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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: 001-36783

BELLICUM PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-1450200**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

3730 Kirby Drive, Suite 1200, Houston, TX	**77098**
(Address of principal executive offices)	**(Zip code)**

(281) 454-3424
(Registrant's telephone number, including area code)

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 $0.01 per share	**BLCM**	**The Nasdaq Capital 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** ☒

As of May 9, 2022, there were 8,609,661 outstanding shares of Bellicum's common stock, par value, $0.01 per share.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Bellicum Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except par value and share data)

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,769	$ 46,156
Restricted cash	1,501	1,501
Accounts receivable, interest and other receivables	207	205
Prepaid expenses and other current assets	1,943	1,269
Total current assets	43,420	49,131
Property and equipment, net	14	12
Total assets	$ 43,434	$ 49,143
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 212	$ 90
Accrued expenses and other current liabilities	3,347	3,849
Warrant derivative liability	4,410	2,773
Total liabilities	7,969	6,712
Commitments and contingencies		
Redeemable preferred stock: $0.01 par value; 10,000,000 shares authorized		
Series 1 redeemable convertible preferred stock, $0.01 par value, 1,517,500 shares authorized at March 31, 2022 and December 31, 2021, 452,000 shares issued and outstanding at March 31, 2022 and December 31, 2021	18,036	18,036
Stockholders' equity:		
Common stock, $0.01 par value; 80,000,000 shares authorized at March 31, 2022 and December 31, 2021, 8,676,903 shares issued and 8,609,157 shares outstanding at March 31, 2022; 8,497,025 shares issued and 8,429,279 shares outstanding at December 31, 2021	87	85
Treasury stock: 67,746 shares held at March 31, 2022 and December 31, 2021	(5,056)	(5,056)
Additional paid-in capital	580,753	580,156
Accumulated other comprehensive loss	(341)	(338)
Accumulated deficit	(558,014)	(550,452)
Total stockholders' equity	17,429	24,395
Total liabilities, redeemable preferred stock and stockholders' equity	$ 43,434	$ 49,143

See accompanying notes, which are an integral part of these unaudited consolidated financial statements.

Bellicum Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses		
Research and development	$ 4,486	$ 6,460
General and administrative	1,453	2,012
Total operating expenses	5,939	8,472
Other operating expense		
Loss on dispositions, net	—	464
Loss from operations	(5,939)	(8,936)
Other income (expense):		
Interest income	14	10
Interest expense	—	(4)
Change in fair value of warrant derivative and private placement option liabilities	(1,637)	(2,337)
Total other expense	(1,623)	(2,331)
Net loss	$ (7,562)	$ (11,267)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.25)	$ (1.12)
Weighted-average shares outstanding, basic and diluted	30,819,578	10,034,970
Net loss	$ (7,562)	$ (11,267)
Other comprehensive loss:		
Foreign currency translation adjustment	(3)	—
Comprehensive loss	$ (7,565)	$ (11,267)

See accompanying notes, which are an integral part of these unaudited consolidated financial statements.

Bellicum Pharmaceuticals, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(amounts in thousands, except share data)

Three Months Ended March 31, 2022

	Series 1 Preferred		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2021	452,000	$ 18,036	8,497,025	$ 85	(67,746)	$ (5,056)	$ 580,156	$ (550,452)	$ (338)	$ 24,395
Share-based compensation	—	—	—	—	—	—	599	—	—	599
Issuance of common stock upon vesting of restricted stock units	—	—	122,928	1	—	—	(1)	—	—	—
Issuance of common stock upon exercise of pre-funded warrants	—	—	56,950	1	—	—	(1)	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(7,562)	(3)	(7,565)
Balance, March 31, 2022	452,000	$ 18,036	8,676,903	$ 87	(67,746)	$ (5,056)	$ 580,753	$ (558,014)	$ (341)	$ 17,429

Three Months Ended March 31, 2021

	Series 1 Preferred		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2020	452,000	$ 18,036	8,385,650	$ 84	(67,746)	$ (5,056)	$ 543,561	$ (540,747)	$ (339)	$ (2,497)
Share-based compensation	—	—	—	—	—	—	903	—	—	903
Exercise of restricted stock unit awards	—	—	369	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(11,267)	—	(11,267)
Balance, March 31, 2021	452,000	$ 18,036	8,386,019	$ 84	(67,746)	$ (5,056)	$ 544,464	$ (552,014)	$ (339)	$ (12,861)

See accompanying notes, which are an integral part of these unaudited consolidated financial statements.

Bellicum Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (7,562)	$ (11,267)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	599	903
Depreciation and amortization expense	5	47
Change in fair value of warrant derivative and private placement option liabilities	1,637	2,337
Amortization of right-of-use assets	—	33
Accretion of lease liability	—	31
Loss on dispositions, net	—	464
Changes in operating assets and liabilities:		
Accounts receivable, interest and other receivables	(2)	—
Prepaid expenses and other assets	(674)	(679)
Accounts payable	122	(222)
Accrued liabilities and other	(502)	60
Net cash used in operating activities	(6,377)	(8,293)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	—	900
Purchases of property and equipment	(7)	—
Net cash (used in) provided by investing activities	(7)	900
Cash flows from financing activities:		
Payment on financing lease obligations	—	(20)
Net cash used in financing activities	—	(20)
Effect of exchange rate changes on cash	(3)	—
Net change in cash, cash equivalents, and restricted cash	(6,387)	(7,413)
Cash, cash equivalents and restricted cash at beginning of period	47,657	36,996
Cash, cash equivalents and restricted cash at end of period	$ 41,270	$ 29,583

See accompanying notes, which are an integral part of these unaudited consolidated financial statements.

Bellicum Pharmaceuticals, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

NOTE 1 - ORGANIZATION, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization

Bellicum Pharmaceuticals, Inc. ("Bellicum") is a clinical stage biopharmaceutical company focused on discovering and developing novel cellular immunotherapies for various forms of cancer. Bellicum is devoting substantially all of its present efforts to developing next-generation CAR-T product candidates in cellular immunotherapy.

Bellicum has two wholly-owned subsidiaries, Bellicum Pharma Limited, a private limited company organized under the laws of the United Kingdom, and Bellicum Pharma GmbH, a private limited liability company organized under German law. Both were formed for the purpose of developing product candidates in Europe. Bellicum, Bellicum Pharma Limited and Bellicum Pharma GmbH are collectively referred to herein as the "Company." All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in conformity with the authoritative U.S. generally accepted accounting principles ("GAAP") for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission ("SEC"). Accordingly, the accompanying unaudited condensed consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto in the Company's Annual Report on Form 10-K ("Annual Report") for the fiscal year ended December 31, 2021, as filed with the SEC on March 24, 2022.

The accompanying interim condensed financial statements have been prepared on a going concern basis, which assumes that the Company will continue to realize its assets and discharge its liabilities in the normal course of business. However, as of March 31, 2022 and December 31, 2021, the Company had an accumulated deficit of $558.0 million and $550.5 million, respectively, and at March 31, 2022, the Company had cash and cash equivalents of approximately $39.8 million and restricted cash of $1.5 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents, revenues and other cash inflows will be sufficient to fund its operating expenses and capital expenditure requirements through June 2023. However, the Company's operating plan may change as a result of many factors currently unknown, and the Company may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty the Company's future expenses given the dynamic nature of its business, the COVID-19 pandemic and the macro-economic environment generally. Existing cash, cash equivalents are not likely to be sufficient to fund the Company's operations through the third quarter of 2023 as management expects to incur additional losses in the future to conduct research and development and recognizes that the Company will need to raise additional capital to fully implement its business plan.

This going concern basis of accounting contemplates the recovery of the Company's assets and the satisfaction of the Company's liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company has recorded losses from operations since its inception and if the Company does not successfully obtain regulatory approval and commercialize any of its product candidates, the Company will not be able to achieve profitability.

The Company is subject to risks common to companies in the biotechnology industry and the future success of the Company is dependent on its ability to successfully complete the development of, and obtain regulatory approval for, its product candidates, manage the growth of the organization, obtain additional financing necessary in order to develop, launch and commercialize its product candidates, and compete successfully with other companies in its industry.

The Company believes that its current capital resources, which consist of cash and cash equivalents, are sufficient to fund operations. The Company may be required to raise additional capital to fund future operations through the sale of additional equity, incurrence of additional debt, the entry into licensing or collaboration agreements with partners, grants or other sources

of financing. Sufficient funds may not be available to the Company at all or on attractive terms when needed from equity or debt financings. If the Company is unable to obtain additional funding from these or other sources when needed, or to the extent needed, it may be necessary to significantly reduce its controllable and variable expenditures and current rate of spending through reductions in staff and delaying, scaling back, or suspending certain research and development, sales and marketing programs and other operational goals.

Use of Estimates

The preparation of the interim condensed consolidated financial statements in accordance with GAAP requires management to make certain estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. Actual results could differ from those estimates.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2022, as compared to the significant accounting policies described in Note 1 of the "Notes to Consolidated Financial Statements" in the Company's audited financial statements included in its Annual Report for the fiscal year ended December 31, 2021.

Cash, Cash Equivalents and Restricted Cash

The Company considers all short-term, highly liquid investments with maturity of three months or less from the date of purchase and that can be liquidated without prior notice or penalty, to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statements of cash flows.

(in thousands)	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 39,769	$ 46,156
Restricted cash	1,501	1,501
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 41,270	$ 47,657

In April 2020, the Company sold its U.S. manufacturing facility to The University of Texas M.D. Anderson Cancer Center ("M.D. Anderson"). Pursuant to the Company's asset purchase agreement with M.D. Anderson, $1.5 million of the cash proceeds received are subject to certain escrow provisions and recorded as restricted cash. The funds are required to be held until any claims against the escrow are resolved.

Disposition of Assets and Liabilities Held for Sale and Held for Use

In the fourth quarter of 2020, in connection with the Company's restructuring plan, Management elected to seek an exit to its leased R&D facility in Houston, Texas. The lease termination and disposal of the assets and liabilities associated with the facility was completed on February 26, 2021. Under the terms of the agreement, a third party assumed the lease for the facility. In addition, the third party paid $1.1 million to the Company for substantially all of the property, and equipment associated with the location. The consideration included $0.9 million in cash and an unsecured promissory note for $0.2 million.

On March 15, 2021, the Company entered an agreement to terminate its sub-lease of the South San Francisco office space contingent upon consent of the prime lessor. Under the terms of the agreement, the company agreed to pay a lease termination fee of $0.9 million while the security deposit of $0.2 million will be returned to the Company. The decision to exit this lease reflects the ability of the Company to carry on administrative functions remotely. On March 26, 2021, the Company met all of the conditions of the agreement and disposed of substantially all of the assets and liabilities associated with the lease including the a right-of-use asset of $0.6 million, leased equipment with net book value less than $0.1 million, and the related lease liability of $1 million. The Company recognized a loss on termination of $0.5 million during the first quarter of 2021.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities consist of the following:

(in thousands)	March 31, 2022	December 31, 2021
Accrued payroll	$ 166	$ 320
Accrued patient treatment costs	1,393	2,086
Accrued clinical research costs	663	479
Accrued manufacturing costs	388	328
Accrued professional services	417	305
Accrued other	320	331
Total accrued expenses and other current liabilities	$ 3,347	$ 3,849

Net Loss and Net Loss per Share of Common Stock Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period without consideration for common stock equivalents. Diluted earnings per share is based on the more dilutive method between the two-class method and the treasury stock method and includes the effect from potential issuance of ordinary shares, such as shares issuable pursuant to the conversion of preferred stock to common stock, exercise of warrants to purchase common stock, exercise of stock options, and vesting of restricted stock units. For periods of net loss, diluted net loss per share is calculated similarly to basic net loss per share.

For warrants that are recorded as a liability in the accompanying condensed consolidated balance sheets, the calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to loss per share for the period, an adjustment is made to net loss used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

The following outstanding shares of common stock equivalents were excluded from the computations of diluted loss per share of common stock attributable to common stockholders for the periods presented as the effect of including such securities would be anti-dilutive.

	March 31, 2022	March 31, 2021
Anti-dilutive common stock equivalents:	Number of Shares	
Redeemable convertible series 1 preferred stock	4,520,000	4,520,000
Warrants to purchase common stock	5,750,000	11,616,080
Private placement option	—	9,675,000
Options to purchase common stock	2,064,537	1,400,470
Unvested shares of restricted stock units	10,500	262,010
Total anti-dilutive common stock equivalents	12,345,037	27,473,560

NOTE 2 - FAIR VALUE MEASUREMENTS AND INVESTMENT SECURITIES

Fair Value of Financial Instruments

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, a fair value hierarchy has been established that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

These inputs are classified into the following hierarchy:

Level 1 Inputs - quoted prices (unadjusted) in active markets for identical assets that the reporting entity has the ability to access at the measurement date;

Level 2 Inputs - inputs other than quoted prices included within Level 1 that are observable for the asset, either directly or indirectly; and

Level 3 Inputs - unobservable inputs for the assets.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The Company believes the recorded values of its financial instruments, including cash and cash equivalents, accounts payable, and accrued liabilities approximate their fair values due to the short-term nature of these instruments.

Investment Securities

The following table presents the Company's investment securities (including, if applicable, those classified on the Company's balance sheet as cash equivalents) that are measured at fair value on a recurring basis as of March 31, 2022 and December 31, 2021:

	Fair Value at March 31, 2022			Fair Value at December 31, 2021		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Cash equivalents:						
Money market funds	$ 34,999	$ —	$ —	$ 42,487	$ —	$ —
Total cash equivalents	$ 34,999	$ —	$ —	$ 42,487	$ —	$ —

As of March 31, 2022 and December 31, 2021, an additional $1.5 million of restricted cash on the Company's balance sheet is held in a money market fund and would be considered a level 1 measurement.

Money market funds are valued based on various observable inputs such as benchmark yields, reported trades, broker/dealer quotes, benchmark securities and bids.

Warrant Derivative Liability and Private Placement Option Liability

The Company's financial liabilities recorded at fair value on a recurring basis include the fair values of the warrant derivative liability and the private placement option liability prior to its derecognition in December 2021. Inputs used to determine estimated fair value (Level 3) of the warrants include the fair value of the underlying stock relative to the warrant exercise price at the valuation measurement date, volatility of the price of the underlying stock, the expected term of the warrants, and risk-free interest rates.

The fair values of the warrant derivative liability and the private placement option liability, prior to its derecognition in December 2021, are classified as current liabilities in the accompanying condensed consolidated balance sheets. These liabilities will be shown as current liabilities on the balance sheet when it is deemed more probable than not by management to be exercised within one year. On December 4, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Securities Purchase Agreement"), pursuant to which certain of the investors irrevocably waived the right to cause the Company

to conduct the "First Closing" and "Second Closing" under the private placement option contained in the 2019 Securities Purchase Agreement (each term as defined in the 2019 Securities Purchase Agreement). The Company derecognized the private placement option liability of $2.8 million during the fourth quarter of 2021, out of which $2.6 million was recorded as gain on change in the fair value in the accompanying statements of operations and comprehensive loss, and $0.2 million was recorded as additional paid-in capital in the accompanying balance sheets.

The fair value of the warrants has been estimated with the following weighted-average assumptions, including the most sensitive input, volatility:

	March 31, 2022	December 31, 2021
Risk-free interest rate	2.40%	1.22%
Volatility	92.00%	94.00%
Expected term (years)	4.38	4.64

The following table provides the warrant derivative liability reported at fair value and measured on a recurring basis:

	Fair Value at March 31, 2022			Fair Value at December 31, 2021		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant derivative liability	$ —	$ —	$ 4,410	$ —	$ —	$ 2,773
Total fair value	$ —	$ —	$ 4,410	$ —	$ —	$ 2,773

The ending balance of the Level 3 financial instruments presented above represents the Company's best estimate of valuation and may not be substantiated by comparison to independent markets and, in many cases, could not be realized in immediate settlement of the instruments.

NOTE 3 - LEASES

The Company entered into two agreements and exited its Houston and South San Francisco office locations during the first quarter of 2021 and, therefore, did not have any lease liabilities as of March 31, 2022. In connection with the lease termination and exit of the Houston office, a third party also acquired all of the property and equipment associated with the location. The consideration included an unsecured promissory note of $0.2 million with a simple interest of 4% per annum, which is due and payable on or before June 30, 2022.

Components of lease cost are as follows:

	Three Months Ended	
(in thousands)	March 31, 2022	March 31, 2021
Finance lease cost:		
Amortization of leased asset	$ —	$ 10
Interest on lease liabilities	—	4
Operating lease cost	—	54
Short-term lease cost	—	52
Total lease cost	$ —	$ 120

NOTE 4 - PUBLIC OFFERING AND PRIVATE PLACEMENT

December 2021 Private Placement

On December 4, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Securities Purchase Agreement") with certain institutional investors, pursuant to which the Company issued pre-funded warrants to purchase an aggregate of 20,559,210 shares of its common stock and accompanying common warrants to purchase an aggregate of 2,055,920 shares of its common stock. Each pre-funded warrant to purchase one share of common stock was sold together with one warrant to purchase one-tenth of one share of common stock at a combined unit price of $1.7024. The pre-funded warrants were immediately exercisable at an exercise price of $0.0001 per share of common stock. The accompanying common warrants were immediately exercisable at an exercise price of $1.69 per share of common stock and will expire seven years from the date of issuance.

The gross proceeds to the Company from the private placement were approximately $35.0 million before deducting placement agent commissions and offering expenses payable by the Company, excluding any proceeds that may be received upon exercise of the accompanying warrants.

In addition, pursuant to the 2021 Securities Purchase Agreement, purchasers 2019 Securities Purchase Agreement (defined below) irrevocably waived the right to cause the Company to conduct the "First Closing" and "Second Closing" under the 2019 Securities Purchase Agreement (each term as defined in the 2019 Securities Purchase Agreement), which releases the Company of potential cash or equity obligations.

November 2020 Underwritten Offering

On November 2, 2020, the Company closed an underwritten offering of 1,040,000 shares of its common stock, pre-funded warrants to purchase 3,109,378 shares of its common stock, and accompanying common warrants to purchase up to an aggregate of 4,149,378 shares of its common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $6.025 and $6.024 for each pre-funded warrant. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock. The common warrants were immediately exercisable at an exercise price of $6.50 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The gross proceeds to the Company were approximately $25.0 million before deducting underwriting discounts and commissions and other offering expenses.

August 2019 Public Offering

On August 16, 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC and Wells Fargo Securities, LLC, as representatives of the several underwriters named therein (the "Underwriters"), relating to an underwritten public offering (the "Offering") of 575,000 shares of the Series 1 Redeemable Convertible Non-Voting Preferred Stock of the Company (the "Series 1 Preferred Stock") and warrants (the "Public Warrants") to purchase up to 5,750,000 shares of its common stock. Each share of Series 1 Preferred Stock was being sold together with a warrant to purchase 10 shares of common stock at a combined price to the public of $100.00. Under certain circumstances, each warrant to purchase 10 shares of common stock will be exercisable, at the irrevocable election of the holder, for one share of Series 1 Preferred Stock. The offering closed on August 21, 2019, and the net proceeds to the Company from the Offering were approximately $53.8 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, and excluding any proceeds that the Company may receive upon exercise of the Public Warrants.

All of the Public Warrants sold in the Offering have an exercise price of $13.00 per share of common stock or, in certain circumstances, for $130.00 per share of Series 1 Preferred Stock, subject to proportional adjustments in the event of stock splits or combinations or similar events. The Public Warrants were immediately exercisable upon issuance, provided that the holder is prohibited, subject to certain exceptions, from exercising a warrant for shares of common stock to the extent that immediately prior to or after giving effect to such exercise, the holder, together with its affiliates and other attribution parties, would own more than 9.99% of the total number of shares of common stock then issued and outstanding, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 19.99% upon 61 days' notice to the Company. The Public Warrants will expire on August 21, 2026, unless exercised prior to that date.

The following table reflects the fair value roll forward reconciliation of the warrant derivative liabilities for the period ended March 31, 2022:

(in thousands)	Warrant Derivative Liability
Balance, December 31, 2021	$ 2,773
Change in fair value	1,637
Balance, March 31, 2022	$ 4,410

Private Placement

On August 16, 2019, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional investors named therein (the "Purchasers"), pursuant to which the Company agreed to issue in a private placement (i) 350,000 shares of its Series 2 Redeemable Convertible Non-Voting Preferred Stock (the "Series 2 Preferred Stock"), at a purchase price of $100.00 per share, and related warrants (the "Private Warrants") to purchase up to 2,800,000 shares of common stock at an exercise price of $10.00 per share, and (ii) 250,000 shares of its Series 3 Redeemable Convertible Non-Voting Preferred Stock (the "Series 3 Preferred Stock" and, together with the Series 1 Preferred Stock and Series 2 Preferred Stock, the "Preferred Stock"), at a purchase price of $140.00 per share, and related warrants (also, "Private Warrants") to purchase up to 875,000 shares of common stock at an exercise price of $14.00 per share. The Company received $11.2 million in net option fee proceeds, net of offering costs, upon the execution of the 2019 Securities Purchase Agreement.

Pursuant to the 2021 Securities Purchase Agreement entered into on December 4, 2021, the Purchasers irrevocably waived the right to purchase such securities, and the Company derecognized the private placement option liability for the year ended December 31, 2021. The Company is no longer obligated to issue the Series 2 Preferred Stock, Series 3 Preferred Stock, or any associated Private Warrants.

A summary of warrants outstanding and exercisable as of March 31, 2022 is as follows:

Year Issued	Warrants Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price (per share)
2019	5,750,000	4.39	$ 13.00
2020	4,149,378	3.59	$ 6.50
2020[1]	1,659,752	—	$ —
2021	2,055,920	6.69	$ 1.69
2021[2]	20,559,210	—	$ —
	34,174,260		

NOTE 5 - REDEEMABLE CONVERTIBLE PREFERRED STOCK

In August 2019, the Company sold Series 1 Preferred Stock pursuant to the Offering. The Company has 10,000,000 authorized shares of preferred stock with a par value of $0.01 per share, of which the Company has designated 1,517,500 shares as Series 1 Preferred Stock, 350,000 shares as Series 2 Preferred Stock and 250,000 shares as Series 3 Preferred Stock. There were 452,000 shares of Series 1 Preferred Stock and no shares of Series 2 or Series 3 Preferred Stock issued and outstanding as of March 31, 2022.

As of March 31, 2022, the Company classified the Series 1 Preferred Stock as mezzanine equity, because the Series 1 Preferred Stock is redeemable at the option of the holders upon passage of time, which is outside of the Company's control to prevent. Subsequent adjustment of the amount presented in mezzanine equity to its redemption amount is necessary unless it is probable that the instrument will not become redeemable.

The Series 1 Preferred Stock is not redeemable at March 31, 2022, and is only currently redeemable upon a fundamental change in a redemption price. The Company does not believe a fundamental change is considered probable until it occurs. As (i) a fundamental change is not probable, and (ii) the occurrence of Transition Date (defined below) is probable, the Company did not accrete the Series 1 Preferred Stock to its redemption amount because it is probable the instrument will not become redeemable.

Optional Conversion

Each share of Preferred Stock is initially convertible into 10 shares of Common Stock. The conversion price at which Preferred Stock may be converted into shares of common stock, is subject to adjustment in connection with certain specified events.

Redemption

Until the applicable Transition Date (defined below), at any time on or after the date that is the fifth (5th) anniversary of the initial issue date of the applicable series of preferred stock, all or any portion of the preferred stock is redeemable at the option

[1] *The pre-funded warrants issued on November 2, 2020 do not have an expiration date.*
[2] *The pre-funded warrants issued on December 7, 2021 do not have an expiration date.*

of the holder at a redemption price of $100.00 per share (for Series 1 Preferred Stock). The "Transition Date" means the first date following August 21, 2021, on which each of the Conditions (as defined below) is met.

The "Conditions" mean: (1) the closing price of the Company's common stock has been equal to or exceeded $25.00 per share for 180 calendar days (for determining if the Conditions are met for the Series 1 preferred stock) for 180 calendar days; (2) the 50-day average trading volume of the Company's common stock on the Nasdaq stock market is greater than 50,000 shares; and (3) a Phase 3 or Phase 2 pivotal clinical trial for one of the Company's CAR-T product candidates has been initiated, meaning that at least one clinical trial site has been activated.

Dividends

Shares of Preferred Stock will be entitled to receive dividends equal to (on an as-if-converted-to-common stock basis), and in the same form and manner as, dividends actually paid on shares of common stock.

Liquidation

Until the applicable Transition Date, in the event of a liquidation, dissolution, winding up or deemed liquidation, holders of the Preferred Stock will receive a payment equal to the applicable per share purchase price of their Preferred Stock before any proceeds are distributed to the holders of Common Stock. The liquidation preferences, protective voting provisions and redemption rights of the Preferred Stock will terminate upon the occurrence of certain events.

Voting

Shares of Preferred Stock will generally have no voting rights, except to the extent expressly provided in the Company's certificate of incorporation or as otherwise required by law.

NOTE 6- SHARE-BASED COMPENSATION PLANS

Share-Based Compensation Plans

The Company has five share-based compensation plans, including the 2019 Equity Incentive Plan (the "2019 Plan"), which was adopted in June 2019. Each plan authorizes the granting of shares of common stock and/or options to purchase common stock to employees and directors of the Company, as well as non-employee consultants, and allows the holder of the option to purchase common stock at a stated exercise price. The only plan under which the Company may currently grant equity awards is the 2019 Equity Incentive Plan although there remain outstanding awards under the other four plans. Options vest according to the terms of the grant, which may be immediately or based on the passage of time, generally over two to four years, and have a term of up to 10 years. Unexercised stock options terminate on the expiration date of the grant. The Company recognizes the share-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period.

Share-Based Compensation Expense

Share-based compensation expense by classification for the three months ended March 31, 2022 and 2021 are as follows:

	Three Months Ended	
(in thousands)	March 31, 2022	March 31, 2021
Research and development	$ 294	$ 263
General and administrative	305	640
Total	$ 599	$ 903

At March 31, 2022, total compensation cost not yet recognized was $2.6 million and the weighted-average period over which this amount is expected to be recognized is 1.3 years.

NOTE 7 - COMMITMENTS AND CONTINGENCIES

Co-Development and Co-Commercialization Agreement - Adaptimmune Therapeutics plc

On December 16, 2016, the Company entered into a Co-Development and Co-Commercialization Agreement with and Adaptimmune Therapeutics plc (Adaptimmune) in order to facilitate a staged collaboration to evaluate, develop and commercialize next generation T cell therapies. Under the Agreement, the parties agreed to evaluate the Company's GoTCR technology (inducible MyD88/CD40 co-stimulation, or iMC) with Adaptimmune's affinity-optimized SPEAR® T cells for the potential to create enhanced TCR product candidates. Depending on results of the preclinical proof-of-concept phase, the parties expect to progress to a two-target co-development and co-commercialization phase. To the extent necessary, and in furtherance of the parties' proof-of-concept and co-development efforts, the parties granted each other a royalty-free, non-transferable, non-exclusive license covering their respective technologies for purposes of facilitating such proof-of-concept and co-development efforts. In addition, as to covered therapies developed under the agreement, the parties granted each other a reciprocal exclusive license for the commercialization of such therapies. With respect to any joint commercialization of a covered therapy, the parties agreed to negotiate in good faith the commercially reasonable terms of a co-commercialization agreement. The parties also agreed that any such agreement shall provide for, among other things, equal sharing of the costs of any such joint commercialization and the calculation of profit shares as set forth in the Agreement. The Agreement will expire on a country-by-country basis once the parties cease commercialization of the T cell therapies covered by the Agreement, unless earlier terminated by either party for material breach, non-performance or cessation of development, bankruptcy/insolvency, or failure to progress to co-development phase.

License Agreement - Baylor

In 2008, 2010, 2014 and 2016, the Company and Baylor College of Medicine ("BCM") entered into license agreements pursuant to which the Company obtained exclusive rights to certain technologies and patent rights owned by BCM.

Under the 2014 license agreement, the Company is required to pay BCM a low annual maintenance fee on each anniversary of the agreement date. The Company is also required to make royalty payments in the low single digits, subject to certain annual minimums, on net sales of products covered by the license and, to the extent the Company enters into a sublicensing agreement relating to a licensed product, the Company is also required to pay BCM a percentage in the low double-digits on all non-royalty income received from sublicensing revenue.

License Agreement - Agensys, Inc.

On December 10, 2015, the Company and Agensys, Inc. ("Agensys"), entered into a license agreement (the "Agensys Agreement"), pursuant to which (i) Agensys granted the Company, within the field of cell and gene therapy of diseases in humans, an exclusive, worldwide license and sublicense to its patent rights directed to prostate stem cell antigen 1 ("PSCA") and related antibodies, and (ii) the Company granted Agensys a non-exclusive, fully paid license to the Company's patents directed to inventions that were made by the Company in the course of developing the Company's licensed products, solely for use with Agensys therapeutic products containing a soluble antibody that binds to PSCA or, to the extent not based upon the Company's other proprietary technology, to non-therapeutic applications of antibodies not used within the field. As consideration for the rights granted to the Company under the Agreement, the Company agreed to pay to Agensys a non-refundable upfront fee of $3.0 million, which was included in license fee expense. The Company is also required to make aggregate milestone payments to Agensys of up to (i) $5.0 million upon the first achievement of certain specified clinical milestones for its licensed products, (ii) $50.0 million upon the achievement of certain specified clinical milestones for each licensed product, and (iii) $75.0 million upon the achievement of certain sales milestones for each licensed product. The Agreement additionally provides that the Company will pay to Agensys a royalty that ranges from the mid to high single digits based on the level of annual net sales of licensed products by the Company, its affiliates or permitted sublicensees. The royalty payments are subject to reduction under specified circumstances. These milestone and royalty payments will be expensed as incurred. Under the Agreement, Agensys also was granted the option to obtain an exclusive license, on a product-by-product basis, from the Company to commercialize in Japan each licensed product developed under the Agensys Agreement that has completed a phase 2 clinical trial. As to each such licensed product, if Agensys or its affiliate, Astellas Pharma, Inc., exercises the option, the Agensys Agreement provides that the Company will be paid an option exercise fee of $5.0 million. In addition, the Agensys Agreement provides that the Company will be paid a royalty that ranges from the mid to high single digits based on the level of annual net sales in Japan of each such licensed product. If the option is exercised, the aggregate milestone payments payable by the Company to Agensys, described above with respect to each licensed product, would be reduced by up to an aggregate of $65.0 million upon the achievement of certain specified clinical and sales milestones. The Agensys

Agreement will terminate upon the expiration of the last royalty term for the products covered by the Agensys Agreement, which is the earlier of (i) the date of expiration or abandonment of the last valid claim within the licensed patent rights covering any licensed products under the Agreement, (ii) the expiration of regulatory exclusivity as to a licensed product, and (iii) 10 years after the first commercial sale of a licensed product. Either party may terminate the Agensys Agreement upon a material breach by the other party that remains uncured following 60 days after the date of written notice of such breach (or 30 days if such material breach is related to failure to make payment of amounts due under the Agensys Agreement) or upon certain insolvency events. In addition, Agensys may terminate the Agensys Agreement immediately upon written notice to the Company if the Company or any of its affiliates or permitted sublicensees commences an interference proceeding or challenges the validity or enforceability of any of Agensys' patent rights.

License Agreement - BioVec

On June 10, 2015, the Company and BioVec Pharma, Inc. ("BioVec") entered into a license agreement (the "BioVec Agreement") pursuant to which BioVec agreed to supply the Company with certain proprietary cell lines and granted to the Company a non-exclusive, worldwide license to certain of its patent rights and related know-how related to such proprietary cell lines. As consideration for the products supplied and rights granted to the Company under the BioVec Agreement, the Company agreed to pay to BioVec an upfront fee of $100,000 within ten business days of the effective date of the BioVec Agreement and a fee of $300,000 within ten business days of its receipt of the first release of GMP lot of the products licensed under the BioVec Agreement. In addition, the Company agreed to pay to BioVec an annual fee of $150,000, commencing 30 days following the first filing of an Investigational New Drug Application (an IND filing), or its foreign equivalent, for a product covered by the license; with such annual fees being creditable against any royalties payable by the Company to BioVec under the BioVec Agreement. The Company also is required to make a $250,000 milestone payment to BioVec for each of the first three licensed products to enter into a clinical phase trial and one-time milestone payments of $2.0 million upon receipt of a registration granted by the Federal Drug Administration or European Medicines Agency on each of the Company's first three licensed products. The BioVec Agreement additionally provides that the Company will pay to BioVec a royalty in the low single digits on net sales of products covered by the BioVec Agreement. The Company may also grant sublicensees under the licensed patent rights and know-how to third parties for limited purposes related to the use, sale and other exploitation of the products licensed under the BioVec Agreement. The BioVec Agreement will continue until terminated. The BioVec Agreement may be terminated by the Company, in its sole discretion, at any time upon 90 days written notice to BioVec. Either party may terminate the BioVec Agreement in the event of a breach by the other party of any material provision of the BioVec Agreement that remains uncured on the date that is 60 days after written notice of such failure or upon certain insolvency events that remain uncured following the date that is 30 days after the date of written notice to a party regarding such insolvency event.

Litigation

On May 29, 2019, Bellicum was served with a second amended complaint indicating that the Company had been added as an additional defendant in an ongoing civil tort lawsuit, captioned Kelly v. Children's Hospital of Los Angeles et al., filed in the Los Angeles County Superior Court, Case No. BC681477. On July 10, 2019 plaintiffs filed a third amended complaint seeking unspecified monetary damages including punitive damages and alleging claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability - failure to warn, breach of express warranty and products liability design or manufacturing defect. Bellicum filed a demurrer and motion to strike plaintiffs' third amended complaint, which were granted in part on August 5, 2020 with the Court dismissing (without prejudice) all claims against Bellicum with the exception of the breach of express warranty and products liability design or manufacturing defect causes of action. The Court also granted Bellicum's motion to strike plaintiffs' claim for punitive damages. On September 15, 2020, plaintiffs filed a fourth amended complaint alleging the same causes of action and damages against Bellicum as were pled in the third amended complaint. On November 3, 2020, Bellicum filed a demurrer and motion to strike the fourth amended complaint, which is set for hearing on May 19, 2022.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 24, 2022, or our Annual Report, as well as our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q, or this Quarterly Report.

Forward-Looking Statements

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

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel, controllable cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors. We are advancing CAR-T cell therapies which are an innovative approach in which a patient's or donor's T cells are genetically modified to carry chimeric antigen receptors, or CARs. We are using our proprietary Chemical Induction of Dimerization, or CID, technology platform to engineer our product candidates with switch technologies that are designed to control components of the immune system in real time. By incorporating our CID platform, our product candidates may offer better efficacy and safety outcomes than are seen with current cellular immunotherapies.

Cell behavior is controlled by cascades of specialized signaling proteins. CID consists of molecular switches, modified forms of these signaling proteins, which are triggered inside the patient by infusion of a small molecule, instead of by natural upstream signals. We genetically introduce these molecular switches into the appropriate immune cells and deliver the cells to the patient in the manner of conventional cellular immunotherapy. We have developed two such switches: an "activation switch," designed to stimulate activation, proliferation and persistence of the immunotherapy cells and provide other immunomodulatory benefits, and a "safety switch," designed to initiate programmed cell death, or apoptosis, of the immunotherapy cells. Each of our product candidates incorporates one or both switches, for enhanced, real time control of efficacy and safety:

- The inducible MyD88/CD40 (iMC) activation switch that is incorporated into our GoCAR product candidates is designed to enhance CAR-based cell therapies by augmenting multiple mechanisms of action, including: 1) boosting effector cell proliferation; 2) enhancing functional persistence by resisting exhaustion and inhibitory signals found in the tumor microenvironment; and 3) stimulating the cancer patient's own immune system to intensify tumor killing. Unlike other CAR therapies that can behave unpredictably due to their autonomous activity, GoCAR antitumor effects are controlled through scheduled administration of rimiducid. In the event of severe side effects, GoCAR activity can be attenuated by extending the interval between rimiducid doses or suspending further rimiducid administration.

- Our CaspaCIDe™ safety switch (also known as inducible Caspase-9, or iC9) is designed to be inactive unless the patient experiences a serious side effect (e.g., cytokine release syndrome, or CRS, neurologic toxicities or off-tumor / on-target toxicities). In that event, rimiducid or temsirolimus is administered to induce Caspase-9 and eliminate the cells, with the goal of attenuating the therapy and resolving the serious side effect.

- Some of our product candidates are "dual-switch" GoCARs that are designed to provide a user-controlled system for managing proliferation, persistence and safety of tumor antigen-specific CAR cells by incorporating both our iMC and CaspaCIDe switches. We also have an active research effort to further develop and enhance these molecular switch approaches.

By incorporating our novel switch technologies, we are developing product candidates with the potential to elicit positive clinical outcomes and ultimately change the treatment paradigm in various areas of cellular immunotherapy. Our most advanced programs are described below.

- **BPX-601** is an autologous GoCAR-T product candidate containing our proprietary iMC activation switch, designed to treat solid tumors expressing prostate stem cell antigen, or PSCA. We believe iMC enhances T cell proliferation and persistence, enhances host immune activity, and modulates the tumor microenvironment to improve the potential to treat solid tumors compared to traditional CAR-T therapies. A Phase 1/2 clinical trial called BP-012 in patients with metastatic castration-resistant prostate cancer and metastatic pancreatic cancer expressing PSCA is ongoing.

- **BPX-603** is an autologous dual-switch GoCAR-T product candidate containing both the iMC activation and CaspaCIDe safety switches. BPX-603 is our first dual-switch GoCAR-T product candidate and is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen, or HER2. A Phase 1/2 clinical trial, called BPX603-201A, in patients with metastatic HER2+ solid tumors is ongoing.

We have developed efficient and scalable processes to manufacture genetically modified T cells of high quality, which are currently being used to generate products for our clinical trials. We are leveraging this know how in combination with our proprietary cellular control technologies, resources, capabilities and expertise for the manufacture of CAR-T product candidates to create and develop first and best-in-class product candidates.

Impact of COVID-19

We have experienced limited impact to date, and do not anticipate experiencing a substantial impact in the future to our operations as a result of the ongoing COVID-19 pandemic. However, depending the duration and severity of the pandemic, we could experience impact in the future, including with respect to the operations of our manufacturing partners, clinical trial sites and regulatory agencies, all of which we are substantially dependent upon for our business. In particular, as we seek to pursue clinical trial enrollment and site activation for BPX-601 and BPX-603, it is possible that we may experience challenges in site enrollment due to factors related to the COVID-19 pandemic. For example, in Q4 2021 and Q1 2022, we experienced delays related to COVID-19 in patient screening and enrollment and site activation activities, delaying anticipated data presentations from our studies from 2022 to the first half of 2023. We are continuing to closely monitor the impact and potential future of the COVID-19 pandemic on our business.

Results of Operations

The following table sets forth a summary of our statement of operations for the periods indicated:

	Three Months Ended		
(in thousands)	March 31, 2022	March 31, 2021	Change
Operating expenses:			
Research and development	$ 4,486	$ 6,460	$ (1,974)
General and administrative	1,453	2,012	(559)
Total operating expenses	5,939	8,472	(2,533)
Loss on dispositions, net	—	464	(464)
Loss from operations	(5,939)	(8,936)	2,997
Other income (expense):			
Interest income	14	10	4
Interest expense	—	(4)	4
Change in fair value of warrant derivative and private placement option liabilities	(1,637)	(2,337)	700
Total other expense	(1,623)	(2,331)	708
Net loss	$ (7,562)	$ (11,267)	$ 3,705

Research and Development Expenses (R&D)

The decrease in R&D expenses for the three months ended March 31, 2022, compared to the same period last year, was primarily due to continued reduction of expenses related to rivo-cel activities in connection with our restructuring plan effected in late 2020. We discontinued active efforts to identify a partner for rivo-cel in late 2021. As a result, we have further decreased the budget on rivo-cel by limiting activities to maintaining regulatory compliance and long-term follow-up and monitoring of patients previously enrolled in rivo-cel clinical trials. This reduction in activity resulted in a $1.6 million reduction in clinical research and pharmaceutical development expenses and a $0.3 million reduction in salaries, benefits, travel, depreciation and share-based compensation related charges.

General and Administrative Expenses (G&A)

The decrease in G&A expenses for the three months ended March 31, 2022, compared to the same period last year, was primarily due to reduced share-based compensation expenses by $0.3 million. This is a result of expiration of stock options along with lower cost of new stock option grants driven by a lower average stock price. Additionally, our exit from the Houston and South San Francisco leases along with the sale of our Houston facilities resulted in a combined reduction of $0.3 million in facility charges, depreciation expenses, and business property tax. The total change in G&A expenses was partially offset by an increase in the insurance premium and consulting expenses by $0.1 million.

Loss on dispositions, net

For the three months ended March 31, 2022, we did not incur any gain or loss on dispositions. The loss recognized for the three months ended March 31, 2021 was due to the lease termination of the South San Francisco office space. Upon the termination and exit of the office space, we disposed of substantially all of the assets and liabilities associated with the lease including a right-of-use asset of $0.6 million, leased equipment with net book value less than $0.1 million, and the related lease liability of $1.0 million. A loss on termination of $0.5 million was recognized for the three months ended March 31, 2021.

Other Income (Expense)

Other expense primarily consists of interest income, offset by changes in fair value of our warrant derivative liability, which is remeasured at each reporting period. Due to the nature of the inputs in the model used to assess the fair value of the warrant derivative liability, the Company may experience significant fluctuations at each reporting period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in stock price volatility over the remaining term of the warrants.

The increase in other income (expense) for the three months ended March 31, 2022, compared to the same period last year, was primarily due to a decreased loss from the change in fair value of our warrant liability of $1.6 million, compared to the loss from change in fair value of $2.3 million for the three months ended March 31, 2021. The bigger change in fair value over the first quarter of 2021 was primarily driven by a more significant increase in our stock price compared to the first three months of 2022.

Liquidity and Capital Resources

Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As of March 31, 2022, we had cash and cash equivalents of $39.8 million, restricted cash of $1.5 million, and net cash used in operations of approximately $6.4 million for the three months ended March 31, 2022. Notably, in December 2021, we completed a private placement equity financing transaction for gross proceeds of approximately $35.0 million before deducting placement agent commissions and offering expenses.

Our cash resources are primarily consumed by operating activities and we expect negative cash flows from operations to continue for at least the next 12 months. We do not have any material contractual obligations or commitments as of March 31, 2022. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses, and general overhead costs. Based on the Company's current business plan, we believe that our cash and cash equivalents, revenues and other cash inflows will be sufficient to fund our operating expenses and capital expenditure requirements through June 2023. However, the Company's operating plan may change as a result of many factors currently unknown, and the Company may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty the Company's future expenses given the dynamic nature of its business, the COVID-19 pandemic and the macro-economic environment generally. Existing cash, cash equivalents are not likely to be sufficient to fund the Company's operations through the third quarter of 2023 as management expects to incur additional losses in the future to conduct research and development and recognizes that the Company will need to raise additional capital to fully implement its business plan.

We plan to continue attempting to obtain future financing and/or engage in strategic transactions, but we cannot predict, with certainty, the outcome of our actions to generate liquidity, including the availability of additional equity or debt financing, or whether such actions would generate the expected liquidity as currently planned. To continue as a going concern, we may postpone or eliminate some of our research and development programs and reduce our administrative costs. We may also intend to seek additional funding including, but not limited to any or all of the following potential sources:

We have an effective shelf registration statement on Form S-3 for the offer and sale of up to $400.0 million of our securities, of which approximately $290.5 million remains available for future offerings. We may pursue additional funding through the sale of our securities in one or more offerings under this registration statement; however, we cannot assure you that we will be able to do so on favorable terms. Our ability to offer and sell our securities in a primary offering on our Form S-3 is currently limited by Instruction I.B.6 of Form S-3, commonly referred to as the "baby shelf" limitation. If we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that could adversely affect the rights of our existing stockholders. If we raise additional capital through the issuance of debt securities, we could incur fixed payment obligations and become subject to certain restrictive covenants, including limitations on our ability to incur additional debt and acquire or license intellectual property rights, and other operating restrictions that could restrict our ability to conduct our business

In addition, we may receive additional capital through the exercise of outstanding warrants to purchase our stock if our stock price sufficiently increases. As of March 31, 2022, warrants to purchase 5,750,000 shares of our Series 1 preferred stock at an exercise price of $130.00 per share (equivalent to $13.00 per share of common stock), warrants to purchase 4,149,378 shares of our common stock at an exercise price of $6.50 per share and warrants to purchase 2,055,920 shares of our common stock at an exercise price of $1.69 per share were outstanding. The preferred stock warrants expire on August 21, 2026 and the common warrants expire on November 3, 2025 and December 7, 2028, respectively.

As a result of the COVID-19 pandemic, global inflation and the ongoing military conflict between Russian and Ukraine, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Further deterioration in credit and financial markets and confidence in economic conditions could occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. Moreover, if we do not obtain such additional funds, there could be substantial doubt about our ability to

continue as a going concern and increased risk of insolvency, which could result in a total loss of investment to our stockholders and other security holders.

C***ash Flows***

Operating Activities

Net cash used in operating activities during the quarter ended March 31, 2022, was $6.4 million compared to $8.3 million for the same period last year. The primary operating activities during the three months ended March 31, 2022, were (1) $7.6 million of net losses, (2) a non-cash loss of $1.6 million recognized from the change in the fair value of the warrant derivative liability, and (3) $0.6 million share-based compensation expenses. These activities were partially offset by a $1.1 million decrease from changes in operating assets and liabilities.

Investing Activities

Net cash used in investing activities during the quarter ended March 31, 2022, was less than $0.1 million compared to net cash provided by investing activities of less than $0.9 million for the same period last year. The cash used in investing activities during the three months ended March 31, 2022, was primarily for the purchase of computer equipment.

Financing Activities

There was no cash used in or provided by financing activities during the quarter ended March 31, 2022, compared to net cash used in financing activities of less than $0.1 million for the same period last year primarily due to payment on financing lease obligations.

As of March 31, 2022, we do not have any short-term or long-term lease liabilities, debt obligations or other material capital commitments. The expected capital expenditures for the next 12 months are minimal.

Critical Accounting Policies and Estimates

There have been no material changes to the Company's critical accounting policies and use of estimates from those disclosed in the Company's Form 10-K for the year ended December 31, 2021. For a discussion of our critical accounting policies and use of estimates, refer to Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Estimates in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021.

Recent Accounting Pronouncements

See Note 1 - Organization, Basis of Presentation, and Summary of Significant Accounting Policies for discussion regarding recent accounting pronouncements.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commissions.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2022. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company 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 SEC'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 company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Principal Executive and Principal Financial Officer, 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 of achieving their 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 Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The information set forth under the "Litigation" subheading in Note 7 - Commitments and Contingencies of Notes to Consolidated Financial Statements in Part I, Item I of this Quarterly Report on Form 10-Q is incorporated herein by reference.

Item 1A. Risk Factors

Summary of Risk Factors

There are a number of risks related to our business and our securities. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found under the heading "Risk Factors" below.

- We have incurred net losses from operations in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require significant funding to complete the development and commercialization of our product candidates. If we fail to obtain additional financing, we may have to delay, reduce or eliminate our development programs or commercialization efforts.
- Our current product candidates are in early stage clinical trials, and we may experience unfavorable results in the future.
- Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 outbreak, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market.
- We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.
- If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Capital Market.
- Our principal stockholders own a significant percentage of our stock and can exert significant control over matters subject to stockholder approval.

Risk Factors

Our business and results of operations are subject to a number of risks and uncertainties. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that have changed since the issuance of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 24, 2022, or our Annual Report.

Risks Related to Our Business and Industry

We have incurred net losses from operations in every year since our inception and anticipate that we will continue to incur these net losses in the future.*

We are a clinical stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have incurred significant losses since our inception in 2004. To date, we have financed our operations primarily through equity and debt financings. As of March 31, 2022, we had an accumulated deficit of $558.0 million. We expect to continue to incur significant losses from operations for the foreseeable future, and we expect these accumulated losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

In addition, if we obtain regulatory approval of and seek to commercialize any of our product candidates, we will likely incur significant sales, marketing and manufacturing expenses and may continue to incur substantial research and development expenses for additional post-marketing approval development requirements related to such product.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate 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 significant funding to complete the development and commercialization of our product candidates. If we fail to obtain additional financing, we may have to delay, reduce or eliminate our development programs or commercialization efforts.*

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates and other research and development programs.

As of March 31, 2022, we had cash, cash equivalents and restricted cash of approximately $41.3 million. We maintain our cash and cash equivalents with high quality, accredited financial institutions. These amounts at times may exceed federally insured limits. Cash, cash equivalents and restricted cash are expected to be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2023.

We will need to finance future cash needs through public or private equity offerings, debt financings, strategic partnerships and alliances or licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the pandemic. If the disruption persists and/ or deepens, we could experience an inability to access additional capital, which could in the future negatively affect our capacity to fund research and development programs, including discovery research, preclinical and clinical development activities. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to significantly delay, scale back or discontinue the development or commercialization of our product candidates. We also could be required to:

- seek collaborators for one or more of our current or future product candidates on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or

- seek a third party to acquire us or our assets.

If we are unable to raise additional funds on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our development programs, or implement further reduction of costs for administration beyond our October 2020 restructuring. Moreover, if we do not obtain such additional funds, there could be substantial doubt about our ability to continue as a going concern and increased risk of insolvency, which could result in a total loss of investment to our stockholders and other security holders.

The FDA and other regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our business and future success depends, in part, on our ability to obtain regulatory authority assent to conduct human clinical trials, obtain regulatory approval to launch a product based on evidence of clinical safety and efficacy and then successfully commercialize our clinical product candidates. All of our product candidates will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can expect to generate any revenue from product sales.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- The FDA or comparable regulatory authority or an Institutional Review Board or comparable ethics oversight body may decline to clear the applicable Investigational New Drug Application (IND) or equivalent regulatory submission necessary to conduct human clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates have the necessary safety, purity, and potency for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- we may encounter serious and unexpected adverse events during clinical trials that render our products unsafe for use in humans;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in Europe, the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes and/or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. We have never generated any revenue from product sales and may never be profitable.

We have devoted substantially all of our financial resources and efforts to developing our proprietary CID technology platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We are in the early stages of developing our product candidates, and we have not completed development of any products. Our ability to generate revenue and achieve profitability depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of products for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing requisite clinical trials through all phases of clinical development of our current product candidates;
- seeking and obtaining marketing approvals for product candidates that successfully complete clinical trials, if any;

- launching and commercializing product candidates for which we obtain marketing approval, if any, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- identifying and developing new product candidates;
- progressing our pre-clinical programs into human clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- developing new molecular switches based on our proprietary CID technology platform;
- maintaining, protecting, expanding and enforcing our intellectual property; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biologic product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of any of our current or future product candidates or when we will be able to achieve or maintain profitability, if ever. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain the regulatory approvals to market and sell one or more of our product candidates, we may never generate significant revenues from any commercial sales for several reasons, including because the market for our products may be smaller than we anticipate, or products may not be adopted by physicians and payors or because our products may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize one or more products, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition and results of operations will be adversely affected. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies and clinical trials in addition to those that we currently anticipate for our product candidates, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. Further, if one or more of the product candidates that we independently develop is approved for commercial sale, we expect to incur significant costs associated with commercializing any such product candidates. Finally, even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our CID technology is novel and largely unproven.

Our proprietary CID technology platform is novel and there are no approved products or third-party product candidates in late-stage clinical trials based on this technology. Additionally, the safety and efficacy profile of rimiducid has not been subject to large scale clinical testing. If rimiducid is found to have a poor safety profile in clinical trials, or if our technology is not effective, we may be required to redesign all of our product candidates, which would require significant time and expense. In addition, our CID platform technology may not be applicable or effective in the development of additional cellular immunotherapies beyond our current programs which would adversely affect our business and prospects.

Cell therapies are novel and present significant challenges.

CAR-T and other cell therapy product candidates represent a relatively new field of cellular immunotherapy. Advancing this novel and personalized therapy creates significant challenges for us, including:

- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of cell therapies for cancer;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process our product candidates;
- developing a consistent and reliable process, while limiting contamination risks, for engineering and manufacturing T cells ex vivo and infusing the engineered cells into the patient;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

Our inability to successfully develop CAR-T and other cell therapies or develop processes related to the manufacture or commercialization of these therapies would adversely affect our business, results of operations and prospects.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Clinical testing is expensive, takes many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our product candidates are subject to the risks of failure inherent in biologic drug development. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing, even at statistically significant levels. We will be required to demonstrate through clinical trials that our product candidates are safe and effective for use in the target indication before we can obtain regulatory approvals for commercial sale. Companies frequently suffer significant setbacks in late-stage clinical trials, even after earlier clinical trials have shown promising results and most product candidates that commence clinical trials are never approved as products. We expect there may be greater variability in results for cellular immunotherapy products processed and administered on a patient-by-patient basis like some of our CID technology-based development and product candidates than for "off-the-shelf" products, like many drugs.

If any of our product candidates fail to demonstrate sufficient safety or efficacy, we would experience potentially significant delays in, or be required to abandon our development of the product candidate, which would have a material and adverse impact on our business, prospects, financial condition and results of operations.

Our current product candidates are in early stage clinical trials, and we may experience unfavorable results in the future.

A Phase 1/2 clinical trial is ongoing for BPX-601 for the treatment of prostate and pancreatic cancer, and a Phase 1/2 clinical trial for BPX-603 in HER2-positive solid tumors. We may not be able to commence clinical trials in the time frames we expect or we may encounter delays. For example, in December 2020, we announced that the FDA had placed a clinical hold on our BPX-601 trial in pancreatic cancer due to the death of a patient in the trial. Although the FDA released the hold in January 2021, there can be no assurance that future patient deaths in this or any of our clinical trials will not trigger additional clinical holds. As these product candidates are in early stages of development, we face significant uncertainty regarding whether they will be effective and safe in human patients, and the results from preclinical studies, such as in vitro and in vivo studies, of BPX-601 and BPX-603 may not be indicative of the results of clinical trials of these product candidates. For example, in October 2020, we announced that the first four pancreatic cancer patients treated with BPX-601 followed by repeat rimiducid dosing showed evidence of rimiducid-mediated CAR-T cell activation but clinically meaningful efficacy as measured by RECIST criteria was not observed. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Even if clinical trials are successfully completed, the FDA or foreign regulatory authorities may not interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of our clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

We may not be successful in our efforts to use and expand our CID platform to build a pipeline of product candidates and develop marketable products.

We believe that our CID platform, which serves as the foundation of our CaspaCIDe and GoCAR-T technologies, can be further leveraged to discover other novel technologies, therapeutic applications and market opportunities. We are at an early stage of development and our platform has not yet, and may never lead to, approved or marketable products. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including for reasons related to their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our technological approach, we may not be able to obtain product or partnership revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

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

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials under agreements with us. Negotiations of

budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities could require us to perform additional clinical trials before approving our marketing applications. It is possible that, upon inspection, such regulatory authorities could determine that any of our clinical trials fail to comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these 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.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical 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 drug 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. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Our business could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, as well as the business or operations of our research partners, customers and other third parties with whom we conduct business.*

Our business could be adversely affected by health epidemics in regions in which we have operations or conduct research activities or clinical trials. Such health epidemics could also affect the business or operations of contract manufacturers, raw material suppliers, clinical trial sites, and other third parties with whom we conduct business.

For example, the effects of government stay-at-home orders or related adjustments in our business are likely to negatively impact productivity, disrupt our business and delay our timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

Severe and/or long-term disruptions in our operations will negatively impact our business, operating results and financial condition. Specifically, COVID-19 related delays in clinical trial enrollment, patient care, data availability, or monitoring may delay the timeline to our integrity of data from our trials and could affect their acceptability to the FDA or other regulatory authorities, which would represent significant setbacks for the applicable program. For example, in Q4 2021 and Q1 2022, we experienced delays related to COVID-19 in patient screening and enrollment and site activation activities, delaying anticipated data presentations from our studies from 2022 to the first half of 2023. More significant disruptions may occur if the pandemic worsens in the geographies in which our study sites or manufacturing facilities are located. In addition, quarantines, stay-at-home, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, the effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely. In addition, to the extent the ongoing COVID-19 outbreak adversely affects our business, financial condition, results of operations and growth prospects, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the impact of the COVID-19 pandemic;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion; and
- competing clinical trials and approved therapies available for patients.

In particular, some of our clinical trials will look to enroll patients with characteristics which are found in a very small population, for example, patients with rare cancers with specific attributes that are targeted with our product candidates. Our clinical trials will compete with other companies' clinical trials for product candidates that are in the same 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 clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. 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 in these clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and antibody therapy, rather than enroll patients in any of our future clinical trials. Patients may also be unwilling to participate in our clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Any adverse developments that occur during any clinical trials conducted by academic investigators, our collaborators or other entities conducting clinical trials under independent INDs may affect our ability to obtain regulatory approval or commercialize our product candidates.

Rimiducid and CaspaCIDe-containing cell therapy constructs are being used by third parties in clinical trials for which we are collaborating or in clinical trials which are completely independent of our development programs. We have little to no control over the conduct of those clinical trials. If serious adverse events occur during these or any other clinical trials using our product candidates, the FDA and other regulatory authorities may delay, limit or deny approval of our product candidate or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for any product candidate and a new and serious safety issue is identified in clinical trials conducted by third parties, the applicable regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell our product. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize our product.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Adoptive cell therapy with autologous T cells is associated with a range of potentially severe immune-mediated adverse effects. In third party clinical trials involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse side effects attributed to CAR-T cells were severe and life-threatening in some patients. The life-threatening events were related to kidney dysfunction and toxicities of the central nervous system. Severe and life-threatening toxicities occurred primarily in the first two weeks after cell infusion and generally resolved within three weeks. In the past, several patients have also died in clinical trials by others involving CAR-T cells.

Undesirable side effects observed in our clinical trials, whether or not they are caused by our product candidates, could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities for a number of reasons. In addition, because the patients in our clinical trials are suffering from life-threatening diseases, are often suffering from multiple complicating conditions and are in a position of extreme immune deficiency at the time that they receive our therapy, it may be difficult to accurately assess the relationship between our product candidates and adverse events experienced by very ill patients. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on relatively new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. Costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from therapies such as our current and future product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products. In addition, our proposed product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials to demonstrate the safety and efficacy of our product candidates.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

Specifically, genetically engineering T cells is a competitive endeavor. Multiple companies are engaged in the engineering of T cells, including (but not limited to): 2seventy bio, Inc., Adaptimmune, Alaunos Therapeutics, Inc., Allogene Therapeutics, Inc., Amgen Inc., Atara Biotherapeutics, Inc., Athenex, Inc., Autolus Therapeutics plc, BioNTech Europe GmbH, Bristol-Meyer Squibb Co., Cellectis SA, Celyad S.A., CRISPR Therapeutics, Fate Therapeutics Inc., GlaxoSmithKline plc, Gilead Sciences, Inc., Immatics N.V., ImmunityBio, Inc., Iovance Biotherapeutics, Inc., Janssen Pharmaceutical, Legend Biotech, Lyell

Immunopharma, Inc., Medigene AG, Mustang Bio, Inc., Novartis AG, Obsidian Therapeutics, Poseida Therapeutics, Precigen Inc., Precision Biosciences, Inc., Sana Biotechnology, Sorrento Therapeutics, Inc., and Takeda Pharmaceutical Co.

In addition to other cell based treatments, our product candidates may compete in their solid tumor indications with novel therapeutics of other modalities, including small molecules, monoclonal antibodies, bi-specific antibodies, antibody-drug conjugates, and targeted radionuclides.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Item 1. Business Competition" under Part I of our Annual Report.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Workforce and expense reductions may have an adverse impact on our internal programs, our ability to hire and retain key personnel and may be distracting to management.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We currently employ a small number of employees and are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and substantially harm our business.

We substantially decreased our workforce in October 2020 and, depending on our need for additional funding and expense control, we may be required to implement further workforce and expense reductions in the future. Further workforce and expense reductions may not result in efficiencies and anticipated savings and could result in reduced progress on our internal programs. In addition, employees, whether or not directly affected by a reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidentiality of certain proprietary information and knowledge may not be maintained in the course of any such future employment. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. In addition, the implementation of expense reduction programs may result in the diversion of efforts of our executive management team and other key employees, which could adversely affect our business.

Furthermore, we have identified and may continue to identify deficiencies in our internal control over financial reporting due in part to our limited staffing and resources. If we are unable to maintain effective controls over financial reporting, it is possible that a misstatement of our annual or interim financial statements would not be prevented or detected on a timely basis. We have implemented and continue to implement measures designed to improve our internal control over financial reporting, including the retention of accounting consultants to assist in areas of complex accounting and financial reporting. However, if we are unsuccessful in maintaining the effectiveness of our internal control over financial reporting, the accuracy and timing of our financial reporting may be harmed, which could result in, among other things, restatements of our financial statements, failure to comply with SEC requirements, loss of investor confidence in our financial reporting, and a decline in our stock price.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units, or RSUs, that vest over time. The value to employees of stock options and RSUs that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. In addition, we believe the shares currently available for grant under our equity incentive plan are insufficient to meet our anticipate needs for attracting, retaining and motivating future and current employees. If we are unable to obtain stockholder approval of a sufficient increase in the number of shares available for issuance under our equity incentive plan, we would not be able to continue to grant equity awards to our employees, which could put us at a competitive disadvantage in retaining talent, and also make it more difficult for us to align employee interests with those of our stockholders through a program that includes stock ownership.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the

lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled scientific and medical personnel.

The terms of our 2019 private placement of equity restrict our operating and financial flexibility, and give priority to certain investors, both of which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

In August 2019, we entered into an agreement with certain institutional investors providing for a private placement. Pursuant to the terms of the 2019 securities purchase agreement for the private placement transaction, the investors in the private placement transaction have consent rights over certain significant matters of our business. These include decisions to authorize or issue equity securities that are senior or pari passu to the Series 1 preferred stock with respect to liquidation preference, the occurrence of indebtedness in excess of $1,000,000, the sale or license of certain of our technology and the payment of dividends. As a result, these stockholders, acting together, will have significant influence over certain matters affecting our business. The investors in the private placement may not exercise their rights to purchase additional tranches of preferred stock and may not consent to us seeking additional funds through debt or other equity financings. In addition, potential investors in the Company may decline to do so because of the preferential rights granted under the private placement agreement. Each of these factors could negatively impact our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

We are reliant on a third party to manufacture our clinical product candidates and may not be able to secure adequate manufacturing capacity.

In April 2020, we announced the closing of the sale of our U.S. manufacturing facility to M.D. Anderson. When M.D. Anderson assumed ownership of the facility, we became reliant on M.D. Anderson to supply our current clinical product candidates. We have endeavored to structure the transaction in a manner that ensures availability of adequate capacity and priority access thereto for the continued clinical development of our product candidates. Given the complexity of the manufacturing processes for cellular therapies, M.D. Anderson may be unable to effectively manufacture or release our products in accordance with applicable cGMP standards, which could result in significant costs or delays to our programs.

We oversee a complex manufacturing supply chain of cellular therapy product candidates, viral vectors and small molecule drugs.

Because of the complex nature of our cell therapy products, we need to oversee the manufacture of multiple components that require a diverse knowledge base and appropriate manufacturing personnel. The supply chain for these components is separate and distinct, and no single manufacturer can supply more than one component of each of our products. Additionally, it is likely that the cell therapy products will need to be made within an appropriate geographic location for the area in which the products will be utilized, so one cell therapy manufacturing facility may not be able to supply diverse geographic areas. Any lack of capabilities to store, freeze, thaw and infuse our cell therapies would adversely affect our business and prospects.

Our autologous GoCAR-T product candidates, including BPX-601 and BPX-603 are manufactured on a patient-by-patient basis using each patient's own cells. Efficient manufacturing of these products relies upon our ability to sufficiently expand and activate the cells of patients who have undergone multiple lines of prior therapy, often including immunosuppressive chemotherapy. Rimiducid, the small molecule drug used to activate both our iMC and iC9 switches, is a complex molecule to synthesize and is relatively insoluble and lipophilic, rendering it difficult to formulate. We have limited internal expertise in small molecule drug development and manufacturing, and we have identified specialty contract manufacturers to produce the rimiducid drug substance and drug product. It is uncertain whether the drug substance and drug product manufacturers will be able to manufacture sufficient quantity and quality of rimiducid to conduct the necessary non-clinical and clinical trials.

We have not yet caused our product candidates to be manufactured or processed on a commercial scale. We may not be able to scale patient-by-patient manufacturing and processing to satisfy clinical or commercial demands for any of our product candidates. In addition, our anticipated reliance on a limited number of third-party manufacturers for manufacturing exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and any replacement contractor must be approved by regulatory authorities. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory approval, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by regulatory agencies to ensure strict compliance with cGMP and other government regulations and standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party manufacturers could breach or terminate their agreement with us.

Each of these risks could delay our clinical trials, the approval, if any of our product candidates or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

We have limited information available regarding the ultimate cost of our products, and cannot estimate what the cost of our products will be upon commercialization, should that occur.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. Because of the patient-specific nature of our manufacturing process, it is not amenable to traditional "scale up" to manufacture larger lots as is performed for traditional drugs and biological agents.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Gene-modified cell therapy manufacture requires many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product. Some suppliers typically support biomedical researchers or blood-based hospital businesses and may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have commercial supply arrangements with many of these suppliers and may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the U.S. and, accordingly, we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls; and
- business interruptions resulting from geo-political actions, including war and terrorism, and the impact of the COVID-19 pandemic.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations and enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. It is possible that, following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

Because we rely on third parties to manufacture our drug substance and product, and because we collaborate with various organizations and academic institutions on the advancement of our technology platform, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We and our contractors utilize hazardous materials in our business operations, and any claims relating to improper handling, storage, or disposal of these materials could harm our business.

Our activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials, and similar laws in other geographic regions. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our internal computer systems, or those used by our clinical investigators, contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

System outages, network disruptions and cyber-security threats could interrupt the operation of our business.

We are dependent on the use of information technology systems for our operations. Outages, disruptions and threats could have an adverse impact on our ability to conduct operations. Cyber-security threats, such as malware, phishing and network attacks, are on the rise. These attacks can affect the availability of our information technology systems, including their data, as well as the confidentiality and integrity of these systems. A security breach poses a risk to confidential data, including but not limited to intellectual property and trade secrets resulting in financial, legal or reputational harm to us. Insider threats may exist if an individual authorized to access our technology systems improperly discloses sensitive data to unauthorized persons or the public. We also have outsourced elements of our operations, including elements of our information technology infrastructure, and thus manage several independent vendor relationships with third parties who may have access to our confidential information. Confidentiality agreements are in place for authorized users and third parties to support the prevention of confidential information being improperly disclosed. We have policies and procedures in place, including controls around the access and activity of authorized users, active system monitoring, back-up and recovery, information technology security and mandatory annual information technology security awareness training to assist in the prevention and mitigation of an outage, disruption or threat. In addition, we have invested in high availability, redundant technologies that will reduce the risk of an outage, disruption or threat. However, our efforts may not prevent an outage, disruption or threat that would materially adversely affect us. We also may not have sufficient liability insurance, either type or amount, to cover us against claims related to a cyber-security threat.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our clinical investigators, contractors and consultants, could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. In particular, certain third-party manufacturers may be unable to comply with their contractual obligations to us due to disruptions caused by COVID-19, including reduced operations or headcount reductions, or otherwise, and in certain cases we may have limited recourse if the non-compliance is due to factors outside of the manufacturer's control.

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 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 of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or 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 U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalties law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health and Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as require certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, including the European Union General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018, and which imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects.

Additionally, we are subject to state and foreign equivalents of each of the U.S. healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement 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 any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. We may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. For example, in May 2019, we were added as an additional defendant in an ongoing civil tort lawsuit in federal court in Los Angeles, California. The complaint alleges claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability-failure to warn, breach of express warranty and products liability design or manufacturing defect. Claims could also be asserted under state consumer protection acts. We have filed a demurrer and motion to strike the fourth amended complaint, which is not currently set for hearing but will be rescheduled pursuant to a further order from the court. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, federal or state liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;

- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop, alone or with corporate collaborators. We currently carry product liability insurance covering our clinical trials, with other coverage limits as appropriate for certain foreign jurisdictions. Although we maintain such insurance, our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2021, we had aggregate U.S. net operating loss carryforwards of approximately $478.0 million, and aggregate U.S. federal and Texas state research and development credits of approximately $13.0 million and $5.1 million, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal net operating loss carryforwards generated in taxable years beginning before January 1, 2018, may be carried forward only 20 years to offset future taxable income, if any. Under current U.S. federal income tax law, U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such net operating loss carryforwards in taxable years beginning after December 31, 2020, is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced one or more ownership changes in the past, including with respect to our August 2019 public offering, and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

We have not previously submitted a BLA to the FDA, or similar approval filings to other foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. It must also include significant information regarding the chemistry, manufacturing and controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, FDA's Office of Tissues and Advanced Therapies, or OTAT, has limited experience with combination products that include a small molecule component. Approval of our GoCAR-T product candidates, will likely require this FDA office to consult with other divisions of the FDA, which may result in further challenges in obtaining regulatory approval, including in developing final product labeling. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol, failing to follow GCPs, or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a subject by subject basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, or recommended for termination by the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, in December 2020 we announced that the FDA had placed a clinical hold on our BPX-601 trial in pancreatic cancer due to the death of a patient in the trial. Although the FDA released the hold in January 2021, there can be no assurance that future patients' deaths in this or any of our clinical trials will not trigger additional clinical holds. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the EU or U.S., including additional preclinical studies or clinical trials. Studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the EU and U.S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties and/or withdrawal of product approval if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

- suspension or termination of manufacturing at one or more manufacturing facilities;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. 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, and we may not achieve or sustain profitability.

Foreign legislative changes may also affect our ability to commercialize our product candidates. Effective as of May 25, 2018, the GDPR imposes privacy and security obligations on any entity that collects and/or processes personal information from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

The use of engineered T cells as potential cancer treatments is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community. Many factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the extent and quality of the clinical evidence supporting the efficacy and safety of our product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the pricing of our product candidates and the availability of adequate reimbursement by third-party payors and government authorities;
- the willingness and ability of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- confusion or lack of understanding regarding the effects of rimiducid and the timing and size of dosing of rimiducid after immune cell therapy; and
- the effectiveness of our sales and marketing efforts.

In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such clinical trials to demonstrate that these therapies are safe and effective may limit market acceptance our product candidates. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Market acceptance and sales of our product candidates will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, successful commercialization of our products will depend in part on the availability of governmental and third-party payor reimbursement for the cost of our product candidates and/or payment to the physician for administering our product candidates. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. One third-party payor's decision to cover a particular medical product or service does not assure that other payors will also provide coverage for the medical product or service, or to provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. Further, a third-party payor's decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. The market for our product candidates will depend significantly on access to third-party payors' formularies or lists of treatments for which third-party payors provide coverage and reimbursement. Third party payors may also have difficulty in determining the appropriate coverage of our product candidates, if approved, due to the fact that they are combination products that include a small molecule drug, rimiducid.

Third-party payors establish coverage and reimbursement policies for new products, including our product candidates. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, became law in the United States. PPACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following: (i) an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; (ii) an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; (iii) a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (iv) extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expansion of health care fraud and abuse laws, including the federal civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive judicial and Congressional challenges to other aspects of the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through December 31, 2022 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers.

Further, recently there has been heightened governmental scrutiny in the United States over the manner in which drug manufacturers set prices for their marketed products, in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance on September 24, 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the MFN model, on December 27, 2021, CMS published a final rule that rescinded the MFN model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that

additional federal and state healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business. For example, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

We expect that additional federal and state healthcare reform measures, such as further amendments and changes to the PPACA will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business.

Certain countries have a very difficult reimbursement environment and we may not obtain reimbursement or pricing approval, if required, in all countries where we expect to market a product, or we may obtain reimbursement approval at a level that would make marketing a product in certain countries not viable.

We expect to experience pricing pressures in connection with the sale of any products that we may develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals. If we fail to successfully secure and maintain adequate coverage and reimbursement for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and expected revenue and profitability which would have a material adverse effect on our business, prospects, financial condition and results of operations.

Due to the novel nature of our technology and the small size of our target patient populations, we face uncertainty related to pricing and reimbursement for these product candidates.

Our target patient populations for our potential product candidates are relatively small, as a result, the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial and manufacturing infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to our product candidates, for example, reimbursement for administration of our product candidates to patients, is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business.

We are subject to laws and regulations governing data privacy and the protection of personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third-party transactions, but also to transfers of information within our company, including employee information. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third-party service providers process, including in clinical trials conducted in the United States and European Union. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the European Union and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Additionally, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act, or the CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. As of January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. As currently written, the CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively, Trade Laws. We can face serious consequences for violations.

Among other matters, Trade Laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We also expect our non-U.S. activities to increase in time. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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, or FCPA, 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 for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, 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 the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products 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, including beginning on December 22, 2018 and ending on January 25, 2019, 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 repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, 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.

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We license from Baylor College of Medicine, or Baylor, certain intellectual property related to methods for activating antigen presenting cells, to certain genetic constructs and to certain methods for inducing apoptosis. Baylor may terminate or modify our licenses in the event of a material breach by us that remains uncured following the date that is 90 days after written notice of such breach or upon certain insolvency events that remain uncured following the date that is 30 days following written notice of such insolvency event. In addition, we have funded certain of our clinical development activities and may fund certain of our future clinical development with funds from the State of Texas. The State of Texas may have rights to commercialize the results of those clinical trials if it determines that we have failed, after notice and an opportunity to cure, to use diligent and commercially reasonable efforts to commercialize or otherwise bring to practical application the results of the funded clinical trials. We are also dependent on our license agreements with Agensys, Inc. (a subsidiary of Astellas Pharma, Inc.) with respect to PSCA-targeted CARs, and BioVec Pharma Inc. with respect to making retrovirus for all of our programs. The termination of any of these licenses could have a material adverse effect on our business.

Any termination of these agreements, or other agreements to which we are a party could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and our licensors and other partners regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If our efforts to protect the proprietary nature of our technologies are not adequate, we may not be able to compete effectively in our market.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Certain intellectual property which is covered by our in-license agreements has been developed at academic institutions which have retained non-commercial rights to such intellectual property.

There are several pending U.S. and foreign patent applications in our portfolio, and we anticipate additional patent applications will be filed both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property. We cannot be certain that the claims in our pending patent applications directed to compositions of matter for our product candidates will be considered patentable by the U.S. Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries. Method of use patents have claims directed to the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, it is possible that patent applications in our portfolio may not be the first filed patent applications related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a "first to file" system in the U.S. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements; however, it is possible that our trade secrets and other confidential proprietary information could be disclosed or that competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including inter parties review and post grant review have been implemented. As stated above, this reform is untried and untested and will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware or have not sufficiently analyzed with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, methods of use, including combination therapy or patient selection methods or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. It is possible that any such license would not be available at all or on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

For example, we are aware of a third-party patent having claims directed to chimeric DNA comprising DNA segments encoding (1) a single chain antibody domain and (2) transmembrane and cytoplasmic domains of an endogenous protein. Even though we have reason to believe that our product candidates are not covered by claims of this patent, an owner or licensee of the patent still might bring a patent infringement suit against us. If the patent is asserted against us, we may not prevail in defending against claims of infringement and/or challenging the validity of claims in the patent. We may not successfully develop alternative technologies or enter into an agreement by which we obtain rights to the patent. These rights, if necessary, may not be available on terms acceptable to us.

We are aware of third-party patents having claims that may be considered as being directed to single-chain antibody fragments that bind to PSCA and these patents may be considered relevant to BPX-601 and related technologies we are developing. We currently are evaluating whether or not we need to obtain rights to these patents under a license, and if it is determined that we need to obtain such rights, whether these rights can be obtained.

Also, while we are aware there are other third-party patents having claims that may be considered relevant to technologies for which we are seeking, or plan to seek, regulatory approval, we believe those patents have a patent term that may expire prior to the time we expect to obtain regulatory approval for these technologies. The estimated expiration dates for those patents were determined according to information on the face pages of the patents, and certain factors that could influence patent term, such as patent term adjustment and patent term extension, for example, were not factored into these estimates. Accordingly, the estimated expiration dates of those patents may not be accurate and one or more of those patents may not expire before we obtain regulatory approval for an applicable technology. Owners or licensees of one or more of those patents may bring a patent infringement suit against us. If one or more of those patents are asserted against us, we may be able to assert a defense for a safe harbor to patent infringement under 35 U.S.C. 271(e)(1) if certain requirements are met. It is possible that (1) certain of these requirements may not be met, and/or (2) one or more of the third-party patents might expire after one or more of our technologies obtain regulatory approval, and consequently we may not successfully assert such a defense to patent infringement. If we are unsuccessful in asserting a defense under 35 U.S.C. 271(e)(1), it is possible we may not prevail in defending against claims of infringement and/or challenging the validity of claims in those patents. We may not successfully develop alternative technologies or enter into agreements by which we obtain rights to applicable patents. These rights, if necessary, may not be available on terms acceptable to us.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

We may not be able to successfully complete negotiations and ultimately acquire the rights to the intellectual property that we may seek to acquire in the future.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is 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 or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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. It also is possible that a competitor we sue for patent infringement could countersue us for allegedly infringing one or more of their own patents or one or more patents they licensed from another entity. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. It also is possible that third parties could institute a patent office post-grant proceeding against one or more of our patents, or one or more patents licensed to us, such as a post grant review proceeding, inter parties review proceeding or reexamination proceeding at the USPTO, or an opposition proceeding in a jurisdiction outside the U.S. An unfavorable outcome in a post-grant proceeding could result in a loss of our patent rights. Litigation, interference proceedings or patent office post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We also may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. 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 process. While an

inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us, and (2) patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., 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 U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions, for example, opposition proceedings. Any such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patents directed to our product candidates. A loss of patent rights could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the recent case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. 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 and 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. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of our Common Stock

If we fail to satisfy applicable listing standards, our common stock may be delisted from the Nasdaq Capital Market.

Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. On May 5, 2021, we were notified by The Nasdaq Stock Market LLC ("Nasdaq"), that we were in breach of Listing Rule 5450(b)(2)(A), for continued listing on The Nasdaq Capital Market because the market value of our listed securities for 30 consecutive business days had been less than $35 million. On December 10, 2021, we were notified by Nasdaq that we had regained compliance with Listing Rule 5550(b)(1), which requires stockholders' equity of at least $2.5 million for continued listing of our common stock. Accordingly, we regained compliance with the continued listing requirements of The Nasdaq Capital Market.

Although we were able to regain compliance with the continued listing requirements of The Nasdaq Capital Market, we cannot assure you that we will be able to do so in the future. If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing.

In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by Nasdaq, the price of our common stock may decline, and although our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our shareholders to sell our common stock in the secondary market.

The price of our stock is volatile and you could lose all or part of your investment.

The trading price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including market conditions in general and a limited trading volume for our shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in our Annual Report, these factors include:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in our ongoing or future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our CID technology platform and our small molecule drug rimiducid;
- adverse developments concerning our contract manufacturers;
- changes in the structure of healthcare payment systems;
- our inability to maintain successful collaborations or to establish new collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of diseases and cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future

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

Holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant portion of our voting stock, including shares subject to outstanding options. As a result, if these shareholders were to choose to act together, they would have the ability to significantly influence all matters requiring stockholder approval. For example, these stockholders may be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Changes in accounting rules, assumptions and/or judgments could materially and adversely affect us.

Accounting rules and interpretations for certain aspects of our operations are highly complex and involve significant assumptions and judgment. These complexities could lead to a delay in the preparation and dissemination of our financial statements. Furthermore, changes in accounting rules and interpretations or in our accounting assumptions and/or judgments, such as asset impairments, could significantly impact our financial statements. In some cases, we could be required to apply a new or revised standard retroactively, resulting in restating prior period financial statements. Any of these circumstances could have a material adverse effect on our business, prospects, liquidity, financial condition and results of operations.

Our consolidated financial statements, including our liabilities and statements of operations are subject to quarterly changes in our accounting of our outstanding Series 1 Preferred Stock and related warrants.

In accordance with ASC Topic 815*, Accounting for Derivative Instruments and Hedging Activities*, and ASC Topic 480, *Liabilities-Distinguishing from Equity*, convertible preferred shares are accounted for as temporary equity and warrants are accounted for as liabilities at their fair value during periods where they can be net cash settled in case of a change in control transaction. The warrants are accounted for as a liability at their fair value at each reporting period. The value of the derivative warrant liability is re-measured at each reporting period with changes in fair value recorded in earnings. To derive an estimate of the fair value of these warrants, the binomial model is utilized, adjusted for the effect of dilution, which embodies all of the requisite assumptions (including trading volatility, estimated terms, dilution and risk-free rates) necessary to determine the fair value of these instruments. This process requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. As a result, our consolidated financial statements and results of operations may fluctuate quarterly, based on factors, such as the trading value of our common stock and certain assumptions, which are outside of our control. Consequently, our liabilities and consolidated statements of operations may vary quarterly, based on factors other than our revenues and expenses. The liabilities and accounting line items associated with our derivative securities on our balance sheet and statement of operations are non-cash items, and the inclusion of such items in our financial statements may materially affect the outcome of our quarterly and annual results, even though such items are non-cash and do not affect the cash we have available for operations. Investors should take such derivative accounting matters and other non-cash items into account when comparing our quarter-to-quarter and year-to-year operating results and financial statements.

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

Certain holders of our outstanding shares of common stock, are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Any sales of these shares by such stockholders could have a material adverse effect on the trading price of our common stock.

We register on Form S-8 all shares of common stock that are issuable under our 2019 Equity Incentive Plan, as amended. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our EIP and shelf registration statement, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including pursuant to our shelf registration statement on Form S-3 that we filed with the SEC. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. For example, in December 2021 we completed a private placement pursuant to which we issued pre-funded warrants to purchase an aggregate of 20,559,210 shares of our common stock and accompanying warrants to purchase an aggregate of 2,055,920 shares of common stock, and our outstanding shares of common stock as of May 9, 2022 was 8,609,661. This transaction resulted, and any similar future transactions may also result, in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the existing holders of our common stock.

We completed a public offering of our Series 1 preferred stock on August 21, 2019, and if we are required to redeem shares of preferred stock, our cash position will be negatively impacted. In addition, we may not have sufficient funds to redeem such shares of preferred stock.

We issued 575,000 shares of Series 1 preferred stock in connection with our August 2019 public offering. Subject to the terms of our certificate of incorporation, at any time on or after August 21, 2024, some or all of our outstanding shares of preferred stock will be redeemable at the option of the holder at a redemption price of $100.00 per share of Series 1, upon delivery of an irrevocable written notice to us. If a holder of preferred stock requests redemption we will be required to redeem such shares of preferred stock. However, we may be unable to redeem such preferred stock if restrictions under applicable law or contractual obligations prohibit such redemption. For example, Delaware law provides that a redemption on capital stock may only be paid from "surplus" or, if there is no "surplus," from a corporation's net profits for the then-current or the preceding fiscal year. Unless we operate profitably, our ability to redeem the preferred stock would require the availability of adequate "surplus," which is defined as the excess, if any, of our net assets (total assets less total liabilities) over our capital. To date, we have operated at a loss. Accordingly, if we do not have sufficient "surplus" under Delaware law, we would be unable to effect such redemption. If we do have sufficient "surplus" to effect such redemption, our available cash will be negatively impacted and our ability to use the net proceeds from this offering could be substantially limited. In addition, such reduction in our available cash could decrease the trading price of our common stock, and, accordingly, the preferred stock and our warrants.

Certain investors in the 2019 private placement will have the ability to control or significantly influence certain business decisions.

Pursuant to the terms of the 2019 securities purchase agreement for the private placement transaction, certain investors in the private placement transaction have consent rights over certain significant matters of the Company's business. These include decisions to authorize or issue equity securities that are senior or pari passu to the Series 3 preferred stock with respect to liquidation preference, the incurrence of indebtedness in excess of $1,000,000, the sale or license of the Company's iMC switch technology and the payment of dividends. As a result, these stockholders, acting together, will have significant influence over certain matters affecting our business.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Our amended and restated certificate of incorporation and our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

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

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event securities or industry analysts that cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended by Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant and the Second Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report Form 10-Q with the SEC on August 6, 2020).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on August 5, 2019).
3.3	Certificate of Designations, Preferences and Rights of Series 1 Redeemable Convertible Non-Voting Preferred Stock, Series 2 Redeemable Convertible Non-Voting Preferred Stock and Series 3 Redeemable Convertible Non-Voting Preferred Stock of Bellicum Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's report on Form 8-K, filed with the SEC on August 19, 2019).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
4.3	Registration Rights Agreement by and among the Registrant and Baker Brothers Life Sciences, LP, and two of its affiliated funds, dated January 15, 2016 (incorporated by reference to Exhibit 4.4 to Registrant's Registration Statement on Form S-3 (File No. 333-209012), filed with the SEC on January 15, 2016).
4.4	Form of Warrant issued in public offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.5	Form of Warrant issued in private offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.6	Securities Purchase Agreement, dated August 16, 2019, by and among the Company and the institutional investors named therein, (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.7	Form of pre-funded warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783). filed with the SEC on November 2, 2020).
4.8	Form of warrant to purchase common stock (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No.001-36783), filed with the SEC on November 2, 2020).
4.10	Form of Pre-Funded Warrant issued in private placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
4.11	Form of Accompanying Common Warrant issued in private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
4.12	Securities Purchase Agreement dated December 4, 2021, by and among the Company, Baker Brothers Life Sciences, LP, and Boxer Capital, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
10.1+	Bellicum Pharmaceuticals, Inc. Non-Employee Director Compensation Policy.
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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

+ Indicates management contract or compensatory plan.

Signatures

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

Bellicum Pharmaceuticals, Inc.

Date: May 12, 2022

By: /s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer and Principal Financial Officer

Date: May 12, 2022

By: /s/ Charles S. Grass
Charles S. Grass
Principal Accounting Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard A. Fair, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: 5/12/2022

By: /s/ Richard A. Fair

Richard A. Fair

President and Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (the "Report") of Bellicum Pharmaceuticals, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, the undersigned, in his capacity as an officer of the Registrant, does hereby certify, that, to the best of his knowledge:

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

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

/s/ Richard A. Fair
Richard A. Fair
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)
May 12, 2022

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.