around the development of PBI-0451 as a potential treatment for coronavirus generally, and SARS-CoV-2 infections and COVID-19 specifically.
- We must attract and retain highly skilled employees to succeed. If we are not able to retain our current team or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.
- PBI-0451 may face significant competition from other treatments for SARS-CoV-2 infections that are in development. If our competitors develop and market products faster or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for SARS-CoV-2 infections, if approved, could also be impacted by the success or failure of other entities, or perceived success or failure of their therapeutic candidates.
- We may expend resources in anticipation of clinical trials and potential commercialization of PBI-0451, which we may not be able to recover if PBI-0451 is not authorized or approved for the treatment of SARS-CoV-2 or we are not successful at commercializing PBI-0451.
- COVID-19 continues to cause significant morbidity and mortality globally. The number of infections, and the morbidity associated with those infections, however, change continuously. As a result, we may find enrollment of patients for clinical trials to be a challenge, and/or may find that the severity of disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints related to hospitalizations, morbidity and mortality. If enrollment is delayed or takes longer than expected this could impact our ability to seek an EUA while the pathway is available and could delay the collection of data sufficient to meet our endpoints and seek marketing approval.

- The regulatory pathways for our product candidates targeting coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.
- In addition to seeking an emergency use authorization ("EUA") for PBI-0451, if available when we have sufficient clinical data and which the FDA has applied to certain COVID-19 treatments, we may also attempt to secure conditional approvals or emergency authorizations in other countries outside of the US. If we are unable to obtain such authorizations, or those pathways are no longer available to us at the time we would be seeking authorizations, we may be required to conduct additional nonclinical studies or clinical trials beyond those contemplated for accelerated authorization, which could delay our ability to generate revenue and increase the expense of obtaining, and delay in the receipt of, necessary marketing approvals. Even if we receive an emergency authorization from the FDA or other regulators, if our confirmatory clinical trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or other regulators may seek to withdraw conditional approval or emergency authorization.
- Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. Proprietary rights and technology are difficult and costly to protect, and we may not be able to ensure their protection.
- We contract with third parties for the manufacture of our product candidates for nonclinical and clinical testing and expect to continue to do so for subsequent clinical trials and for commercialization. Significant portions of our clinical manufacturing are currently conducted by outside of the United States, including China. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or that such supply will not be available to us at an acceptable cost and in accordance with anticipated timelines, which could delay, prevent or impair our development or commercialization efforts.
- We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- The price of our common stock may be volatile.
- The future sales of shares by existing stockholders and future exercise of registration rights may adversely affect the market price of our common stock.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Financial Statements (Unaudited).

PARDES BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and par value data)

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 247,919	$ 268,678
Prepaid expenses and other current assets	7,225	6,581
Total current assets	255,144	275,259
Total assets	$ 255,144	$ 275,259
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,366	$ 2,385
Accrued expenses	6,397	6,580
Total current liabilities	8,763	8,965
Total liabilities	8,763	8,965
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.0001 par value; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common stock: $0.0001 par value at March 31, 2022 and December 31, 2021; 250,000,000 shares authorized at March 31, 2022 and December 31, 2021; 62,378,996 shares issued at March 31, 2022 and December 31, 2021; and 57,376,298 and 56,765,533 shares outstanding at March 31, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	319,339	317,812
Accumulated deficit	(72,964)	(51,524)
Total stockholders' equity	246,381	266,294
Total liabilities and stockholders' equity	$ 255,144	$ 275,259

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

PARDES BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 13,199	$ 3,445
General and administrative	8,226	1,081
Total operating expenses	21,425	4,526
Other income (expense):		
Other (expense) income, net	(15)	3
Net loss and comprehensive loss	$ (21,440)	$ (4,523)
Net loss per share, basic and diluted	$ (0.38)	$ (6.19)
Weighted-average number of common shares used in computing net loss per share, basic and diluted	57,039,069	731,175

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

PARDES BIOSCIENCES, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)
(in thousands, except share amounts)

	Three Months Ended March 31, 2022						
	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	$0.0001 Par Value			
Balance at December 31, 2021	—	$ —	56,765,533	$ 6	$ 317,812	$ (51,524)	$ 266,294
Vesting of restricted stock awards into common stock	—	—	610,765	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,527	—	1,527
Net loss	—	—	—	—	—	(21,440)	(21,440)
Balance at March 31, 2022	—	$ —	57,376,298	$ 6	$ 319,339	$ (72,964)	$ 246,381

	Three Months Ended March 31, 2021						
	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	$0.00001 Par Value			
Balance at December 31, 2020	—	$ —	—	$ —	$ —	$ (13,006)	$ (13,006)
Issuance of Series A convertible preferred stock for cash, net of issuance costs of $176	13,756,122	44,324	—	—	—	—	—
Conversion of SAFE agreements into shares of convertible preferred stock	5,845,071	14,808	—	—	—	—	—
Vesting of restricted stock awards into common stock	—	—	1,534,646	—	—	—	—
Stock-based compensation expense	—	—	—	—	76	—	76
Net loss	—	—	—	—	—	(4,523)	(4,523)
Balance at March 31, 2021	19,601,193	$ 59,132	1,534,646	$ —	$ 76	$ (17,529)	$ (17,453)

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

PARDES BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Operating activities:		
Net loss	$ (21,440)	$ (4,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,527	76
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(645)	(6)
Accounts payable	216	(303)
Accrued expenses	(20)	1,008
Net cash used in operating activities	(20,362)	(3,748)
Financing activities:		
Proceeds from issuance of convertible preferred stock	—	44,500
Cash paid for deferred offering costs	(397)	(83)
Payment of issuance costs for convertible preferred stock	—	(176)
Net cash provided by financing activities	(397)	44,241
(Decrease) increase in cash and cash equivalents	(20,759)	40,493
Cash and cash equivalents at beginning of period	268,678	3,410
Cash and cash equivalents at end of period	$ 247,919	$ 43,903
Non-cash financing activities:		
Conversion of 2020 SAFE agreements into shares of convertible preferred stock	$ —	$ 14,808
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 174

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

Note 1. Description of Business

Description of Business

Unless the context otherwise requires, references in these notes to "Pardes," "the Company," "we," "us" and "our" and any related terms are intended to mean Pardes Biosciences, Inc. and its subsidiary.

Pardes Biosciences, Inc. is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics to improve the lives of patients suffering from life-threatening disease, starting with our lead product candidate, PBI-0451, which is in clinical development and intended to treat and prevent coronaviral (CoV) infections. COVID-19 is caused by infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and has emerged as the most significant pandemic threat to the world in many decades. We have built a discovery platform designed to target reactive nucleophiles, such as those in cysteine proteases. By leveraging our deep understanding of structure-based drug design, reversible covalent chemistry and viral biology, we have discovered and are developing novel product candidates with low nanomolar potency against SARS-CoV-2 and broad activity against all known pathogenic human coronaviruses. Our lead product candidate, PBI-0451, inhibits the main coronaviral cysteine protease, a viral protein essential for replication of all known coronaviruses, including SARS-CoV-2.

References in these notes to the unaudited condensed financial statements to "Pardes Biosciences, Inc.," refer to Pardes Biosciences Sub, Inc., a Delaware corporation incorporated in February 2020 and formerly known as Pardes Biosciences, Inc. ("Old Pardes"), for the periods prior to its business combination transaction that took place on December 23, 2021 and Pardes Biosciences, Inc., a Delaware corporation incorporated in August 2020 and formerly known as FS Development Corp. II ("FSDC II"), and its subsidiary for the periods following the Business Combination.

Business Combination

On December 23, 2021 (the "Closing Date"), Old Pardes and FSDC II completed the transactions contemplated by the Agreement and Plan of Merger, dated as of June 29, 2021 (as amended on November 7, 2021, the "Merger Agreement"), by and among Old Pardes, Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the Company Securityholders (as defined in the Merger Agreement), FSDC II and Orchard Merger Sub Inc., a Delaware corporation and a wholly-owned subsidiary of FSDC II ("Merger Sub"). FSDC II was formed in August 2020 for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

On the day prior to the Closing Date, Old Pardes changed its name to "Pardes Biosciences Sub, Inc." Pursuant to the Merger Agreement, on the Closing Date, (i) FSDC II changed its name to "Pardes Biosciences, Inc." (together with its consolidated subsidiary, "New Pardes"), and (ii) Old Pardes merged with and into Merger Sub (the "Merger"), with Old Pardes as the surviving company in the Merger and, after giving effect to such Merger, Old Pardes becoming a wholly-owned subsidiary of New Pardes. On January 31, 2022, Old Pardes merged with and into New Pardes.

In connection with the transactions contemplated under the Merger Agreement and described above (collectively, the "Business Combination") certain investors purchased an aggregate of $75.0 million of our common stock in a private placement of public equity (the "PIPE Investment"). Together with FSDC II's cash resources and funding of the PIPE Investment, we received net proceeds of approximately $257.5 million.

For additional information on the Business Combination, please refer to Note 4, *Business Combination*, to the consolidated financial statements included in Part II, Item 8 of our Form 10-K for the fiscal year ended December 31, 2021.

Through March 31, 2022, we have funded our operations primarily with proceeds from the issuance of Simple Agreements for Future Equity ("SAFEs"), convertible preferred stock financing, the Business Combination and the PIPE Investment. We believe that our $247.9 million of cash and cash equivalents as of March 31, 2022 will enable us to fund our current planned operations for at least twelve months from the issuance date of these condensed financial statements, though we may raise additional capital through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements, government funding and grants. Management's expectations with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management, and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us or at all, and we may need to seek additional funds sooner than anticipated. If adequate funds are not available to us on a timely basis, on acceptable terms or at all, management may be required to delay, limit, reduce or terminate certain of its research, product development or future commercialization efforts, obtain funds through arrangements with collaborators on terms unfavorable to us, or pursue merger or acquisition strategies, all of which could adversely affect the holdings or the rights of our stockholders.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as filed with the Securities and Exchange Commission ("SEC") on March 29, 2022, from which we derived our balance sheet as of December 31, 2021. The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of our management, necessary to a fair statement of the results for the interim periods presented. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022 or for any other future annual or interim period.

As a result of the Business Combination, the shares and corresponding capital amounts and loss per share amounts related to Old Pardes' outstanding redeemable convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the conversion ratio of 1.4078 ("Conversion Ratio") established in the Merger Agreement. For additional information on the Business Combination and the Conversion Ratio, please read Note 4, *Business Combination*, to the audited consolidated financial statements included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Use of Estimates

The preparation of the unaudited condensed financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect the amounts reported on our unaudited condensed financial statements and accompanying notes. The amounts reported could differ under different estimates and assumptions. On an ongoing basis, we evaluate our estimates and judgements, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. Though the impact of the COVID-19 pandemic on our business and operating results presents additional uncertainty, we continue to use the best information available to form our critical accounting estimates. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

Impact of COVID-19

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced. Since then, COVID-19 has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. The outbreak and government measures taken in response thereto have had a significant impact, both direct and indirect, on businesses and commerce, as certain worker shortages have occurred, supply chains have been disrupted, and facilities and production have been suspended. The future progression of the pandemic and its effects on our business and operations are uncertain.

We are monitoring the potential impact of COVID-19 on our business and condensed financial statements. The effects of the public health directives and our work-from-home policies may negatively impact productivity, disrupt our business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact business, results of operations and financial condition, including our ability to obtain financing.

To date, we have not incurred impairment losses in the carrying values of our assets as a result of the COVID-19 pandemic and are not aware of any specific related event or circumstance that would require us to revise our estimates reflected in the unaudited condensed financial statements.

We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and prospects. The extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

Significant Accounting Policies

The accounting policies we follow are set forth in our audited consolidated financial statements for the fiscal year ended December 31, 2021. For further information, please refer to the consolidated financial statements and footnotes thereto included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There have been no material changes to these accounting policies.

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 for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury-stock method. Common stock equivalents are only included in the calculation of diluted earnings per common share when net income is reported and their effect is dilutive. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as shares of unvested restricted stock are considered participating securities. Our participating securities do not have a contractual obligation to share in our losses. As such, the net loss was attributed entirely to common stockholders for all periods presented.

As a result of the Business Combination, we have retroactively restated the weighted-average number of common shares and common stock equivalent outstanding prior to December 23, 2021 to give effect to the Conversion Ratio.

The following outstanding shares of potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would be anti-dilutive (in common stock equivalent shares):

	March 31, 2022	March 31, 2021
Conversion of outstanding convertible preferred stock	—	19,601,193
Outstanding stock options	6,380,596	1,154,302
Restricted common stock subject to repurchase or forfeiture	4,944,626	8,227,040
Total	11,325,222	28,982,534

New Accounting Pronouncements Adopted and Not Yet Adopted

In August 2020, the Financial Accounting Standards Board ("FASB") issued ASU No. 2020-06 ("ASU 2020-06"): Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. The diluted net income per share calculation for convertible instruments will require us to use the if-converted method. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective for us on January 1, 2024, with early adoption permitted. ASU No. 2020-06 can be adopted on either a fully retrospective or modified retrospective basis. We early adopted this update on January 1, 2022 using the modified retrospective method of transition and the impact on our financial statements was not material.

In December 2019, the FASB issued ASU 2019-12 – Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, an authoritative guidance that simplifies the accounting for income taxes by removing certain exceptions and making simplifications in other areas. ASU 2019-12 is effective from the first quarter of fiscal year 2022. We adopted this update on January 1, 2022 and the impact on our financial statements was not material.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 362): Measurement of Credit Losses on Financial Statements ("ASU 2016-13"). The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, Financial Instruments-Overall, applied on an instrument-by-instrument basis for eligible instruments. ASU 2016-13 is effective for us on January 1, 2023, with early adoption permitted. We do not expect this update to have a material impact on our financial statements.

Note 3. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. 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. 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 liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Observable inputs such as quoted prices in active markets;

Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 — Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

At March 31, 2022 and December 31, 2021, we did not have financial assets that are measured at fair value on a recurring basis.

As further described in Note 6, between April 2020 and December 2020, we entered into several SAFEs, (collectively the "2020 SAFEs") with certain investors. We recorded the liability related to the 2020 SAFEs at fair value and subsequently remeasured the instruments to fair value using Level 3 fair value measurements.

The fair value of the 2020 SAFEs was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. We determined the fair value of the 2020 SAFEs based on the amount of proceeds received from new third-party investors for the 2020 SAFEs, the terms of the 2020 SAFEs, including the rate at which the 2020 SAFEs convert into qualified equity financing securities, the probability and timing of a qualified equity financing and the fair value of the underlying preferred stock. Estimates and assumptions impacting the fair value measurement include the probability of a qualified equity financing as defined in the 2020 SAFEs agreements, the expected timing of such event, and the fair value of our Series A preferred stock (the "Series A Preferred"). We estimated the probability and timing of the qualified equity financing based on management's assumptions and knowledge of specified events at issuance and as of each reporting date.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

Balance as of January 1, 2021	$ 14,808
Conversion into shares of convertible preferred stock	(14,808)
Balance as of March 31, 2021	$ —

Note 4. Prepaid Expenses And Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Prepaid insurance	$ 4,331	$ 5,286
Prepaid research and development costs	2,185	639
Other prepaid expenses and current assets	709	656
Total	$ 7,225	$ 6,581

Note 5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Research and development accruals	$ 4,499	$ 4,050
Accrued compensation	1,271	1,659
Other accrued expenses	627	871
Total	$ 6,397	$ 6,580

Note 6. Simple Agreements for Future Equity

Between April 2020 and December 2020, we entered into the 2020 SAFEs, pursuant to which we received funding of $7.1 million in cash in exchange for SAFEs providing the investors the right to receive shares of our capital stock.

The 2020 SAFEs contained a number of conversion and redemption provisions, including settlement upon liquidity or dissolution events. The 2020 SAFEs required that we issue equity to the SAFE holders in exchange for their investment upon an equity financing. An equity financing was defined as a transaction or series of transactions with the principal purpose of raising capital, pursuant to which we issued and sold preferred stock at a fixed valuation. The number of shares to be received by the 2020 SAFE investors was determined as the greater of the SAFE purchase amount divided by (i) the lowest price per share of the Series A Preferred or (ii) the SAFE purchase amount divided by the SAFE price per share. A liquidity event meant a change in control, a direct listing, or an initial public offering. In a liquidity or dissolution event, the investors' right to receive cash out was junior to payment of outstanding indebtedness and creditor claims, on par for other SAFEs and preferred stock, and senior to common stock. The 2020 SAFEs had no interest rate or maturity date, and the 2020 SAFE investors had no voting right prior to conversion.

The 2020 SAFEs were automatically converted on January 19, 2021, into 3,967,207 shares (2,818,034 shares as originally issued) of Series A-1 Preferred Stock, 852,908 shares (605,850 shares as originally issued) of Series A-2 Preferred Stock and 1,024,956 shares (728,058 shares as originally issued) of Series A-3 Preferred Stock with an aggregate fair value of $14.8 million based on the conversion ratio described in each respective SAFE agreement. The conversion price was $1.2420 for the Series A-1 Preferred Stock, $2.4841 for the Series A-2 Preferred Stock and $2.8981 for the Series A-3 Preferred Stock.

Note 7. Stockholders' Equity

The condensed statements of stockholders' equity have been retroactively adjusted for all periods presented to reflect the Business Combination and reverse capitalization as defined in Note 4, *Business Combination,* to the consolidated financial statements included in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Convertible Preferred Stock

In January 2021, we sold 13,756,122 shares (9,771,414 shares as originally issued) of Series A Preferred Stock for gross proceeds of $44.5 million and issued a total of 5,845,071 shares (4,151,942 shares as originally issued) of Series A-1, A-2 and A-3 Preferred Stock in satisfaction of our obligation under the 2020 SAFEs. On December 23, 2021, in connection with the closing of the Business Combination and pursuant to the Merger Agreement, all previously issued and outstanding Series A and Series A-1, A-2 and A-3 Preferred Stock were exchanged for shares of our common stock, respectively, pursuant to the Conversion Ratio. All fractional shares were rounded down.

Upon the closing of the Business Combination, pursuant to the terms of the Second Amended and Restated Certificate of Incorporation dated December 23, 2021 (the "Certificate of Incorporation"), we authorized 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated. Our board of directors (the "Board") has the authority, without further action by the stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designations, powers, voting, and other rights, preferences and privileges of the shares. As of March 31, 2022 and December 31, 2021, there were no shares of preferred stock outstanding.

Common Stock

In January 2021, we sold 105,585 shares (75,000 shares as originally issued) of restricted common stock to two directors of our Board for their Board services. The proceeds from the restricted common stock sale were immaterial to the condensed consolidated financial statements. The stock is subject to vesting ratably each month over 48 months.

Pursuant to the Certificate of Incorporation, as of March 31, 2022 and December 31, 2021, there were 250,000,000 shares of common stock, par value $0.0001 per share, authorized. There were 62,378,996 shares issued as of March 31, 2022 and December 31, 2021.

In March 2022, in connection with the departure of a former employee, the Company repurchased 58,072 unvested shares of common stock for an aggregate purchase price of $0.41. For accounting purposes, unvested restricted stock and the unvested shares repurchased by us are not deemed to be outstanding. Accordingly, there were 57,376,298 and 56,765,533 shares deemed outstanding as March 31, 2022 and December 31, 2021, respectively.

Note 8. Stock-Based Compensation

The following table summarizes stock-based compensation expense for all stock-based compensation arrangements (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 463	$ 14
General and administrative	1,064	62
Total stock-based compensation	$ 1,527	$ 76

As of March 31, 2022, the total unrecognized compensation cost related to outstanding time-based options was $26.7 million, which is expected to be recognized over a weighted-average period of 3.4 years.

During the three months ended March 31, 2022 and 2021, we granted options to purchase 3,071,250 shares and 1,154,299 shares, respectively, of our common stock at the weighted-average grant date fair value of $9.55 and $3.78 per share, respectively. The assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock options granted in the three months ended March 31, 2022 and 2021, were as follows:

	Three Months Ended March 31,	
	2022	2021
Risk-free interest rate	1.62 - 1.79%	1.20%
Expected volatility	61.48 - 61.56%	81.60%
Expected option life (in years)	6.00 - 6.08	6.20
Expected dividend yield	-%	-%
Exercise price	$6.00-$11.32	$0.01-$3.84

As disclosed in the Note 10 below, on March 25, 2022, our former Chief Executive Officer and President, Dr. Lopatin entered into the Transition and Separation Agreement and General Release of Claims (the “Separation Agreement”) and Consulting Agreement (the “Consulting Agreement”) with us, according to which Dr. Lopatin will continue as our full-time employee in the role of Chief Scientific and Strategic Advisor until April 30, 2022. Commencing May 1, 2022, and continuing through July 31, 2022, Dr. Lopatin’s hours will be reduced, and his annualized base salary will be subject to proportionate reduction upon reduction in hours. Starting from August 1, 2022, Dr. Lopatin will perform consulting services for us. As a result, Dr. Lopatin’s status as an employee will change. We considered Dr. Lopatin’s continued employment through July 31, 2022 as substantive for accounting purposes; however, his consulting service beginning on August 1, 2022 is not considered by us to be substantive for accounting purposes. This resulted in the recognition of Dr. Lopatin’s remaining unrecognized stock compensation expense in the amount of $2.6 million as of March 25, 2022 over the remaining vesting period of March 25, 2022 through July 31, 2022. The amount of stock-based compensation expense related to the three months ended March 31, 2022 is nominal.

Note 9. Commitments and Contingencies

Contingencies

From time to time, we may become subject to claims or suits arising in the ordinary course of business. We accrue a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of March 31, 2022 and December 31, 2021, we were not a party to any material legal proceedings.

Note 10. Related Party Transactions

Consulting agreements

On March 1, 2022, Dr. Lopatin, our former Chief Executive Officer and President transitioned to the non-executive employee role of Chief Scientific and Strategic Advisor. On March 25, 2022, Dr. Lopatin entered into the Separation Agreement and Consulting Agreement with us. The Separation Agreement provides that until April 30, 2022, Dr. Lopatin will continue as our full-time employee in the role of Chief Scientific and Strategic Advisor and will continue to receive his base salary at his then current annualized rate. Commencing May 1, 2022, and continuing through July 31, 2022 (the "Separation Date"), Dr. Lopatin's hours will be reduced and his annualized base salary will be subject to proportionate reduction upon reduction in hours. Immediately following the Separation Date, Dr. Lopatin will transition to a consultant pursuant to the Consulting Agreement. Dr. Lopatin will also remain on our Board as a Class III director until our 2024 annual meeting of stockholders and until his successor is duly elected and qualified, or, if sooner, until his earlier death, resignation or removal. Following the Separation Date, Dr. Lopatin will be entitled to compensation for his Board service consistent with the compensation provided to other non-employee directors under our Non-Employee Director Compensation Policy. Pursuant to the Separation Agreement, subject to Dr. Lopatin agreeing to a release of claims in favor of us and complying with certain other continuing obligations contained therein, we will provide Dr. Lopatin the severance benefits of a Tier 1 Executive under the terms and conditions set forth in the Executive Severance Plan, including (i) a severance amount equal to 12 months of his annual base salary in effect as of the date the Separation Agreement was signed and (ii) up to 12 months of monthly cash payments equal to the monthly employer contribution that we would have made to provide health insurance for Dr. Lopatin if he had remained employed by us based on the premiums as of the date of the Separation Date. We and Dr. Lopatin also executed the Consulting Agreement to be effective immediately following the Separation Date. Under the Consulting Agreement, Dr. Lopatin will additionally serve as a part-time consultant providing scientific and strategic advisory services and other projects as may be requested by the Chief Executive Officer until March 2, 2024, unless earlier terminated by either party in accordance with the terms of the Consulting Agreement. As of March 31, 2022, we accrued $0.5 million for Dr. Lopatin's severance and compensation.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 and with our audited consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 29, 2022, and other filings we have made with the SEC. As discussed under the heading "Cautionary Note Regarding Forward-Looking Statements", this discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q. Actual results may differ materially from those described in or implied by any forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics to improve the lives of patients suffering from life-threatening disease, starting with our lead product candidate, PBI-0451, which is in clinical development and intended to treat and prevent coronaviral (CoV) infections. COVID-19 is caused by infection with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has emerged as the most significant pandemic threat to the world in many decades. We have built a discovery platform designed to target reactive nucleophiles, such as those in cysteine proteases. By leveraging our understanding of structure-based drug design, reversible covalent chemistry and viral biology, we have discovered and are developing novel product candidates with low nanomolar potency against SARS-CoV-2 and broad activity against all known pathogenic human coronaviruses. Our lead product candidate, PBI-0451, inhibits the main coronaviral cysteine protease (M^{pro}), a viral protein essential for replication of all known coronaviruses, including SARS-CoV-2. In preclinical studies, PBI-0451 has demonstrated activity against all coronaviral proteases tested, as well as inhibition of replication of multiple coronaviruses, including SARS-CoV-2. Moreover, in preclinical studies, PBI-0451 demonstrated the potential for oral bioavailability across multiple preclinical species, and more recently, oral bioavailability in healthy volunteers in our first-in-human Phase 1 clinical trial. We believe the anti-viral potency seen against SARS-CoV-2 in preclinical in vitro studies and demonstrated oral bioavailability in humans supports its potential to be an oral direct acting antiviral ("DAA") for use against SARS-CoV-2 infections. We plan to develop PBI-0451 for both oral treatment and prophylaxis of SARS-CoV-2 infection. Given the highly conserved nature of the M^{pro} target, which is shared among all known coronaviruses, including emerging variants of concern, we believe PBI-0451 will likely retain its potency and activity against current and emerging SARS-CoV-2 variants.

On December 23, 2021, we completed the Business Combination with FSDC II, which resulted in FSDC II acquiring 100% of our issued and outstanding securities. Together with FSDC II's cash resources, additional funding for our operations was provided through a private investment in public equity (the "PIPE Investment"), which was completed concurrently with the Merger.

We accounted for the Business Combination as a reverse recapitalization which is the equivalent of Old Pardes issuing stock for the net assets of FSDC II, with FSDC II treated as the acquired company for accounting purposes. The net assets of FSDC II were stated at historical cost with no goodwill or other intangible assets recorded. Reported results from operations included herein prior to the Business Combination are those of Old Pardes. The shares and corresponding capital amounts and loss per share related to Old Pardes' outstanding redeemable convertible preferred stock and common stock prior to the Business Combination have been retroactively restated to reflect the Conversion Ratio established in the Merger Agreement. For additional information please refer to Note 4, *Business Combination*, to the consolidated financial statements included in Part II, Item 8 of our Form 10-K for the fiscal year ended December 31, 2021.

Since inception in 2020, we have devoted substantially all our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates, preparing and filing related patent applications and conducting research and development activities for our product candidates. We do not have any products approved for sale and we have not generated any revenue from product sales. We may never be able to develop or commercialize a marketable product.

In August 2021, we initiated a first-in-human Phase 1 clinical trial of our lead product candidate, PBI-0451, in New Zealand. Dosing in this Phase 1 clinical trial has been completed. In January 2022, the United States Food and Drug Administration ("FDA") cleared our Investigational New Drug ("IND") application for PBI-0451. We anticipate initiating a Phase 2/3 clinical trial for PBI-0451 in mid-2022, pending discussions with regulatory authorities. Our other potential product candidates and our research initiatives are in preclinical or earlier stages of development. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization or partnership of one or more of our product candidates. We have not yet successfully completed any clinical trials evaluating the efficacy of any of our product candidates, including PBI-0451, nor have we obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

Liquidity Overview

As of March 31, 2022, cash and equivalents were $247.9 million and we believe that our existing cash resources will be sufficient for at least the next twelve months to allow us to fund current planned operations, including supporting working capital and capital expenditure requirements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "— *Liquidity and Capital Resources*" below. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Through March 31, 2022, we have funded our operations with gross cash proceeds of $44.5 million from sales of preferred stock, gross cash proceeds of $7.1 million from the sale of SAFEs, which were converted into 5,845,071 shares (4,151,942 shares as originally issued) of convertible preferred stock in January 2021 and net proceeds of approximately $257.5 million in connection with the Business Combination and the PIPE Investment, which we currently believe will be sufficient to allow us to fund current planned operations into the second half of 2023.

We have incurred operating losses since our inception. As of March 31, 2022, we had an accumulated deficit of $73.0 million and had not yet generated revenues. In addition, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. We expect our research and development expenses, and general and administrative expenses to continue to increase. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing development activities, particularly if and as we:

- continue preclinical studies and initiate new clinical trials for PBI-0451, our lead product candidate being tested for the treatment of COVID-19;
- advance the development of our pipeline of other product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support our clinical operations;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- undertake any pre-commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory authorization or approval;
- expand our infrastructure and facilities to accommodate our growing employee base;
- increase manufacturing requirements for our clinical development activities, emergency use authorization and commercial preparedness; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company in prior years.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, as we can generate significant revenue from product sales, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies, government funding, or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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 acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To date, our financial condition and operations have not been significantly impacted by the COVID-19 pandemic. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 pandemic will have on our financial condition and operations, including ongoing and planned clinical trials and other operations required to support those clinical trials and research and development activities to advance our pipeline. The impact of the COVID-19 pandemic on our financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results may be materially adversely affected.

Components of Our Results of Operations

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products in the near future, if ever. If our development efforts are successful and we commercialize our products, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, as well as upfront, milestone and royalty payments from such collaboration or license agreements, or a combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for research activities, including drug discovery efforts, and the development of our potential product candidates. We expense research and development costs as incurred, which include:

- expenses incurred to conduct the necessary preclinical studies, nonclinical studies and clinical trials required to obtain regulatory approval;
- expenses incurred under agreements with contract research organizations (“CROs”) that are primarily engaged in the oversight and conduct of our drug discovery efforts and preclinical studies, clinical trials and contract manufacturing organizations (“CMOs”) that are primarily engaged to provide preclinical and clinical drug substance and product for our research and development programs;
- other costs related to acquiring and manufacturing materials in connection with our drug discovery efforts and preclinical studies and clinical trial materials, including manufacturing validation batches, as well as investigative site and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- employee-related expenses, including salaries and benefits, travel and stock-based compensation expense for employees engaged in research and development functions; and
- costs related to compliance with regulatory requirements.

We recognize research and development expenses as incurred. Any advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered. We estimate and accrue for the value of goods and services received from CROs, CMOs and other third parties each reporting period based on an evaluation of the progress to completion of specific tasks. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs.

At any one time, we may be working on multiple programs. We do not allocate employee costs and overhead costs associated to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery as well as for managing our preclinical, nonclinical, manufacturing and clinical development activities. To date, substantially all of the research and development costs incurred have been in connection with the development of our lead product candidate, PBI-0451.

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. As a result, we expect that our research and development expenses will increase substantially over the next several years as we commence planned clinical trials for PBI-0451, as well as conduct preclinical and clinical development, including submitting regulatory filings, for our other product candidates. We also expect our discovery research efforts and our related personnel costs will increase and, as a result, we expect our research and development expenses, including costs associated with stock-based compensation, will increase above historical levels. In addition, we may incur additional expenses related to milestone and royalty payments payable to third parties with whom we may enter into license, acquisition and option agreements to acquire the rights to future product candidates.

At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of the following:

- the scope, progress, outcome and costs of our preclinical and nonclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety and efficacy profile with clinically enabling trials;
- successful patient enrollment in and the initiation and completion of clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- development and timely delivery of clinical-grade and commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical, nonclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries and related benefits, travel and stock-based compensation for personnel in executive, business development, finance, human resources, legal, information technology, and administrative functions. General and administrative expenses also include insurance costs and professional fees for legal, patent, consulting, investor and public relations, pre-commercial planning, accounting and audit services. Our general and administrative costs are expensed as incurred.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the continued development of our product candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as relates to the sales and marketing of that product candidate.

Income Taxes

We have incurred net losses in every period since our inception and have not recorded any U.S. federal or state income tax benefits for the losses, as they have been offset by valuation allowances.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table sets forth our results of operations for the periods presented (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 13,199	$ 3,445	$ 9,754
General and administrative	8,226	1,081	7,145
Total operating expenses	21,425	4,526	16,899
Other (expense) income, net	(15)	3	(18)
Net loss	$ (21,440)	$ (4,523)	$ (16,917)

Research and Development Expenses

The following table summarizes the components of research and development expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
External costs:			
PBI-0451	$ 10,499	$ 2,790	$ 7,709
Discovery programs	165	—	$ 165
Total external costs	10,664	2,790	7,874
Internal costs:			
Salaries and benefits	1,820	491	1,329
Stock-based compensation	463	14	449
Other unallocated costs	252	150	102
Total internal costs	2,535	655	1,880
Total research and development expenses	$ 13,199	$ 3,445	$ 9,754

Research and development expenses were $13.2 million for the three months ended March 31, 2022, compared to $3.4 million for the three months ended March 31, 2021, an increase of $9.8 million. The increase was due to an increase in program costs related to advancing our lead product candidate, PBI-0451, and increased personnel costs, including stock-based compensation, and unallocated costs as we grew our organization. Unallocated costs include recruiting fees and overhead expenses.

General and Administrative Expenses

General and administrative expenses were $8.2 million for the three months ended March 31, 2022, compared to $1.1 million for the three months ended March 31, 2021, an increase of $7.1 million. The increase was due to increased personnel costs, including stock-based compensation, as we grew our organization, costs associated with being a public company, including directors and officers insurance and audit fees, and increased professional fees related to corporate legal, patent legal, pre-commercial planning, consulting and recruiting services.

Liquidity and Capital Resources

Sources of Liquidity and Capital

Since inception, we have not generated any revenue from any product sales or any other sources and have incurred operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if ever. Through March 31, 2022, we have funded our operations with gross cash proceeds of $44.5 million from sales of preferred stock, gross cash proceeds of $7.1 million from the sale of SAFEs, which were converted into 5,845,071 shares (4,151,942 shares as originally issued) of convertible preferred stock in January 2021 and net proceeds of approximately $257.5 million in connection with the Business Combination and the PIPE Investment.

As of March 31, 2022, we had cash and cash equivalents of $247.9 million and an accumulated deficit of $73.0 million as of March 31, 2022. In the short term, we believe that our existing cash resources will be sufficient for at least the next 12 months to allow us to fund current planned operations, including supporting working capital and capital expenditure requirements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.
In the long term, our ability to support working capital and capital expenditure requirements will depend on many factors, including our ability to raise additional capital to finance our operations. See "*— Liquidity Overview*" above.

CRO and CMO Agreements

We have entered into agreements in the normal course of business with certain vendors for the provision of goods and services, which includes manufacturing services with CMOs and development services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement.

We did not have during the periods presented, and we do not currently have, any commitments or obligations, including contingent obligations, arising from arrangements with unconsolidated entities or persons that have or are reasonably likely to have a material current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, cash requirements or capital resources.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Net cash used in operating activities	$ (20,362)	$ (3,748)
Net cash (used in) provided by financing activities	(397)	44,241
Net (decrease) increase in cash and cash equivalents	$ (20,759)	$ 40,493

Operating Activities

During the three months ended March 31, 2022, net cash used in operating activities consisted of a net loss of $21.4 million and a decrease in prepaid expenses and other current assets, accounts payable, and accrued expenses of $0.8 million; partially offset by a non-cash charge of $1.5 million related to stock-based compensation expense.

During the three months ended March 31, 2021, net cash used in operating activities was $3.7 million, primarily resulting from a net loss of $4.5 million, partially offset by a non-cash charge of $0.1 million related to stock-based compensation and an increase in accrued expenses due to growth in our operations, the advancement of our product candidates, and the timing of vendor invoicing and payments.

Financing Activities

During the three months ended March 31, 2022, net cash used was payments for transaction costs associated with the Business Combination.

During the three months ended March 31, 2021, net cash provided by financing activities was $44.2 million, consisting of proceeds from the issuance of shares of Series A convertible preferred stock.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily related to our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly if and as we advance into Phase 2/3 clinical trials for PBI-0451. We also expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance preclinical development of our early-stage programs and initiate clinical trials of our product candidates;
- manufacture, or have manufactured on our behalf, our preclinical, nonclinical and clinical drug material and develop processes for late stage and commercial manufacturing;

- seek regulatory authorizations and/or approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing, medical affairs, managed care, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- manage the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- manage the costs of operating as a public company.

Working Capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and nonclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our clinical and preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support a potential future commercial launch;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our condensed financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities, as of the date of the financial statements, and the reported amounts of revenue and expenses during the reported period. If these estimates differ significantly from actual results, the impact to the condensed consolidated financial statements may be material. There have been no material changes in our critical accounting policies and estimates from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. Please refer to Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 for a discussion of our critical accounting policies and estimates.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is also disclosed in Note 2, *Summary of Significant Accounting Policies* to our unaudited condensed financial statements appearing in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by a registrant in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a registrant in the reports that it files or submits under the Exchange Act is accumulated and communicated to the registrant's management, including its principal executive and principal financial officers, or persons performing similar functions as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance and not absolute assurance of achieving their desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no material changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of March 31, 2022, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the 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.

Our business faces significant risks and uncertainties. If any of the following risks, or other risks not presently known to us or that we currently believe to not be material, are realized, our business, financial condition and results of operations could be materially and adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment. You should carefully review and consider the full discussion of our risk factors below, together with all other information in this Quarterly Report on Form 10-Q, including our condensed financial statements and notes thereto, and in our other filings with the SEC.

Risks Related to our Business

We have a limited operating history and no history of successfully developing or commercializing any approved therapeutic products, which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability and ability to generate revenue and become profitable in the future.

We are a clinical-stage biopharmaceutical company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, developing our technology and identifying and developing our lead product candidate, PBI-0451, and conducting nonclinical studies and Phase 1 clinical trials of PBI-0451. We have not yet demonstrated our ability to complete any late-stage or pivotal clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization or arrange for third parties to do these activities on our behalf. Investment in biotechnology and pharmaceutical product development is highly speculative because it entails substantial upfront expenditures in contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”) and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. If we successfully develop a product candidate, we will eventually need to transition from a company with a research and development focus to a company capable of supporting late-stage and commercial activities. We may not be successful in this transition. For example, we may need to rapidly develop our commercialization capabilities if PBI-0451 is approved for the treatment of SARS-CoV-2 or receives emergency use authorization (“EUA”).

We have completed dosing in our first-in-human Phase 1 clinical trial and phase 1 development is ongoing. We anticipate initiation of a Phase 2/3 clinical trial in mid-2022 for our lead product candidate, PBI-0451, pending discussions with regulatory authorities. We do not expect to receive revenue from PBI-0451 until we obtain initial EUA or full marketing approvals, if ever. To date, we have not generated any revenue and we will not be able to generate product revenue unless and until PBI-0451, or any other product candidate, successfully completes clinical trials, receives EUA and is made available, or receives other regulatory approval and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third parties or funding from government sources. Our ability to generate future product revenue from PBI-0451 or any other product candidates also depends on a number of additional factors, including our or our future collaborators’ (if any) ability to:

- successfully complete nonclinical studies and clinical trials for PBI-0451 and any other product candidates;
- conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates if we are required by the U.S. Food and Drug Administration (the “FDA”) or similar foreign regulatory authorities;
- to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety and efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;

- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtain marketing approval, and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- demonstrate the actual and perceived benefits of PBI-0451, if approved, relative to existing and future alternative therapies for COVID-19 based upon availability, cost, risk profile, drug-drug interactions, side effects and efficacy;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biopharmaceutical product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or comparable foreign regulatory authorities in other jurisdictions where we may pursue regulatory approval, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

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 decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value also could cause you to lose all or part of your investment.

We have incurred significant losses since our inception and expect to incur losses for the foreseeable future.

To date, we have devoted almost all of our financial resources to research and development, including preclinical and clinical development activities, and we expect to continue to incur significant research and development and other expenses related to our ongoing operations and the development of our lead therapeutic candidate, PBI-0451. As a result, we are not profitable and have incurred significant losses since our inception in February 2020. As of March 31, 2022, we had an accumulated deficit of $73.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we seek to advance PBI-0451 through clinical development, continue preclinical development, expand our research and development activities, develop new product candidates, complete preclinical studies and clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our product candidates.

Even if we succeed in commercializing PBI-0451 or any other product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business for any reason, including as a result of the ongoing and unpredictable COVID-19 pandemic. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of PBI-0451 or any other product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance PBI-0451 through clinical development.

As of March 31, 2022, we had $247.9 million of cash and cash equivalents. We believe our existing cash and cash equivalents will fund our current planned operations into the second half of 2023. Our forecast of the period of time through which our financial reserves will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "*Risk Factors*" section. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of nonclinical studies and anticipated clinical trials for PBI-0451 or any other product candidates we may develop;
- any COVID-19 related delays or other effects the disease progression may have on our development programs;
- the outcome, timing and cost of seeking and obtaining an EUA or regulatory approval from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or require our clinical trial designs to differ from those currently contemplated;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological, such as vaccines, antibody therapies or other oral antivirals, the status of the current pandemic, and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the stability, scale, yield and cost of manufacturing our product candidates for clinical trials, in preparation for an EUA, regulatory approval and in preparation for commercialization;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize;
- the ability to establish, nature, and timing of potential partnerships around current or future PBI-0451 assets; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, government funding, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We are heavily dependent on the success of PBI-0451, our lead product candidate. Failure to obtain regulatory approval for PBI-0451 will prevent us from commercializing and marketing PBI-0451.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our lead product candidate, PBI-0451. Accordingly, our business and future success currently depends heavily on the successful development, regulatory approval, and commercialization of PBI-0451 for treatment of coronaviruses, including the coronavirus that causes COVID-19. Our development of PBI-0451 for the treatment of COVID-19 is in early clinical stage of development. We cannot be certain that PBI-0451 will successfully commence or complete later stage clinical trials, receive an EUA or regulatory approval or be successfully commercialized even if we receive regulatory approval. If we are required to discontinue development of PBI-0451 or if PBI-0451 does not receive EUA or regulatory approval or fails to achieve significant market acceptance, we would be substantially delayed in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labelling, approval, sale, marketing, and distribution of PBI-0451 is, and will remain, subject to comprehensive regulation by the FDA and comparable foreign regulatory authorities. Failure to obtain regulatory approval for PBI-0451 will prevent us from commercializing and marketing PBI-0451.

Further, our future clinical trials of PBI-0451 may not be able to replicate the results from our preclinical and nonclinical studies of PBI-0451. To the extent this occurs, our expected development time and development costs for PBI-0451 may be increased.

Even if we are able to successfully obtain an EUA or FDA or comparable foreign regulatory authority approval for PBI-0451, any EUA or approval might contain significant limitations related to use, including limitations on the stage of disease PBI-0451 is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Furthermore, even if we obtain regulatory approval for PBI-0451, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize PBI-0451, we may not be able to generate sufficient revenue to continue our business.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing other product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although we plan to devote a majority of our current resources to the continued clinical testing and potential approval of PBI-0451 for the treatment of SARS-CoV-2 infection, another key element of our strategy is to discover, develop and commercialize a broader portfolio of products. We are currently intending to do so through our internal discovery programs, but our resources are limited, and those resources that we have available have been and are largely geared towards preclinical and nonclinical testing, clinically enabling studies and clinical development of PBI-0451, including our Phase 1 clinical trials and preparation for our Phase 2/3 clinical trials in patients, which we anticipate initiating in mid-2022, pending discussions with regulatory authorities. We may also explore strategic collaborations for the development of new product candidates, but we may not be successful in entering into such relationships. Other than PBI-0451, we have no product candidates in the clinical stage of development. Research programs to identify additional product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- a product candidate may, on further clinical trials, be shown to have harmful side effects or toxicities, be unable to achieve clinically relevant concentration after dosing or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- intellectual property, patents or other proprietary rights of third parties may cover the product candidates that we develop or potentially block our entry into certain markets or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed, and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

Nonclinical development is uncertain. Our nonclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain approval from the FDA and other major regulatory agencies in non-U.S. countries to market a new product candidate, we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive nonclinical studies that support our planned Investigational New Drug ("IND") or clinical trial applications ("CTAs"), in the United States and other countries, respectively. We cannot be certain of the timely completion or outcome of our nonclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our nonclinical studies will ultimately support further development of our programs. In addition, the FDA may decline to accept the data we obtain from foreign clinical trials in support of an IND in the United States, which may require us to repeat or conduct additional nonclinical studies or clinical trials that we did not anticipate. As a result, we cannot be sure that we will be able to submit INDs in the United States, or CTAs or similar applications in other jurisdictions, on the timelines we expect, if at all, and we cannot be sure that submission of INDs, CTAs or similar applications will result in the FDA or other regulatory authorities allowing additional clinical trials to begin.

Conducting nonclinical testing is a complex, lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can take several years or more per program. Delays associated with programs for which we are directly conducting nonclinical studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the studies of certain programs that are the responsibility of potential future partners, if any, over which we have no control. The commencement and rate of completion of nonclinical studies for a product candidate may be delayed by many factors, including:

- inability or failure by us or third parties to comply with regulatory requirements, including the requirements of GLP;
- inability to generate sufficient nonclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on clinical trial design and obtaining regulatory authorization to commence clinical trials;
- challenges in obtaining sufficient quantities of our product candidates for use in nonclinical studies from third-party suppliers on a timely basis;
- delays due to the ongoing COVID-19 pandemic, including due to reduced workforce productivity as a result of our implementation of a hybrid work-from-home policy or illness among personnel, or due to delays at our third-party CROs and CMOs throughout the world for similar reasons or due to restrictions imposed by applicable governmental authorities; and
- delays due to other global-scale potentially catastrophic events, including other pandemics, terrorism, war (including Russia's invasion of the Ukraine), supply chain disruptions, and climate change.

Moreover, even if candidates from our product programs advance into clinical trials, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any product candidates we develop. Even if we obtain positive results from nonclinical studies or initial clinical trials, we may not achieve the same success in future trials.

PBI-0451 and any other product candidates we may develop must undergo rigorous clinical trials and regulatory approvals, and results from early nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.

PBI-0451 and any other product candidates we may develop will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities. The approval process is typically lengthy and expensive, and approval is never certain. We have limited experience in conducting the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our clinical trials may not demonstrate that our potential products, including PBI-0451, will be active, safe or effective or achieve sufficient exposure to be of clinical benefit. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in earlier nonclinical studies and earlier-stage clinical trials does not ensure that later nonclinical studies or clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether our results may support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Historically there is a high failure rate for drugs proceeding through clinical trials at every stage. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical 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 due to changes in regulatory policy during the period of development of our product candidates. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

While not currently planned, our future clinical trials may use an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Our subsequent clinical trials may reveal significant adverse events not seen in our earlier clinical trials or preclinical or nonclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical and nonclinical studies and clinical trials that our product candidates are both safe and effective for use in each target indication. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. If the results of our preclinical and nonclinical studies and clinical trials demonstrate a safety concern associated with our product candidates, we may be prevented or delayed in obtaining authorization to initiate clinical trials. Additionally, if the results of our preclinical and nonclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, our product candidates could cause undesirable side effects that we have not observed yet to date. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Interim, “topline” and preliminary data 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. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies, nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data 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, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies, nonclinical studies and clinical trials. Interim data 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our product candidates.

We contract with third-party CMOs to make our drug substance and drug product to support current and planned clinical trials and for commercial sale, if approved. We will need to negotiate and maintain contractual arrangements with these CMOs for the supply of PBI-0451 and our future product candidates and we may not be able to do so on favorable terms. Most of our CMOs are outside the United States, including in the People's Republic of China. Our CMOs may not be able to adopt, adapt or scale up the manufacturing process in a timely manner to support our future clinical trials. Additionally, the current COVID-19 outbreak in China could impact the ability of our CMOs to manufacture the quantities of drug substance and drug product required for our future clinical trials and in accordance with proposed timelines. The process of manufacturing our product is complex, highly regulated and subject to several risks, including:

- failure to meet acceptance criteria;
- the manufacturing process is susceptible to product loss due to equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions, and even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, changes in manufacturing lines, labor and raw material shortages, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest, politically driven embargoes or trade agreements affecting supply of raw materials, and numerous other factors; and
- any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

Manufacturers sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for preclinical studies, nonclinical studies and early clinical trials to a validated process needed for pivotal clinical trials and commercial launch. These problems often include failure to meet target production costs and yields, sub-par quality control testing, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as failure to comply with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of PBI-0451 or any other product candidates will not occur in the future.

We do not have and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether.

We may develop product candidates in combination with other therapies, which exposes us to additional risks.

We may develop product candidates in combination with other product candidates or existing therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used in antiviral treatments, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than currently anticipated. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell the product candidates we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market the product candidates we develop.

Currently, we intend to progress PBI-0451 clinical development as a stand-alone therapy.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of March 31, 2022, we had 47 full-time employees. As we continue development and pursue the potential commercialization of our product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We must attract and retain highly skilled employees to succeed. If we are not able to retain our current team or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel. We face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. We are dependent on the members of our management team and our scientific and commercial advisors for our business success, including our Chief Executive Officer, Thomas G. Wiggans, our Chief Development Officer, Brian P. Kearney, PharmD, our Chief Commercial Officer, Sean P. Brusky, our Chief Business & Strategy Officer, Philippe Tinmouth, our General Counsel and Corporate Secretary, Elizabeth H. Lacy, and our Chief Financial Officer, Heidi Henson. We do not maintain “key person” insurance for any of our key personnel. An important element of our strategy is to take advantage of the research and development expertise of our current management. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers could result in a significant loss in the knowledge and experience that we, as an organization, possesses and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

There is intense competition for qualified personnel, including management in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of our product candidates. In particular, we have experienced a very competitive hiring environment in California, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and comparable foreign regulatory authorities, fails to provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our future activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. If any such actions are instituted against us, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. It is not always possible to identify and deter employee 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourself or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including significant competition for recruiting patients with COVID-19 in clinical trials, the availability of other therapies and currently declining infection rates.

Identifying and qualifying patients to participate in our clinical trials is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing of our product candidates. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites where patients are to be enrolled;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- the inability to obtain and maintain patient consents;
- the risk that enrolled participants will drop out before completion;
- the declining infection rates for SARS-CoV-2;
- competition with other companies for clinical sites or patients and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new products that may be authorized or approved for the indications we are investigating; and
- other factors outside of our control, such as the ongoing and evolving nature of the COVID-19 pandemic.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same or similar therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or use other available therapies. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

In addition, if any significant adverse events or other side effects are observed in any of our current or planned clinical trials, recruitment of patients to our clinical trials may be more difficult for us and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on us.

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

The biotechnology and pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology and pharmaceutical companies and universities and other research institutions. A number of our competitors are pursuing the development or marketing of pharmaceuticals or other drug products that target SARS-CoV-2 viral infections or COVID-19 disease and other therapeutic indications that we may pursue. It is also probable that the number of companies seeking to develop products and therapies for the treatment of SARS-CoV-2 virus and other coronaviruses will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market pharmaceutical or medicinal products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical or medicinal products and in obtaining regulatory approvals of human therapeutic products. Moreover, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Some of our competitors have been granted EUAs with respect to their investigational products for COVID-19, which allows for use of such therapies outside of clinical trials and sales to governments while clinical trials are ongoing and prior to approval by the FDA. Accordingly, our competitors may succeed in obtaining FDA approval for competing products sooner than we are able to obtain approval. Additionally, some competitors have also received regulatory authorization or approval from the FDA for their products for the treatment or prevention of COVID-19. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. Some competitors have also entered into procurement and supply agreements with governments that may impact our ability to enter into similar agreements. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If we are unable to compete effectively, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

We commenced operations in February 2020, at the beginning of the COVID-19 pandemic and the commencement of stay-at-home orders by the State of California. As a result, all employees work remotely, and we have not established any physical location. We continuously review and assess the adequacy of our internal computer security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations.

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to failure or damage from computer viruses and other malware, unauthorized access or other cybersecurity attacks, natural disasters (including hurricanes and earthquakes), terrorism, war, fire and telecommunication or electrical failures. In the ordinary course of our business, we directly or indirectly collect, store and transmit sensitive data, including intellectual property, confidential information, preclinical data, proprietary business information, personal data and, upon entering the clinic, clinical trial data and personally identifiable health information of our clinical trial subjects, in our data centers and on our networks, or on those of third parties. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to employee error, a technical vulnerability, malfeasance or other disruptions. The risk of a security breach or disruption, particularly through cyber-attacks 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. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our CROs and other contractors and consultants.

If a security incident were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of preclinical study or nonclinical or clinical trial data from completed, ongoing or planned studies or trials could result in delays in our regulatory approval efforts. We may need to incur significant costs in order to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and such an event could disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

While we have not, to our knowledge, experienced any such material system failure or security breach of our internal systems to date, some of our documents and data were compromised and taken without our permission as a result of a hack of a file transfer vendor used by one of our service providers in 2021. While this security incident did not result in a loss of, or damage to data, our confidential information could prematurely be disclosed by third parties. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be hindered or delayed.

Our business may be impacted by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control.

War, terrorism, geopolitical uncertainties and other business interruptions could cause damage to, disrupt or cause us to cancel the conduct of our planned Phase 2/3 clinical trials on a global or regional basis, which could have a material adverse effect on our business,. Such events could also decrease patient demand to enroll in our clinical trials, make it difficult or impossible for us to deliver products and services to our clinical investigational sites or impact the vendors with which we do business. In addition, territorial invasions can lead to cybersecurity attacks on companies, such as ours, located far outside of a conflict zone. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in Russia or Ukraine, but we do not and cannot know if the ongoing conflict in the Ukraine, which is unfolding in real-time, may escalate and result in broad and adverse economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials or otherwise materially impact our business.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. As a result of inflation, we may experience cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost of inflation is incurred.

We might not be able to utilize a significant portion of our U.S. net operating loss ("NOL") carryforwards and U.S. research and development tax credit carryforwards.

As of December 31, 2021, we had U.S. federal and state NOL carryforwards of approximately $41.0 million and $0.6 million, respectively, and federal and state research and development tax credit carryforwards of zero and $52,000, respectively. Our federal NOL carryforwards do not expire. If not utilized, our state NOL carryforwards and state research and development tax credits will expire at various dates beginning in 2036. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act of 2017, unused losses generated in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the Coronavirus Aid, Relief, and Economic Security Act, a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 is permitted. Additionally, for taxable years beginning after December 31, 2017, the deductibility of such U.S. federal NOLs is limited to 80% of our taxable income in any future taxable year. In addition, under Section 382 of the Internal Revenue Code ("Code"), the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50% over a three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of the transactions consummated on December 23, 2021 (the "Business Combination") pursuant that certain Agreement and Plan of Merger, dated June 29, 2021 (as amended on November 7, 2021, the "Merger Agreement"), by and among Old Pardes, Shareholder Representative Services LLC, a Colorado limited liability company solely in its capacity as the representative, agent and attorney-in-fact of the Company Securityholders (as defined in the Merger Agreement), and subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of U.S. federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows. Additionally, effective January 1, 2022, research and development expenses are required to be capitalized and amortized for U.S. tax purposes, which will delay the deductibility of these expenses and potentially increase the amount of cash taxes we pay, if any.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, clinical trials, workers' compensation, umbrella, and directors' and officers' insurance.

Any product liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for any of our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the development and commercialization of any product candidates we develop. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that, given our stage of development and intended therapeutic indication, operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs and retention levels to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors ("Board"), our Board committees or as executive officers. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash and cash equivalents position and results of operations.

Risks Related to COVID-19

We have completed dosing of PBI-0451, our lead product candidate, in our first-in-human Phase 1 clinical trial, but we have not commenced clinical trials on efficacy. Accordingly, there is significant uncertainty around the development of PBI-0451 as a potential treatment for coronavirus generally, and SARS-CoV-2 infections and COVID-19 specifically.

In August 2021, we initiated our first-in-human Phase 1 clinical trial of PBI-0451 in healthy adults in New Zealand. Dosing in the first-in-human Phase 1 clinical trial has been completed and other Phase 1 clinical trials are ongoing. We anticipate commencing a Phase 2/3 clinical trial in mid-2022, pending discussion with regulatory authorities. Given the early stage of development, there is significant uncertainty whether PBI-0451 can be successfully developed as a potential treatment or prevention for SARS-CoV-2 infections. We have committed and plan to continue to commit significant financial and personnel resources to the development of PBI-0451. We seek to develop PBI-0451 as a potential treatment and prevention for SARS-CoV-2 infections, and the current circulating strains of SARS-CoV-2 that remain highly conserved in the binding region of PBI-0451. However, it is unknown if resistant variants may arise in the future that may reduce the efficacy of PBI-0451 against the SARS-CoV-2 M^{pro}. If the SARS-CoV-2 virus develops resistance to PBI-0451, the long-term demand for and potential commercial success of this product candidate would be adversely impacted.

Further, while our goal is to develop PBI-0451 and explore the effectiveness of PBI-0451 and/or additional potential therapies against other or future coronaviruses in addition to SARS-CoV-2, we cannot be certain we will be successful. If our potential therapies are not effective against SARS-CoV-2 or other coronaviruses, the value and/or sales potential of these therapies may be reduced or eliminated. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our potential therapies, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, there are no assurances that PBI-0451 or our other product candidates, if approved, will be approved for inclusion in government stockpile programs, which may be material to the commercial success of any approved coronavirus-related product candidate, either in the United States or abroad.

COVID-19 continues to cause significant morbidity and mortality globally. The number of infections, and the morbidity associated with those infections, however, change continuously. As a result, we may find enrollment of patients for clinical trials to be a challenge, and/or may find that the severity of disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints related to morbidity and mortality. If enrollment is delayed or takes longer than expected this could impact our ability to seek an EUA while the pathway is available and could delay the collection of data sufficient to meet our endpoints and seek marketing approval.

While there is currently an urgent need for a treatment for SARS-CoV-2 infections, the longevity and extent of the COVID-19 pandemic caused by SARS-CoV-2 is uncertain. If the pandemic were to dissipate, whether due to a significant decrease in new infections, due to the availability of vaccines, or otherwise, the need for a treatment could decrease significantly. A decrease in morbidity or mortality rates due to prior infection or vaccination immunity or due to variants that cause less severe disease, could lessen the demand for treatments.

As a result of the number of infections, and the morbidity associated with SARS-CoV-2 infections, changing continuously, we may find enrollment of patients for clinical trials a challenge, and/or may find that the severity of the disease declines over time such that it becomes challenging to enroll the number of patients required to demonstrate statistically significant improvements in endpoints related to morbidity and mortality. If enrollment is delayed or takes longer than expected this could impact our ability to seek an EUA while the pathway is available and could delay the collection of data sufficient to meet our endpoints and seek marketing approval.

If SARS-CoV-2 evolves into a benign variant and no further pathogenic variants of SARS-CoV-2 or other coronaviruses emerge over the next few years, then commercial, clinical and patient interest in oral antivirals may decline. If the need for a treatment decreases before or soon after commercialization of PBI-0451, if approved, or additional treatments and preventative measures for SARS-CoV-2 infections are developed and commercialized before PBI-0451, thereby reducing the eligible patient population for treatment, our business and prospects could be adversely impacted.

PBI-0451 may face significant competition from other treatments for SARS-CoV-2 infections that are in development. If our competitors develop and market products faster or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted. Our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for SARS-CoV-2 infections, if approved, could also be impacted by the success or failure of other entities, or perceived success or failure of other entities' therapeutic candidates.

Many biotechnology and pharmaceutical companies are developing or have approved or authorized treatments for SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities and some of our competitors have obtained regulatory approvals or an EUA for their products and have entered into U.S. government procurement contracts and funding. Additionally, a number of direct acting antivirals ("DAAs") with oral route of administration are in development by other pharmaceutical and biopharmaceutical companies. For example, in December 2021, Pfizer, Inc. received an EUA for its DAA candidate, PAXLOVID™ (nirmatrelvir (PF-07321332) tablets and ritonavir tablets)) for the treatment of mild to moderate COVID-19 in patients at high risk of hospitalizations or death and has entered into various government procurement contracts. A number of additional clinical and preclinical stage programs, including monoclonal antibodies and other treatment options, are moving forward to potential EUA or approval. Given the products currently approved or authorized for use as well as those in development by others, any treatment we may develop could face significant competition that would negatively impact our commercial opportunity and our ability to obtain future funding for our operations.

If any other company develops treatments more rapidly or effectively than we do, develops a treatment that becomes the standard of care, develops a treatment at a lower cost, develops a treatment with a more convenient or preferred route of administration or is more successful at commercializing an approved treatment, we may not be able to successfully commercialize PBI-0451 for the treatment of SARS-CoV-2 infection, even if approved, or compete with other treatments or vaccines, which could adversely impact our business and operations and our ability to raise funds. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, including gaining exclusivity for their competing products on formularies thereby excluding our products from such formularies, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for our product candidates (if at all), which could result in our competitors establishing a strong market position before we are able to enter the market (if ever). Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products, resulting in reduced competitiveness.

We may expend resources in anticipation of clinical trials and potential commercialization of PBI-0451, which we may not be able to recover if PBI-0451 is not approved for the treatment of SARS-CoV-2 or we are not successful at commercializing PBI-0451.

We believe that there is an urgent unmet need for effective SARS-CoV-2 treatments. If interim data from our proposed Phase 2/3 clinical trial in SARS-CoV-2 infected patients is positive, we may pursue certain expedited development, review and approval programs offered by the FDA or other regulatory authorities to sponsors of drugs designed to treat serious diseases and conditions. These programs may offer the potential for a more rapid approval and commercialization process than traditional review pathways. Although we believe that if our proposed Phase 2/3 trials of PBI-0451 for the treatment and prevention of SARS-CoV-2 infection in non-hospitalized patients with mild to moderate COVID-19 disease are successful, we may be able to seek an EUA and/or to submit an NDA seeking accelerated approval of PBI-0451, we have not yet discussed the design of potential registration-enabling clinical trials or potential registration pathways with the FDA or other regulatory authorities, and there is no guarantee that the FDA or other regulatory authorities will agree with any strategy we may propose or determine that an EUA or accelerated approval is appropriate. However, to prepare for the possibility that we may be required to develop and rapidly commercialize PBI-0451, we may enter into agreements with, and make payments to CMOs prior to obtaining any EUA or approval to market PBI-0451 for the treatment of SARS-CoV-2 infections. As a result, we may not be able to recover these costs if PBI-0451 is not approved, which could have a material adverse effect on our business.

We currently expect that the market for a treatment and prevention of SARS-CoV-2 infections will be large. It is not certain that any CMOs retained to manufacture PBI-0451 will be able to meet any commercial demand for PBI-0451. Even if CMOs are able to manufacture sufficient PBI-0451 to meet commercial demand, we may be unable to purchase sufficient commercial quantities of PBI-0451 due to financial constraints. If we are unable to meet commercial demand, we may not be able to fully capitalize on the commercial potential of PBI-0451, which could have an adverse effect on our business.

Furthermore, we as an organization have never commercialized a product and may not be successful in establishing the capabilities required for commercialization. In order to commercialize PBI-0451, we will need to rapidly establish and build sales, market access, medical affairs, and marketing capabilities prior to obtaining approval to market PBI-0451. If we do not obtain authorization or approval for PBI-0451, we will have expended those resources prematurely, and our business could be adversely affected.

There has also been significant media coverage regarding the pricing of vaccines and treatments for COVID-19. For example, Gilead Sciences, Inc. has come under scrutiny regarding its pricing of remdesivir, after having donated its initial supply of the drug. Pricing for drugs to treat COVID-19 continues to evolve, and we cannot be certain of the factors that will determine the sales price of PBI-0451, if approved. If we are unable to sell PBI-0451 at a sufficient price point, our ability to commercialize PBI-0451, if approved, may be adversely affected.

COVID-19 may materially and adversely affect our business and financial results.

In December 2019, SARS-CoV-2 surfaced in China. Since then, SARS-CoV-2 and the resulting COVID-19 disease has spread globally. In the United States, travel bans, and government stay-at-home orders caused widespread disruption in business operations and economic activity. Governmental authorities around the world have implemented measures to reduce the spread of COVID-19. These measures, including suggested or mandated "shelter-in-place" orders, have adversely affected workforces, customers, consumer sentiment, economies, and financial markets, and, along with decreased consumer spending, have led to disruptions in the U.S. economy. In response to the public health directives and orders and to help minimize the risk of COVID-19 for our employees, all of our employees currently work-from-home. Many of our third-party collaborators, such as our CMOs, CROs, suppliers and others, have taken similar precautionary measures. As certain countries have reopened, they have experienced a new surge of infections and have in some areas reinstated stay at home orders and other containment measures. Efforts to re-open are likely to take a significant amount of time, require additional resources to implement social-distancing and other containment measures, or may not be successful. These measures may disrupt our business and our current and proposed clinical program and timelines.

As a result of the evolving COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, nonclinical studies and clinical trials, including:

- delays or difficulties in enrolling patients in a clinical trial, including rapidly evolving treatment paradigms, and patients that may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- difficulties in enrolling patients due to the number of competing therapies that are approved, authorized or being tested for COVID-19;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, and clinical site staff, or the overwork of existing investigators and staff;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruptions or delays in preclinical studies, nonclinical studies or clinical trials due to restricted or limited operations at research and development laboratory facilities;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state or provincial governments, employers and others or interruption of clinical trial patient visits and clinical trial procedures which may impact the integrity of subject data and clinical trial endpoints;
- 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;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- interruption of or delays in receiving the supplies and materials needed to conduct preclinical studies, nonclinical studies and clinical trials;
- interruption in global shipping that may affect the transport of preclinical and clinical trial materials, such as investigational drug product;
- changes in local regulations as part of a response to the evolving COVID-19 outbreak that 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;
- interruption or delays in the operations of the FDA or other regulatory authorities which may impact review and approval timelines;
- 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
- the refusal of the FDA or other regulators to accept data from clinical trials in SARS-CoV-2 affected geographies.

As a result, the expected timeline for data readouts of our clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect and delay our ability to obtain regulatory approvals for PBI-0451, increase our operating expenses, and have a material adverse effect on our financial condition. We may also experience interruption of or delays in receiving the supplies and materials needed to conduct clinical trials. For example, since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received EUA by the FDA and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. Moreover, SARS-CoV-2 is a novel pathogen, and information regarding the symptoms, progression, and spread of COVID-19 continues to rapidly evolve, which may present additional challenges for the conduct of our clinical trials in COVID-19 patients. For example, COVID-19 patients have presented with a wide range of symptoms and side effects, which may make it more difficult for clinical trial investigators to determine whether any adverse events observed in our clinical trials are related to PBI-0451 or are consistent with the underlying disease. Any increase in the severity or incidence of adverse events deemed to be related to PBI-0451 could delay or prevent our regulatory approval, which could have a material adverse effect on our financial condition.

The impact to our operations due to the COVID-19 pandemic could be severe and could negatively affect our business, financial condition and results of operations. To the extent the COVID-19 pandemic adversely affects our business and financial results, the pandemic may also have the effect of heightening many of the other risk factors described in this "*Risk Factors*" section, such as those relating to our clinical trial timelines, our ability to enroll subjects for clinical trials and obtain materials that are required for the production of our product candidates, and our ability to raise capital.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for PBI-0451 or any other product candidate would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application.

PBI-0451 or our other product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials, including selection of an active versus placebo comparator;
- failure to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authority that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission of an NDA or other comparable submission to a foreign regulatory authority or to obtain regulatory approval in the United States or elsewhere;
- failure to obtain approval of or identify deficiencies within the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations of the FDA or comparable foreign regulatory authorities that render our nonclinical and clinical data insufficient for approval.

The FDA or comparable foreign regulatory authorities may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval of our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve any of our product for fewer or more limited indications than we request, may require specific labeling or a Risk Evaluation Mitigation Strategy ("REMS"), that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Failures or delays in the commencement or completion of, or ambiguous or negative results from, our current or planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether any of our clinical trials will be commenced or completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize our or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold, and may request additional data to permit allowance of our IND;
- delays in filing or receiving allowance of additional IND applications that may be required;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- negative results from our nonclinical studies and clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- the inability of CROs to perform under these agreements, including due to impacts from the COVID-19 pandemic on their workforce;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board ("IRB") approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to clinical sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical trial programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical studies or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, may require us to conduct a comparator trial in lieu of a placebo-controlled trial or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials; and
- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Moreover, preclinical, nonclinical 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, nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, a clinical trial may be suspended or terminated by us, the FDA or comparable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical trial, a data and safety monitoring board ("DSMB"), overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- an inspection of the clinical trial operations or clinical sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;

- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet our stated objectives;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or proposed clinical trials, adverse side effects or lack of effectiveness;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and
- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make changes to a product candidate, such as changes to the formulation or manufacturing, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Further, conducting clinical trials in foreign countries, as we expect to do for the product candidate, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

We have conducted and intend to conduct additional clinical trials of our product candidates in sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

Our first-in-human Phase 1 clinical trial of PBI-0451 was conducted in New Zealand. We may choose to conduct additional clinical trials outside the United States for our product candidates. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions, or such data may not be accepted at all. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with good clinical practice ("GCP") requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an onsite inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including requirements as to the size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from our clinical trials of PBI-0451, it would likely result in the need for additional trials for us to obtain regulatory approval to market PBI-0451 in the U.S., which would be costly and time-consuming and delay or permanently halt our development of our product candidate. In addition, there are risks inherent in conducting clinical trials in multiple jurisdictions, inside and outside of the United States, such as:

- regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct our clinical trials;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- the risk that the patient populations in such trials are not considered representative as compared to the patient population in the target markets where approval is being sought.

A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product 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 can help to identify the most efficient path for clinical development. Product candidates designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe 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 drugs considered for approval under non-expedited FDA review procedures and does 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 no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

The regulatory pathways for our product candidates targeting coronaviruses, including SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.

PBI-0451, our clinical product candidate targeting SARS-CoV-2, the virus that causes COVID-19, is in the early development stages. The speed at which companies and institutions are acting to create and test many therapeutics and vaccines for COVID-19 is unusually rapid and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body and current rates of infection, hospitalizations, morbidity and mortality, may significantly affect the regulatory timelines for our COVID-19 product candidate. Results from our continued development, clinical trials and planned clinical trials may raise new questions and require us to redesign proposed nonclinical studies and clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects, with minimal lead time.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. Depending on the outcomes of our initial nonclinical and clinical testing for our proposed COVID-19 therapies and assuming that a public health emergency has not been terminated by the Secretary of the Department of Health and Human Services (“HHS”), we may seek an EUA for PBI-0451 for use in the ongoing COVID-19 public health emergency, which would permit us to commercialize a product candidate prior to FDA approval of an NDA. However, commercialization under an EUA is permitted only during the underlying public health emergency (as declared by the Secretary of the HHS), meaning that once the emergency declaration is terminated, we would be required to cease distribution of PBI-0451 and obtain NDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA — for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict whether an EUA for PBI-0451 may be granted or, if granted, how long such EUA would remain in place. Any termination or revocation of an EUA (if granted) for one of our product candidates could adversely impact our business in a variety of ways, including if one of our COVID-19 product candidates is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide one of our COVID-19 product candidates under an EUA.

In addition to seeking an EUA for PBI-0451, if available when we have sufficient clinical data and which the FDA has applied to certain COVID-19 treatments, we may also attempt to secure conditional approvals or emergency authorizations in other countries outside of the US. If we are unable to obtain such authorizations, or those pathways are no longer available to us at the time we would be seeking authorizations, we may be required to conduct additional nonclinical studies or clinical trials beyond those contemplated for accelerated authorization, which could delay our ability to generate revenue and increase the expense of obtaining, and delay in the receipt of, necessary marketing approvals. Even if we receive an emergency authorization from the FDA or other regulators, if our confirmatory clinical trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or other regulators may seek to withdraw conditional approval or emergency authorization.

We are developing certain product candidates for the treatment of serious and life-threatening conditions, including PBI-0451 for the treatment of COVID-19, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory clinical trials to verify and describe the drug's clinical benefit. If the sponsor fails to conduct such clinical trials in a timely manner, or if such post-approval clinical trials fail to verify the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

In addition, the FDA currently requires, unless otherwise requested by the agency, pre-approval of promotional materials for products under consideration for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

If we decide to submit an NDA seeking accelerated approval, there can be no assurance that such an application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Failure to obtain accelerated approval for a product candidate would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate, which could harm our competitive position in the marketplace.

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. See the section entitled "*Business - Government Regulation and Product Approval – U.S. Healthcare Reform*" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as PBI-0451 and other therapies we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably, including the Patient Protection and Affordable Care Act. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private third-party payors. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and development, and if approved, market, sell and distribute our products. See the section entitled "*Business – Government Regulation and Product Approval – Other Healthcare Laws*" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. 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, or our arrangements with physicians, could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act ("FTCA") and the California Consumer Privacy Act of 2018 ("CCPA"), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators.

The State of California, for example, recently adopted the CCPA, which became effective January 2020. The CCPA establishes a privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. Additionally, some observers have noted that the CCPA and CPRA have marked the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the U.S., we have witnessed significant developments at the state level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (the "CDPA") and, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act ("CPA") into law. The CDPA and the CPA will both become effective on January 1, 2023. While the CDPA and CPA incorporate many similar concepts to the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"). HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

As we begin to conduct clinical trials globally, we may also become subject to privacy restrictions in various foreign jurisdictions around the world. For example, the collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area ("EEA"), including personal health data, is subject to the General Data Protection Regulation 2016/679 ("GDPR"). The GDPR is wide-ranging and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Importantly, the GDPR prohibits the transfer of personal data from the EEA to the U.S. and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called "adequacy decision" (known as "third countries"), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data to the U.S. was the EU-U.S. Privacy Shield framework administered by the U.S. Department of Commerce. However, certain recent EU court decisions cast doubt on the ability to use one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, to lawfully transfer personal data to the U.S. and other third countries. In addition, the European Commission has recently published new versions of the Standard Contractual Clauses, which must be used for all new transfers of personal data from the EEA to third countries (including the U.S.) starting in September 2021, and all existing transfers of personal data from the EU to third countries relying on the prior versions of the Standard Contractual Clauses must be replaced by December 2022. The implementation of the new Standard Contractual Clauses may necessitate significant contractual overhaul of our data transfer arrangements with sub-processors and vendors. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals, and additional supplementary technical, organizational and/or contractual measures and/or contractual provisions may need to be put in place.

At present, there are few if any viable alternatives to the Standard Contractual Clauses, and there remains some uncertainty with respect to the nature and efficacy of such supplementary measures in ensuring an adequate level of protection of personal data. As supervisory authorities issue further guidance on personal data export mechanisms (including circumstances where the Standard Contractual Clauses can and cannot be used) and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines. In addition, if we are unable to transfer personal data between and among countries and regions in which we conduct clinical trials, operate, engage providers, and/or otherwise transfer personal data, this could affect the manner in which we receive and/or provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results and generally increase compliance risk as a result. Additionally, other countries outside of the EEA have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

In addition, further to the United Kingdom's ("UK") exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK-specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned with the EU's data protection regime. Importantly, the UK Information Commissioner's Office has developed its own bespoke version of the Standard Contractual Clauses to govern cross-border data transfers, which could necessitate the implementation of both UK and EEA versions of Standard Contractual Clauses, depending on the locations of our clinical trials. This would require significant resources and result in significant cost to implement and manage. Further, non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Even if we are able to obtain regulatory approvals for our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for PBI-0451 or any of our other product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects, or the duration of such clinical trials may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns has been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our products, reformulate our products or make changes, create or modify a REMS, such as a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for PBI-0451 and any other product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our products if and when regulatory approvals for such products are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved products or substantially increase the costs and expenses of commercializing and marketing of our products.

Even if our product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on the product candidate, including restrictions on our indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval clinical trials. Further, even if we obtain regulatory approval for a product candidate, we would be subject to ongoing requirements by regulatory authorities as to the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information for the product. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidates, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval clinical trials or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practice ("cGMP"), regulations and standards. Manufacturers and manufacturers' facilities are also required to comply with applicable tracking and tracing requirements for prescription drug products. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- require revisions to the label, including limitation on approved uses or the addition of additional warnings, including "boxed" warnings, contraindications or other safety information, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing clinical trials;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- require us to create a REMS which could include a medication guide outlining the risks of such side effects for distribution to patients or distribution or use restrictions;

- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend or place on hold any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

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

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

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

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

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label product uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our product candidates or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our product candidates in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our common stock.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidates, if approved, which could make it difficult for us to sell our product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which products and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval processes apart from Medicare determinations. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

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

Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining comparable foreign regulatory approvals and compliance with comparable foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidates may be withdrawn if we fail to comply with regulatory requirements as a result of problems that occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain comparable foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidates by comparable foreign regulatory authorities, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in funding for, and other disruptions to, the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process its regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of the Business Combination and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should the FDA determine that an inspection is necessary for approval but that an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process its regulatory submissions, which could have a material adverse effect on its business.

If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

Risks Related to Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. Proprietary rights and technology are difficult and costly to protect, and we may not be able to ensure their protection.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for PBI-0451 and our other product candidates, proprietary platform, and methods of use, as well as on our ability to operate without infringing upon the proprietary rights of others. If we are unable to obtain and maintain sufficient intellectual property protection for our product candidate or other product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired. We generally seek to protect our proprietary position by filing patent applications in the United States and at the appropriate time in those jurisdiction abroad as deemed appropriate, related to our product candidates, proprietary technologies and their uses that are important to our business. Finally, we maintain our non-patented, but proprietary technologies, as company trade secrets. We own three issued patents related to protease inhibitors. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our PBI-0451. In addition, we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, consultants, advisors, and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Therefore, we cannot be certain that we were the first to file for patent protection of the invention claimed in our patent applications.

There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We are currently the assignee of three issued U.S. patents and a number of pending U.S. provisional and non-provisional patent applications directed to PBI-0451 and other compounds and technologies in our programs. U.S. provisional patent applications that we file are not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing the related provisional patent application. If we do not timely file any non-provisional patent application, we may lose our priority date with respect to the provisional patent application and any patent protection on the inventions disclosed in the provisional patent application. We cannot be certain that the claims in U.S. pending nonprovisional patent application or the provisional patent applications when converted to nonprovisional patent applications will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or by the patent offices and courts in foreign countries.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued that protect our product candidates;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- Our competitors, many of whom have substantially greater resources than us and have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products.

Our competitors and other third parties may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

As of May 1, 2022, we own three issued U.S. patents related to protease inhibitors, one of which includes claims directed to PBI-0451. Our issued patents and future patents if issued may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive.

The requirements for patentability may differ in certain countries, particularly in developing countries Consequently, competitors and other third parties 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 may obtain patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and pharmaceuticals. This could make it difficult for us to stop the infringement of our patents if issued or the marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could place our patent applications at risk of not issuing 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.

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

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the USPTO and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. While an inadvertent lapse can, in some cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

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

Third parties may infringe or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or controls. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, competitors or third parties may challenge the scope, validity or enforceability of our patents requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation reexamination, or *inter partes* review, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Even if we obtain a license, we may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patent applications is threatened, that could dissuade companies from collaborating with us to license, develop or commercialize product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and we may distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborations.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or our counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

An unfavorable outcome in any such proceeding could require us to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to us from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

A third party may hold proprietary rights that could prevent our product candidates from being marketed. Moreover, it is possible that we are or may become aware of patents or pending patent applications that we think do not relate to our product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidates and to be valid and enforceable. If any third-party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop, and any other product candidates or technologies covered by the asserted third-party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, we could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Many foreign jurisdictions also have rules of discovery that are different than those in the United States and which may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

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

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights and non-disclosure agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our products are subject to The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (also referred to as the Hatch-Waxman Act), in the United States, which can increase the risk of litigation with generic companies trying to sell our products and may cause us to lose patent protection.

Because our clinical candidates are pharmaceutical molecules reviewed by the Center for Drug Evaluation and Research of the FDA, after commercialization they will be subject in the United States to the patent litigation process of the Hatch-Waxman Act, as currently amended, which allows a generic company to submit an Abbreviated New Drug Application ("ANDA") to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch-Waxman Act, we will have the opportunity to list our patents that cover our drug product or our method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book.

Currently, in the United States, the FDA may grant five years of exclusivity for new chemical entities ("NCEs"), for which our product candidates may qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other New Drug Application ("NDA"). A generic company can submit an ANDA to the FDA four years after approval of our product. The submission of the ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book-listed patents based on arguments from the generic company that our listed patents are invalid, unenforceable or not infringed. Under the Hatch-Waxman Act, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of our data exclusivity period, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, do not timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary protection, and our product can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, the generic litigation may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity or enforceability of our patent.

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

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information, and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Intellectual property rights do not necessarily address all potential threats.

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. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our future collaborators, might not have been the first to make the inventions covered by our pending patent applications;
- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their 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 or those that we may own in the future will not lead to issued patents;
- issued patents that we own currently or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- 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;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents that cover our product candidate could be found invalid or unenforceable if challenged in court or the USPTO.

If we initiate legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patent such that they no longer cover our product candidate. The outcome for any particular patent 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, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidate. A loss of patent protection for our product candidate could have a material adverse impact on our ability to commercialize or license our technology and product candidate and, resultantly, on our business, financial condition, prospects and results of operations.

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

As is the case with other bio pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. 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 decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents we may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents, when issued. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a “first-to-invent” to a “first-inventor-to-file” patent system, and may also affect patent prosecution and litigation, such as by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the “first-inventor-to-file” provisions, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of issued patents all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Reliance on Third Parties

We rely on, and will continue to rely on, third parties to conduct our nonclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We do not have the ability to independently conduct certain nonclinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support certain nonclinical studies and clinical trials for PBI-0451, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our nonclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We have negotiated, and expect to continue negotiating, our budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely heavily on third parties in connection with our clinical development program for PBI-0451, and will continue to do so over the course of our future clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under cGMP requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who conduct our clinical trials are and will not be our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf.

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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our results of operations, financial results 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.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding new CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar 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.

We contract with third parties for the manufacture of our product candidates for nonclinical and clinical testing and expect to continue to do so for subsequent clinical trials and for commercialization. Significant portions of our clinical manufacturing are currently conducted by third party manufacturers outside of the United States, including China. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or that such supply will not be available to us at an acceptable cost and in accordance with anticipated timelines, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of nonclinical, clinical or if approved commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a nonclinical, clinical or commercial scale. We rely on third parties for the supply of our nonclinical and clinical drug supplies (including key starting and intermediate materials), and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have the product candidates manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourself. Any disruption in supply from any supplier or manufacturing location, including on account of the COVID-19 pandemic or the ongoing conflict in the Ukraine, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or comparable foreign regulatory requirements. The facilities used by our CMOs to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulators, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our CMOs 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 finds deficiencies or 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.

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

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If any one of our current contract manufacturers cannot perform its obligations as agreed, we may be required to replace that manufacturer, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement CMO. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

The manufacture of our product candidates involves multi-step processes and we may encounter delays and difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The lengthy multi-step manufacturing processes for our product candidates are expensive, highly-regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and comparable foreign regulatory authority requirements, including, for example, complying with cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and has an adverse effect on our business, financial condition, results of operations, and growth prospects.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of PBI-0451 and its potential commercialization will require substantial additional cash to fund expenses. We may pursue collaborations as a way to secure additional cash and expertise to develop and commercialize PBI-0451 and other product candidates. We face significant competition in seeking appropriate collaborators and some potential collaborators may have competing programs. Whether we reach a definitive agreement for a 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 comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs of manufacturing and delivering such product candidate to patients, the potential of competing products and 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 collaborators 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 candidates.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to reduce or curtail the development of the product candidate for which we are seeking to collaborate, delay our 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 product revenue.

Risks Related to Commercialization

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

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

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

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

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, commercial operations, managed care, customer operations, channel distribution, government price reporting, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or account management team 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 establishes marketing and other commercialization 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 commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourself. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may 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 and they could expose us to regulatory enforcement and legal risk in the execution of their sales and commercialization activities. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition, and prospects will be materially adversely affected.

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

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product, or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions outside the United States where we may pursue regulatory approvals and market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies.

Regulatory agencies in these countries could determine that the pricing for our products should be based on prices of other commercially available products for the same disease, rather than allowing us to market our products at a premium as new drugs. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including vaccines and other anti-viral therapeutics;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration, for example, dosage form, pill burden, or number of days of therapy per course;
- the additional healthcare economic evidence generated, as supported by real-world data or other non-interventional trials, demonstrating cost-effectiveness or budget impact of therapy;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidates or similar therapeutics.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Product liability lawsuits against us could cause the company to incur substantial liabilities and to limit commercialization of any products that we may develop, and insurance coverage may not be adequate.

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 commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering, selling or otherwise coming into contact with our products. If we cannot successfully defend ourself against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products, if approved for commercial sale, that we may develop;

- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects, patients or other claimants;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks Related to our Common Stock

An active trading market for our common stock may never develop or be sustained, which may make it difficult to sell the shares of our common stock you purchase.

An active trading market for our common stock may not develop or continue or, if developed, may not be sustained, which would make it difficult for you to sell your shares of our common stock at an attractive price (or at all). The market price of our common stock may decline below your purchase price, and you may not be able to sell your shares of our common stock at or above the price you paid for such shares (or at all).

The price of our common stock has been, and may continue to, be volatile.

We cannot predict the prices at which our common stock will continue to trade. Since the closing of the Business Combination on December 23, 2021, our closing stock price has ranged from $5.64 to $17.02 through March 31, 2022. The price of our common stock may fluctuate due to a variety of factors, including:

- changes in the industries in which we and our customers operate;
- variations in our operating performance and the performance of our competitors in general;
- material and adverse impact of the COVID-19 pandemic on the markets and the broader global economy;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us, our competitors or our industry;
- the public’s reaction to our press releases, other public announcements and filings with the SEC;
- our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

- the impact of interest rates and inflation;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions such as recessions, interest rates, inflation rates, fuel prices, foreign currency fluctuations, international tariffs, social, political and economic risks and acts of war or terrorism, including geopolitical instability caused by the Russian invasion of the Ukraine.

These market and industry factors may materially reduce the market price of share of our common stock regardless of our operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business, and seriously harm our business.

Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our shares of common stock.

The trading market for our common stock will depend in part on the research and reports that securities research analysts publish about our business. We do not have any control over these analysts and such analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. Our share price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, our share price could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, our share price or trading volume could decline.

The future sales of shares by existing stockholders and future exercise of registration rights may adversely affect the market price of our common stock.

Subject to certain exceptions, certain of our equity holders and affiliates of the sponsor of our Business Combination, entered into lockup agreements pursuant to which such holders agreed not to transfer any shares of our common stock or options to purchase common stock through June 21, 2022, the 180th day following the closing date of the Business Combination. Following the expiration of these lockup agreements, these stockholders will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. Sales of a substantial number of shares of our shares of common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our shares of common stock. Moreover, as restrictions on resale end and the registration statements (that we have filed, or will file, following the closing date of the Business Combination to provide for the resale of such shares from time to time) are available for use, the market price of our shares of common stock could decline if the holders of currently restricted shares sell them or are perceived by the market as intending to sell them.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests, voting rights and the per share value of our common stock to decline.

Because we have no current plans to pay cash dividends on our common stock, you may not receive any return on investment unless you sell your common stock for a price greater than that which you paid for it.

We have no current plans to pay cash dividends on our common stock. The declaration, amount and payment of any future dividends will be at the sole discretion of our Board. Our Board may take into account general and economic conditions, our financial condition and operating results, our available cash, current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications on the payment of dividends by us to our stockholders and such other factors as our Board may deem relevant. Accordingly, we may not pay any dividends on our common stock in the foreseeable future. As a result, you may only receive a return on your investment in our common stock if the market price of our common stock increases.

We expect to incur significant additional costs as a result of being a public company, which may adversely affect our operating results and financial condition.

We expect to incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), as well as rules implemented by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the “Dodd-Frank Act”), the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. In addition, we will incur additional costs associated with our public company reporting requirements and we expect those costs to increase in the future. For example, we will be required to devote significant resources to complete the assessment and documentation of our internal control system and financial process under Section 404, including an assessment of the design of our information systems associated with our internal controls.

To date, we have not conducted a review of our internal control for the purpose of providing the reports required by these rules. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if material weaknesses are identified or arise in the future, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934 (the "Exchange Act"). Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences. We will incur significant costs to remediate any material weaknesses we identify through these efforts. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board, our Board committees, or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

New laws and regulations, as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act and rules adopted by the SEC and Nasdaq, would likely result in increased costs as we respond to their requirements, which may adversely affect our operating results and financial condition.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act ("Section 404"), or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

As a public company, we are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our consolidated financial statements and require us to incur the expense of remediation.

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

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to significantly influence all matters submitted to stockholders for approval.

As of May 1, 2022, our executive officers, directors and their affiliates, in the aggregate, owned approximately 40% of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our Board or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

Provisions in our certificate of incorporation and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our certificate of incorporation and bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our Board. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our Board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our Board;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our Board to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our Board to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our bylaws or repeal the provisions of our certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the Board, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our Board or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to anti-takeover provisions under Delaware law, which could discourage, delay, defer or prevent a merger, tender offer, proxy contest or other change of control transaction that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of common stock held by our stockholders. These anti-takeover provisions as well as certain provisions of Delaware law could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many of our stockholders. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. If prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our common stock. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and to cause us to take other corporate actions that our stockholders desire.

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

The Company's Purchase of Equity Securities

The following table contains information relating to our repurchase of common stock during the three months ended March 31, 2022.

Period	Total Number of Shares Purchased[(1)]	Average Price Paid per Share
January 1 - January 31, 2022	—	$ —
February 1 - February 28, 2022	—	—
March 1 - March 31, 2022	58,072	0.00000706
Total	58,072	$ 0.00000706

(1) Represents shares of unvested common stock that were repurchased by us from a former employee upon termination of employment in accordance with the terms of the employee's restricted stock purchase agreement. We purchased the shares from the former employee at the original exercise prices (as adjusted by the Conversion Ratio calculated pursuant to the Merger Agreement).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) Exhibits

Exhibit Number	Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.1#	Employment Agreement dated March 1, 2022, by and between Pardes Biosciences, Inc. and Thomas G. Wiggans		Exhibit 10.18 on Form 10-K	March 29, 2022	001-40067
10.2#	Transition and Separation Agreement and General Release of Claims dated March 25, 2022, by and between Pardes Biosciences, Inc. and Uri A. Lopatin, M.D.		Exhibit 10.21 to Form 10-K	March 29, 2022	001-40067
10.3#	Consulting Agreement dated March 25, 2022, by and between Pardes Biosciences, Inc. and Uri A. Lopatin, M.D.		Exhibit 10.22 to Form 10-K	March 29, 2022	001-40067
31.1	Certification of Principal Executive Officer 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	x			
31.2	Certification of Principal Financial Officer 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	x			
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	x			
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	x			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document	x			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	x			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	x			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	x			

101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	x
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	x
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	x

# Indicates a management contract or any compensatory plan, contract or arrangement in which directors or executive officers are eligible to participate.

† This certification will not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

PARDES BIOSCIENCES, INC.

Date: May 10, 2022 By: /s/ Thomas G. Wiggans
Thomas G. Wiggans
Chief Executive Officer and
Chair of the Board of Directors
(*Principal Executive Officer*)

Date: May 10, 2022 By: /s/ Heidi Henson
Heidi Henson
Chief Financial Officer
(*Principal Financial and Accounting Officer*)