Table of Contents

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 June 30, 2021

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)**

(832) 384-1100
(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 August 4, 2021, there were 8,397,803 outstanding shares of Bellicum's common stock, par value, $0.01 per share.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,278	$ 35,495
Restricted cash	1,501	1,501
Accounts receivable, interest and other receivables	904	2
Prepaid expenses and other current assets	1,229	802
Assets held for sale	—	1,643
Total current assets	23,912	39,443
Operating lease right-of-use assets	—	645
Property and equipment, net	40	189
Other assets	4	307
Total assets	$ 23,956	$ 40,584
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 760	$ 891
Accrued expenses and other current liabilities	4,457	4,165
Warrant derivative liability	9,629	10,345
Private placement option liability	5,277	7,803
Current portion of lease liabilities	17	825
Liabilities held for sale	—	672
Total current liabilities	20,140	24,701
Long-term lease liabilities	22	344
Total liabilities	20,162	25,045
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 June 30, 2021 and December 31, 2020; 452,000 shares issued and outstanding at June 30, 2021 and December 31, 2020	18,036	18,036
Stockholders' deficit:		
Common stock, $0.01 par value; 80,000,000 shares authorized at June 30, 2021 and December 31, 2020; 8,465,549 shares issued and 8,397,803 shares outstanding at June 30, 2021; 8,385,650 shares issued and 8,317,904 shares outstanding at December 31, 2020	84	84
Treasury stock: 67,746 shares held at June 30, 2021 and December 31, 2020	(5,056)	(5,056)
Additional paid-in capital	545,285	543,561
Accumulated other comprehensive loss	(339)	(339)
Accumulated deficit	(554,216)	(540,747)
Total stockholders' deficit	(14,242)	(2,497)
Total liabilities, preferred stock and stockholders' deficit	$ 23,956	$ 40,584

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		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Revenues				
Supply agreement	$ 700	$ —	$ 700	$ —
Total revenues	700	—	700	—
Operating expenses				
Research and development	6,722	11,758	13,183	22,206
General and administrative	1,765	3,761	3,777	7,932
Total operating expenses	8,487	15,519	16,960	30,138
(Gain) loss on dispositions, net	—	(3,761)	464	(3,761)
Loss from operations	(7,787)	(11,758)	(16,724)	(26,377)
Other income (expense):				
Interest income	8	28	18	382
Interest expense	(1)	(763)	(4)	(1,748)
Change in fair value of warrant and private placement option liabilities	5,579	(30,701)	3,242	2,125
Other expense	(1)	0	(1)	—
Total other income (expense)	5,585	(31,436)	3,255	759
Net loss	$ (2,202)	$ (43,194)	$ (13,469)	$ (25,618)
Net loss per common share attributable to common shareholders, basic and diluted	$ (0.22)	$ (8.55)	$ (1.34)	$ (5.08)
Weighted-average shares outstanding, basic and diluted	10,108,388	5,052,234	10,071,882	5,045,965
Net loss	$ (2,202)	$ (43,194)	$ (13,469)	$ (25,618)
Other comprehensive loss:				
Foreign currency translation adjustment	—	(49)	—	(62)
Comprehensive loss	$ (2,202)	$ (43,243)	$ (13,469)	$ (25,680)

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' Deficit
(amounts in thousands, except share data)
(Unaudited)

Six Months Ended June 30, 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)
Share-based compensation	—	—	—	—	—	—	821	—	—	821
Exercise of restricted stock unit awards	—	—	79,530	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(2,202)	—	(2,202)
Balance, June 30, 2021	452,000	$ 18,036	8,465,549	$ 84	(67,746)	$ (5,056)	$ 545,285	$ (554,216)	$ (339)	$ (14,242)

Six Months Ended June 30, 2020

	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, 2019	538,000	$ 21,468	5,076,593	$ 507	(67,746)	$ (5,056)	$ 511,684	$ (533,025)	$ (327)	$ (26,217)
1-for-10 Reverse Stock Split	—	—	—	(457)	—	—	457	—	—	—
Share-based compensation	—	—	—	—	—	—	1,323	—	—	1,323
Issuance of common stock upon vesting of restricted stock units	—	—	1,045	—	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock	(4,000)	(160)	40,000	1	—	—	159	—	—	160
Comprehensive loss	—	—	—	—	—	—	—	17,576	(13)	17,563
Balance, March 31, 2020	534,000	$ 21,308	5,117,638	$ 51	(67,746)	$ (5,056)	$ 513,623	$ (515,449)	$ (340)	$ (7,171)
Share-based compensation	—	—	—	—	—	—	1,564	—	—	1,564
Issuance of common stock - Employee Stock Purchase Plan	—	—	9,526	—	—	—	65	—	—	65
Issuance of common stock upon vesting of restricted stock units	—	—	361	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(43,194)	(49)	(43,243)
Balance, June 30, 2020	534,000	$ 21,308	5,127,525	$ 51	(67,746)	$ (5,056)	$ 515,252	$ (558,643)	$ (389)	$ (48,785)

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)

	Six Months Ended	
	June 30, 2021	June 30, 2020
Cash flows from operating activities:		
Net loss	$ (13,469)	$ (25,618)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,724	2,887
Depreciation and amortization expense	70	925
Change in fair value of warrant and private placement option liabilities	(3,242)	(2,125)
(Gain) loss on dispositions, net	464	(3,761)
Amortization of right-of-use assets	33	173
Accretion of lease liability	36	(535)
Amortization of deferred issuance costs	—	388
Changes in operating assets and liabilities:		
Accounts receivable, interest and other receivables	(529)	176
Prepaid expenses and other assets	(426)	(160)
Accounts payable	(131)	(157)
Accrued liabilities and other	(612)	(2,662)
Net cash used in operating activities	(16,082)	(30,469)
Cash flows from investing activities:		
Proceeds from sale of property and equipment, net	900	14,909
Purchases of property and equipment	—	(229)
Net cash provided by investing activities	900	14,680
Cash flows from financing activities:		
Payment on debt	—	(10,000)
Proceeds from issuance of stock from employee stock purchase plan	—	65
Payment on financing lease obligations	(35)	(35)
Net cash used in financing activities	(35)	(9,970)
Effect of exchange rate changes on cash	—	(62)
Net change in cash, cash equivalents, and restricted cash	(15,217)	(25,821)
Cash, cash equivalents and restricted cash at beginning of period	36,996	93,816
Cash, cash equivalents and restricted cash at end of period	$ 21,779	$ 67,995
Supplemental cash flow information:		
Cash paid during the period for interest	$ —	$ 1,413
Non-cash investing and financing activities:		
Purchases of property and equipment in accounts payables and accrued liabilities	$ —	$ 60
Conversion of redeemable preferred stock into common stock	$ —	$ 160
Reclassification of property and equipment, net to assets held for sale	$ —	$ 199

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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.

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis. The Company’s chief operating decision maker is its Chief Executive Officer who manages operations and reviews the financial information as a single operating segment for purposes of allocating resources and evaluating its financial performance.

Reverse Stock Split

On February 5, 2020, the Company filed a Certificate of Amendment of the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to (i) effect a reverse stock split of all issued and outstanding shares of the Company’s common stock at a ratio of 1-for-10 and (ii) reduce the number of authorized shares of the Company’s common stock from 200,000,000 to 40,000,000. The accompanying consolidated financial statements and notes to the consolidated financial statements gives retroactive effect to the reverse stock split for all periods presented.

On June 15, 2020, the Company filed with the Secretary of State of the State of Delaware a Second Certificate of Amendment to the Company’s Amended and Restated Certificate of Incorporation to increase the authorized number of shares of the Company’s common stock from 40,000,000 shares to 80,000,000 shares.

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, 2020, as filed with the SEC on March 31, 2021.

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 June 30, 2021, and December 31, 2020, the Company had an accumulated deficit of $554.2 million and $540.7 million, respectively, and at June 30, 2021, the Company had cash, cash equivalents and restricted cash of approximately $21.8 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents, revenues and other cash inflows will be insufficient to fund its operations for one year from the date these financial statements are issued, and therefore, substantial doubt about the entity's ability to continue as a going concern exists. This 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 there is substantial doubt that its current capital resources, which consist of cash and cash equivalents are sufficient to fund operations through at least the next twelve months from the date the accompanying interim financial statements are issued based on the expected cash burn rate. The Company may be required to raise additional capital to fund future operations through the sale of additional equity, incurrence of 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. 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.

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 six months ended June 30, 2021 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, 2020.

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)	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 20,278	$ 35,495
Restricted cash	1,501	1,501
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 21,779	$ 36,996

In connection with the closing of the Asset Purchase Agreement with M.D. Anderson on April 14, 2020, $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 for a period of up to 18 months subsequent to the April 14, 2020 closing date and are listed as Restricted cash at June 30, 2021, and December 31, 2020.

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 manufacturing facility in Houston, Texas. As a result of this decision, the Company reclassified the assets and liabilities associated with the leased facility as held for sale. The reclassified assets and liabilities included a right-of-use asset of $0.5 million, property and equipment of $2.3 million and the related lease liability of $0.7 million. Based on the cost to exit the lease and the net realizable value of the related assets the Company recognized an impairment charge of $1.3 million in the fourth quarter of 2020.

The disposal of the assets and liabilities associated with the Houston 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 was returned to the Company in June 2021. The decision to exit this lease reflects the ability of the Company to carry on administrative function 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 three months ended March 31, 2021 and six months ended June 30, 2021.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities consist of the following:

(in thousands)	June 30, 2021	December 31, 2020
Accrued payroll	$ 224	$ 1,029
Accrued patient treatment costs	2,108	899
Accrued manufacturing costs	140	24
Accrued professional services	404	294
Accrued other	1,581	1,919
Total accrued expenses and other current liabilities	$ 4,457	$ 4,165

Warrant Derivatives

Freestanding warrants are classified as liabilities in the accompanying condensed consolidated balance sheets as they are exercisable for multiple underlying instruments that are potentially redeemable. The Company accounts for these warrants at fair value on the date of issuance and are subject to re-measurement to fair value at each balance sheet date. Any change in fair value is recognized as a component of other income (expense) on the accompanying condensed consolidated statements of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants or a change in control, as defined. The warrants are freely exercisable at any time from the issuance date until the expiration date, provided exercise does not cause a warrant holder to exceed a pre-determined beneficial ownership limit.

The Company estimates the fair value of these liabilities using the Black-Scholes valuation technique, which utilizes assumptions including (i) the fair value of the underlying stock at the valuation measurement date, (ii) volatility of the price of the underlying stock, (iii) the expected term, and (iv) risk-free interest rates.

Private Placement Option

The Company has entered into a security purchase agreement that contains a call option on preferred shares that are puttable outside the control of the Company. The Company recorded the option as a liability and measured the fair value of the option at the time of issuance. The Company will re-measure the option to fair value at each balance sheet date and record changes in fair value in other income (expense) in the accompanying condensed consolidated statement of operations and comprehensive loss at each reporting period. Offering expenses arising from the issuance of the private placement option were expensed as incurred.

The Company estimates the fair value of these liabilities using a binomial lattice model, which utilizes assumptions including (i) the fair value of the underlying stock at the valuation measurement date, (ii) volatility of the price of the underlying stock, (iii) the expected term, and (iv) risk-free interest rates.

Preferred Stock

Preferred shares issued by the Company that are subject to mandatory redemption are classified as liability instruments in the accompanying condensed consolidated balance sheets and are measured at fair value at the date of issuance. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified within mezzanine equity in the accompanying condensed consolidated balance sheets. At all other times, preferred shares are classified within stockholders' deficit.

Operating Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If both criteria are met, upon lease commencement, the Company records a lease liability which represents the Company's obligation to make lease payments arising from the lease, and a corresponding right-of-use ("ROU") asset which represents the Company's right to use an underlying asset during the lease term.

Operating leases are recognized as ROU assets and operating lease liabilities on the balance sheet based on the present value of the future minimum lease payments over the lease term at commencement date calculated using the Company's incremental borrowing rate applicable to the underlying asset unless the implicit rate is readily determinable. Any lease incentives received are deferred and recorded as a reduction of the ROU asset and amortized over the term of the lease. Rent expense, comprised of amortization of the ROU asset and the implicit interest accreted on the operating lease liability, is recognized on a straight-line basis over the lease term. The Company determines the lease term as the non-cancellable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Leases with a term of 12 months or less are not recognized on the balance sheets.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in an orderly transaction between market participants in a principal market on the measurement date.

Accounting standards include disclosure requirements around fair values used for certain financial instruments and establish a fair value hierarchy. The three-tier hierarchy defines a three-tiered valuation hierarchy for disclosures that prioritizes valuation inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market, as described further in Note 2.

Observable inputs reflect readily obtainable data from independent sources, and unobservable inputs reflect the Company's market assumptions.

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.

Financial Instruments and Credit Risks

Financial instruments that potentially subject the Company to credit risk include cash and cash equivalents and accounts receivable. Cash is deposited in demand accounts in federally insured domestic institutions to minimize risk. Insurance is provided through the Federal Deposit Insurance Corporation and Security Investor Protection Corporation. Although the balances in these accounts exceed the federally insured limit from time to time, the Company has not incurred losses related to these deposits.

Equity Issuance Costs

Equity issuance costs represent costs paid to third parties in order to obtain equity financing. The costs related to preferred and common stock have been netted against the proceeds of the equity issuances.

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 of either the two-class method or 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 loss per share is calculated similarly to basic loss per share.

The following outstanding shares of common stock equivalents were excluded from the computations of diluted net 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.

	June 30, 2021	June 30, 2020
Common Stock Equivalents:	Number of Shares	
Redeemable convertible series 1 preferred stock	4,520,000	5,340,000
Warrants to purchase common stock	11,616,080	5,750,000
Private placement option	9,675,000	9,675,000
Options to purchase common stock	1,320,168	1,122,938
Unvested shares of restricted stock units	167,605	187,705
Total common stock equivalents	27,298,853	22,075,643

New Accounting Requirements and Disclosures

Fair Value Measurement

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which* modifies fair value disclosures and removes some disclosure requirements for both public and private companies. In addition, public companies are subject to some new disclosure requirements which requires to disclose the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU No. 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company adopted the standard effective January 1, 2020 with no material effect on its financial statements.

Financial Instruments – Credit Losses

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement of all expected credit losses for financial assets including trade receivables held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. ASU No. 2016-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020 with no material effect on its financial statements. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses*. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 842)*, which did not change the core principle of the guidance in ASU 2016-13 but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. Early adoption is permitted. As a smaller reporting company, the guidance will be effective for the Company during the first quarter of 2023. The Company is in the process of assessing the impact adoption will have on its consolidated financial statements.

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes (Topic 740)*. The guidance eliminates certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. This guidance also includes guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for annual and interim periods in fiscal years beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020 with no material effect on its financial statements.

Investments

In January 2020, the FASB issued Accounting Standards Update No. 2020-01, *Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)—Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force)*, which clarifies the interaction of the accounting for equity securities, investments accounted for under the equity method, and certain forward contracts and purchased options. This update is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years, and early adoption is permitted. The Company is in the process of determining the impact the adoption will have on its consolidated financial statements as well as whether to early adopt the new guidance.

NOTE 2 - FAIR VALUE MEASUREMENTS AND INVESTMENT SECURITIES

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 June 30, 2021 and December 31, 2020:

	Fair Value at June 30, 2021			Fair Value at December 31, 2020		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Cash equivalents:						
Money market funds and treasury bills	$ 12,478	$ —	$ —	$ 27,463	$ —	$ —
Total cash equivalents	$ 12,478	$ —	$ —	$ 27,463	$ —	$ —

As of June 30, 2021 and December 31, 2020, $1.5 million of restricted cash on the Company's balance sheet is held in a money market fund.

Money market funds, U.S. Treasury, U.S. government agency-backed securities, corporate debt securities and municipal bonds 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. As of June 30, 2021, the fair values of the warrant derivative liability and the private placement option liability 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.

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

	June 30, 2021	December 31, 2020
Risk-free interest rate	0.89%	0.46%
Volatility	95.00%	90.00%
Expected term (years)	5.14	5.64

Inputs used to determine estimated fair value (Level 3) of the private placement option include the fair value of the underlying stock relative to the preferred share conversion price and warrant exercise price at the valuation measurement date, volatility of the price of the underlying stock, the expected term of the call option on the preferred shares and expected term of the warrants, and risk-free interest rates.

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

	June 30, 2021	December 31, 2020
Risk-free interest rate	1.26 %	0.77 %
Volatility	95.00 %	90.00 %
Expected term (years)	7.00	7.00

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

	Fair Value at June 30, 2021			Fair Value at December 31, 2020		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant derivative liability	$ —	$ —	$ 9,629	$ —	$ —	$ 10,345
Private placement option liability	—	—	5,277	—	—	7,803
Total fair value	$ —	$ —	$ 14,906	$ —	$ —	$ 18,148

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 determines whether an arrangement is a lease at its inception. Operating leases relate primarily to office space and manufacturing facilities with remaining lease terms of one year to seven years, some of which include options to extend the lease term for up to five years. Management considered the options in determining the lease term used to establish the Company's ROU assets and lease liabilities.

As most of the Company's leases do not provide an implicit rate, the Company's incremental borrowing rate based on the information available at lease commencement date was used to determine the present value of lease payments.

Components of lease cost are as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Finance lease cost:				
Amortization of leased asset	$ 6	$ 18	$ 16	$ 36
Interest on lease liabilities	1	6	5	12
Operating lease cost	1	194	55	499
Short-term lease cost	1	207	53	241
Total lease cost	$ 9	$ 425	$ 129	$ 788

NOTE 4 - PUBLIC OFFERING AND PRIVATE PLACEMENT

November 2020 Underwritten Offering

In November 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 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 was 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 will be immediately exercisable upon issuance, provided that the holder will be 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. No Public Warrants have been exercised as of the balance sheet date.

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 purchase and sale of the securities issuable under the private placement agreement may occur in two or more separate closings, each to be conducted at the Purchasers’ discretion within five days’ notice to the Company. The purchase and sale were subject to the Company’s obtaining stockholder approval for additional authorized shares of Common Stock or a reverse stock split (the “Required Stockholder Approval”), which occurred in the first quarter of 2020. The right of the Purchasers to purchase such securities will expire two and a half years after the Required Stockholder Approval, on June 15, 2022, with respect to the Series 2 Preferred Stock, and three years after such stockholder approval, on January 15, 2023, with respect to the Series 3 Preferred Stock, if not exercised prior to that date. No shares have been exercised as of the balance sheet date.

The Company received $11.2 million in option proceeds, net of offering costs, upon the execution of the Securities Purchase Agreement. Total offering costs incurred by the Company related to the Public Warrants, Private Warrants and options amounted to $3.0 million.

The following table reflects the fair value roll forward reconciliation of the warrant derivative and private placement option liabilities for the period ended June 30, 2021:

(in thousands)	Warrant Derivative Liability	Private Placement Option Liability	Total
Balance, December 31, 2020	$ 10,345	$ 7,803	$ 18,148
Change in fair value	(716)	(2,526)	(3,242)
Balance, June 30, 2021	$ 9,629	$ 5,277	$ 14,906

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, of which the Company has designated 1,517,500 shares as Series 1 redeemable convertible non-voting preferred stock, 350,000 shares as Series 2 redeemable convertible non-voting preferred stock and 250,000 shares as Series 3 redeemable convertible non-voting preferred stock. There were 452,000 shares of Series 1 preferred stock issued and outstanding as of June 30, 2021. There were no shares of Series 2 or 3 preferred stock issued and outstanding as of June 30, 2021.

As of June 30, 2021, the Company classified the Series 1 Preferred Stock as mezzanine equity, as the Series 1 preferred stock will be redeemable at the option of the holders upon passage of time, which is outside of the Company’s control to prevent.

The Series 1 Preferred Stock is not currently redeemable and is only redeemable upon a fundamental change in a redemption price. The Company does not believe a fundamental change is considered probable until it occurs. Subsequent adjustment of the amount presented in mezzanine equity to its redemption amount is unnecessary if it is not probable that the instrument will become redeemable. As (i) the Series 1 Preferred Stock is only redeemable upon a fundamental change, the occurrence of which 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.

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 of the holder at a redemption price of $100.00 per share (for Series 1 and Series 2 Preferred Stock) and $140.00 per share (for Series 3 Preferred Stock). The "Transition Date" means:

- With respect to the Series 1 preferred stock, the first date following August 21, 2021, on which each of the Conditions (as defined below) is met (the "Series 1 Transition Date");
- With respect to the Series 2 preferred stock, the first date following the six-month anniversary of the Series 1 Transition Date on which each of the Conditions is met (the "Series 2 Transition Date"); and
- With respect to the Series 3 preferred stock, the first date following the six-month anniversary of the Series 2 Transition Date on which each of the Conditions 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 and Series 2 preferred stock) and $35.00 per share (for the Series 3 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 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 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 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.

2019 Equity Incentive Plan

The 2019 Plan, is designed to secure and retain the services of the Company’s employees and directors. The 2019 Plan is successor to and continuation of the 2014 Equity Incentive Plan, as amended, the ("2014 Plan"), and no additional awards may be issued from the 2014 Plan. Subject to adjustment for certain changes in the Company’s capitalization, the aggregate number of shares of common stock that may be issued under the 2019 Plan (the "Share Reserve") will not exceed the sum of (i) 250,000 new shares, (ii) an additional 600,000 shares that were approved at the Company’s Special Meeting of Stockholders in January 2020, (iii) an additional 500,000 shares that were approved at the Company's Annual Meeting of Stockholders in June 2020, (iv) an additional 500,000 shares that were approved at the Company's Annual Meeting of Stockholders in June 2021 and plus (v) the Prior Plans’ Returning Shares, as defined in the 2019 Plan documents, in an amount not to exceed 600,540 shares, including any stock award granted under the 2014 Plan, 2011 Stock Option Plan, as amended, or 2006 Stock Option Plan, as amended, that were outstanding as of the date the 2019 Plan was approved by the Company's stockholders, as such shares become available from time to time.

The following shares of common stock (the "2019 Plan Returning Shares") will also become available again for issuance under the 2019 Plan: (i) any shares subject to a stock award granted under the 2019 Plan that are not issued because such stock award expires or otherwise terminates without all of the shares covered by such stock award having been issued; (ii) any shares subject to a stock award granted under the 2019 Plan that are not issued because such stock award is settled in cash; and (iii) any shares issued pursuant to a stock award granted under the 2019 Plan that are forfeited back to or repurchased by the Company because of a failure to vest.

The 2019 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and other stock awards.

The following table summarizes the stock option activity for all stock plans during the six months ended June 30, 2021:

	Options and Inducement Awards
Outstanding at December 31, 2020	1,510,968
Granted	143,000
Exercised	—
Forfeited	(333,800)
Outstanding at June 30, 2021	1,320,168
Exercisable at June 30, 2021	438,548

The following table summarizes the stock award activity for all stock plans during the six months ended June 30, 2021:

	Restricted Stock Awards and Units
Outstanding at December 31, 2020	129,861
Granted	135,251
Vested	(95,001)
Forfeited	(2,506)
Outstanding at June 30, 2021	167,605

2014 Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan (the "ESPP") provides for eligible Company employees, as defined by the ESPP, to be given an opportunity to purchase the Company's common stock at a discount, through payroll deductions, with stock purchases being made upon defined purchase dates. The ESPP authorizes the issuance of up to 55,000 shares of the Company's common stock to participating employees and allows eligible employees to purchase shares of common stock at a 15% discount from the lesser of the grant date or purchase date fair market value. During the six-month periods ended June 30, 2020, there were 9,526 shares purchased by employees under the ESPP. The ESPP has been suspended since December 2020, resulting in the inactivity during the first and second quarter of 2021. As of June 30, 2021, there were 18,488 shares available for issuance under the ESPP.

A summary of activity within the ESPP follows:

	Six Months Ended	
(in thousands)	June 30, 2021	June 30, 2020
Deductions from employees	$ —	$ 62
Share-based compensation expense recognized	—	46
Remaining share-based compensation expense	—	144

Share-Based Compensation Expense

The fair value of option grants is determined using the Black-Scholes option-pricing model and has been estimated with the following weighted-average assumptions:

	Six Months Ended	
	June 30, 2021	June 30, 2020
Risk-free interest rate	0.86 %	1.24 %
Volatility	90.54 %	81.53 %
Expected life (years)	5.59	6.04
Expected dividend yield	—	—

Share-based compensation expense by classification for the three and six months ended June 30, 2021 and 2020 are as follows:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Research and development	$ 271	$ 661	$ 534	$ 1,209
General and administrative	550	903	1,190	1,678
Total	$ 821	$ 1,564	$ 1,724	$ 2,887

At June 30, 2021, total compensation cost not yet recognized was $3.5 million and the weighted-average period over which this amount is expected to be recognized is 1.6 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 Agreements - 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.

During the second quarter of 2021, the Company determined that $0.6 million of sublicense expense was incurred in 2019 through 2020 related to the Company's obligation to pay BCM a percentage of sublicense revenue earned by the Company under the 2014 license agreement. Management evaluated the impact of the adjustment and determined that the amount was immaterial to the consolidated financial statements for the current year and prior years. As such, the entire amount of $0.6 million was recorded during the three and six months ended June 30, 2021.

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 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.

Takeda Supply Agreement

On May 4, 2021, the Company entered a multi-year supply agreement with Takeda Development Center Americas, Inc. (Takeda). The Company will supply Takeda with rimiducid for potential use in clinical trials of TAK-007 (CD19 CAR-NK cell therapy). The Company generated revenue of $0.7 million for the six months ended June 30, 2021, with the possibility of additional revenue from future sales.

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 currently is set for hearing on September 3, 2021. A trial date has not been set in the case.

Compliance with NASDAQ Listing Rules

On May 5, 2021, the Company was notified by The Nasdaq Stock Market LLC, or Nasdaq, that the Company was in breach of Listing Rule 5450(b)(2)(A), or the Market Value Rule, for continued listing on The Nasdaq Capital Market because the market value of the Company's listed securities for 30 consecutive business days had been less than $35 million. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has until November 1, 2021, to regain compliance with the Market Value Rule. To regain compliance, the market value of the Company's listed securities must close at $35 million or more for a minimum of 10 consecutive business days any time prior to November 1, 2021.

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, 2020, filed with the SEC on March 31, 2021, or our Annual Report, as well as our unaudited condensed consolidated 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., 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 or 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 controllable 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 BPX-603-201A in patients with HER2+ solid tumors is ongoing.

- **Rivo-cel (rivogenlecleucel, formerly known as BPX-501)**, is a product candidate containing our proprietary CaspaCIDe safety switch that is intended to improve outcomes of hematopoietic stem cell transplantation in the treatment of hematologic malignancies and inherited blood disorders. We are pursuing a strategic partner for rivo-cel to assume future development and commercialization responsibilities. Concurrently, we have reduced and expect to continue to reduce our rivo-cel related activities.

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 product candidates to create and develop first and best-in-class product candidates.

Impact of COVID-19

In 2019, a novel strain of coronavirus, which causes COVID-19, was identified. Due to the rapid and global spread of the virus, on March 11, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To slow the proliferation of COVID-19, governments have implemented extraordinary measures, which have included the mandatory closure of businesses, restrictions on travel, and quarantine and physical distancing requirements.We have not experienced and do not anticipate a substantial impact to our operations as a result of the pandemic or these government measures. 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. We are continuing to closely monitor the impact 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			Six Months Ended		
(in thousands)	June 30, 2021	June 30, 2020	Change	June 30, 2021	June 30, 2020	Change
Revenues	$ 700	$ —	$ 700	$ 700	$ —	$ 700
Operating expenses:						
Research and development	6,722	11,758	(5,036)	13,183	22,206	(9,023)
General and administrative	1,765	3,761	(1,996)	3,777	7,932	(4,155)
Total operating expenses	8,487	15,519	(7,032)	16,960	30,138	(13,178)
(Gain) loss on dispositions, net	—	(3,761)	3,761	464	(3,761)	4,225
Loss from operations	(7,787)	(11,758)	3,971	(16,724)	(26,377)	9,653
Other income (expense):						
Interest income	8	28	(20)	18	382	(364)
Interest expense	(1)	(763)	762	(4)	(1,748)	1,744
Change in fair value of warrant and private placement option liabilities	5,579	(30,701)	36,280	3,242	2,125	1,117
Other expense	(1)	—	(1)	(1)	—	(1)
Total other income (expense)	5,585	(31,436)	37,021	3,255	759	2,496
Net loss	$ (2,202)	$ (43,194)	$ 40,992	$ (13,469)	$ (25,618)	$ 12,149

Revenues

The increase in revenues for the three and six months ended June 30, 2021, compared to the same periods last year, was related to the supply agreement with Takeda Development Center Americas, Inc. (Takeda) for the supply of rimiducid for potential use in clinical trials of TAK-007 (CD19 CAR-NK cell therapy). The supply was fulfilled in May 2021 which generated revenue of $0.7 million.

Research and Development Expenses (R&D)

The decrease in R&D expenses for the three months ended June 30, 2021, compared to the same period last year, was primarily due to reduced expenses related to reduced rivo-cel related activities, the sale of the manufacturing facility, and the reduction in force that was implemented during the second half of 2020. This resulted in a $3.1 million reduction in salaries, benefits, travel, and share-based compensation related charges and a $1.2 million reduction from general R&D expenses primarily due to lower clinical trial activities. Additionally, depreciation and R&D related overhead expense decreased by $0.7 million due to the exit of manufacturing facility, related laboratories and office space.

The decrease in R&D expenses for the six months ended June 30, 2021, compared to the same period last year, was primarily due to reduced expenses related to reduced rivo-cel related activities, the sale of the manufacturing facility, and the reduction in force that was implemented during the second half of 2020. This resulted in a $6.5 million reduction in salaries, benefits, travel, and share-based compensation related charges and a $0.9 million reduction from general R&D expenses primarily due to lower clinical trial activities. Additionally, depreciation expense and R&D related overhead expense decreased $1.6 million due to the exit of manufacturing facility, related laboratories and office space.

General and Administrative Expenses (G&A)

The decrease in G&A expenses for the three months ended June 30, 2021, compared to the same period last year, was primarily due to the aforementioned reduction in force that reduced employee-related charges by $1.6 million as well as the reduction in rivo-cel related commercialization activities that reduced charges by $0.4 million

The decrease in G&A expenses for the six months ended June 30, 2021, compared to the same period last year, was primarily due to the aforementioned reduction in force that reduced employee-related charges by $3.3 million as well as the reduction in rivo-cel related commercialization activities that reduced charges by $0.9 million.

Gain on dispositions, net

The decrease in gain on dispositions, net, for the three and six months ended June 30, 2021, compared to the same period last year, was primarily due to the disposal of the clinical supply manufacturing facility to M.D. Anderson in the second quarter of 2020 which resulted a gain in 2020. However, there was only a loss on termination of $0.5 million in the first quarter of 2021 as a result of the early termination of the South San Francisco office space.

Other Income (Expense)

Other expense primarily consists of interest expense, partially offset by interest income, and changes in fair values of our warrant liability and the private placement option, which are remeasured at each reporting period. Due to the nature of the inputs in the model used to assess the fair value of the warrant liability and private placement option, we 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 and options.

The increase in other income for the three months ended June 30, 2021, compared to the same period last year, was primarily due to a $5.6 million gain recognized from the change in fair value of our warrant and private placement option liabilities, whereas the same period last year had a $30.7 million loss. The gain recognized during the three months ended June 30, 2021 was driven primarily by a decrease in our stock price over the period.

The increase in other income for the six months ended June 30, 2021, compared to the same period last year, was primarily due to a $3.2 million gain recognized from the change in fair value of our warrant and private placement option liabilities. The gain recognized during the six months ended June 30, 2021 was driven primarily by a decrease in our stock price over the period.

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 June 30, 2021, we had cash, cash equivalents and restricted cash of $21.8 million and net cash used in operations of approximately $16.1 million for the six months ended June 30, 2021.

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. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs. Based on our current research and development plans and our timing expectations related to the progress of our programs, we believe there is substantial doubt that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2022.

We plan to continue to attempt 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. 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 June 30, 2021, 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) and warrants to purchase 4,149,378 shares of our common stock at an exercise price of $6.50 per share were outstanding. The preferred stock warrants expire on August 21, 2026 and the common warrants expire on November 3, 2025.

As a result of the COVID-19 pandemic and actions taken to slow its spread, 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. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not 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 six months ended June 30, 2021 was $16.1 million compared to $30.5 million for the same period last year. The changes in cash flow from operating activities during the six months ended June 30, 2021 were due to $13.5 million of net losses, a non-cash gain of $3.2 million recognized from the change in the derivative warrant and private placement option fair value liability and a $1.7 million decrease from changes in operating assets and liabilities. This was partially offset by $1.7 million of share-based compensation and $0.1 million of depreciation expense.

Investing Activities

Net cash provided by investing activities during the six months ended June 30, 2021 was $0.9 million compared to $14.7 million for the same period last year. The change in cash flow from investing activities during the six months ended June 30, 2021 was due to $0.9 million net proceeds received from the sale of property and equipment. Cash provided by investing activities for the same period last year was due to $14.9 million of proceeds from the sale of property and equipment.

Financing Activities

Net cash used in financing activities during the six months ended June 30, 2021 was less than $0.1 million on financing lease obligations compared to net cash used in financing activities of $10.0 million for the same period last year primarily due to principal debt repayments.

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, 2020. 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, 2020.

Recent Accounting Pronouncements

The Company is subject to several recently issued accounting pronouncements. Note 1 – Organization, Basis of Presentation, and Summary of Significant Accounting Policies – New Accounting Requirements and Disclosures which is contained in Part I, Item 1 of this Quarterly Report on Form 10-Q, describes these new accounting pronouncements and is incorporated herein by reference.

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 Commission.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There have been no material changes to the information provided under Item 7A. "Quantitative and Qualitative Disclosures About Market Risk" which is included and described in the Form 10-K for the year ended December 31, 2020.

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 June 30, 2021. 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 June 30, 2021, 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

In May 2021, we announced the appointment of a new principal accounting officer, who was appointed to assist with SEC and technical reporting as well as general financial reporting and technical accounting matters, in order to improve our internal control over financial reporting. There were no other 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 these 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.
- Many of 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 COVID-19 pandemic, 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 reflect additional risk factors since the issuance of our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission on March 31, 2021, 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 June 30, 2021, we had an accumulated deficit of $554.2 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.*

This report includes disclosures stating that our existing cash resources and our accumulated stockholders' deficit raise substantial doubt about our ability to continue as a going concern. 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 June 30, 2021, we had cash, restricted cash and cash equivalents of approximately $21.8 million. We maintain our cash and cash equivalents with high quality, accredited financial institutions. These amounts at times may exceed federally insured limits. Currently, substantial doubt exists that our cash, restricted cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the first half of 2022. Our cash position, together with our short-term liabilities and anticipated operating losses due to continued research and development projects, raises substantial doubt about our ability to continue as a going concern.

We expect 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 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. In addition, the securities purchase agreement for the August 2019 private placement transaction requires us to obtain investor consent prior to taking a range of corporate financing actions, including issuing equity securities that are senior or pari passu to the Series 3 preferred stock and incurring new debt in excess of $1,000,000. 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 facilities and administration. For example, in October 2020, we announced that we implemented a restructuring plan, which included, among other things, a 79% reduction in staff, from 68 to 14 full-time employees, by the end of 2020 and discontinuation of discovery research and new product development. We have incurred $2.5 million in restructuring expenses, including severance expenses of $1.2 million and the Houston office's impairment of $1.3 million. Moreover, if we do not raise such additional funds, there will continue to 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 and other immune cell types *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.

Many of our current product candidates are in early stage clinical trials, and we may experience unfavorable results in the future.*

Phase 1/2 clinical trials are ongoing for BPX-601 for the treatment of prostate and pancreatic cancer and 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 how effective and safe they will be 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.

Also, we are conducting clinical trials in Europe and may plan additional testing of our technology and product candidates in other foreign jurisdictions. We currently have limited staffing and capabilities in foreign countries and may not be able to effectively resolve potential disputes with our independent investigators and collaborators.

Our business could be adversely affected by the effects of health epidemics, including the 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. To date, we have experienced COVID-19-related impacts on screening and enrollment which may impact the speed of enrollment and the timing of data presentations from our ongoing studies. 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. In fact, in April 2020 M.D. Anderson temporarily halted all research activity in order to reduce the spread and impact of COVID-19 on their institution and their patients and this included temporarily suspending activity in the manufacturing facility in which the product candidates for our clinical development programs are manufactured. M.D. Anderson subsequently restarted manufacturing but if the pandemic worsens and they again suspend research activities, we may be unable to enroll patients in our clinical trials until manufacturing resumes at the facility.

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 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, in the case of transplant patients, 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 faces significant competition from multiple companies, including, Adaptimmune, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, bluebird bio, Inc., Bristol-Meyer Squibb Co., Cellectis SA, Celyad S.A., Fate Therapeutics Inc., GlaxoSmithKline plc, Intrexon Corporation, Immune Design Corp., Gilead Sciences, Inc., Iovance Biotherapeutics, Inc., Janssen Pharmaceutical, Legend Biotech, Lyell Immunopharma, Inc., Medigene AG, MolMed S.p.A., Mustang Bio, Inc., NantKwest, Inc., Nkarta Inc., Novartis AG, Obsidian Therapeutics, Poseida Therapeutics, Precision Biosciences, Inc., Takeda Pharmaceutical Co, and Ziopharm Oncology.

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, and could harm our internal control over financial reporting.*

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 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 harm our business.

Primarily due to our restructuring plan announced in October 2020, we have reduced our staff to 6 employees as of June 30, 2021. This reduction in our staff included our Chief Financial Officer, our Chief Legal and Strategy Officer and various scientific personnel. 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. 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 completed an underwritten public offering of 575,000 shares of our Series 1 preferred stock and warrants to purchase up to 5,750,000 shares of our common stock. Concurrent with the public offering we entered into an agreement with certain institutional investors providing for a private placement, pursuant to which we agreed to sell at two or more separate closings, each at the option of the investors and subject to certain conditions, shares of Series 2 preferred stock and warrants to purchase common stock, and shares of Series 3 preferred stock and warrants to purchase common stock, for aggregate gross proceeds of up to $70.0 million. Pursuant to the terms of the 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 3 preferred stock with respect to liquidation preference, the incurrence of indebtedness in excess of $1,000,000, the sale or license of certain of the Company's 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 additional 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, or may not have sufficient capacity to fulfill demand for products for our clinical trials, 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. Manufacturing of GoCAR-T cells requires adequate supply of viral vector to genetically modify them. We rely on third parties to manufacture viral vector, and they may be unable to manufacture sufficient quantity and quality of virus to meet the demand from our clinical trials. 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.

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.

If we are unable to identify a strategic partner for rivo-cel, we may not realize value from this asset and we will continue to incur substantial costs.

We are actively pursuing a strategic partner for our CaspaCIDe-containing polyclonal T cell product candidate called rivogenleceucel, or rivo-cel. A partner would assume current and future development and commercialization responsibilities for this product candidate on a worldwide basis. Concurrently, we have substantially reduced and will continue to reduce our rivo-cel-related activities and spending. For example, we have closed our UK office, which was established to prepare for commercialization in Europe. If we are unable to identify an appropriate strategic partner or to negotiate and consummate a license agreement with such a partner, then it will be impossible to submit the planned Marketing Authorisation Applications, or MAA required to seek approval to commercialize this product candidate in Europe. Such a delay in the process of preparing and submitting the MAA will make it more difficult for us or any possible strategic partner to restart the process in the future and ultimately obtain approval for the product, increasing the likelihood that we may be unable to derive any meaningful revenue from this asset. In addition, we are obligated to continue certain regulatory and clinical activities following conclusion of the rivo-cel clinical trials and if we are unable to identify a strategic partner, we will continue to incur the costs for the internal and external resources required to complete those activities.

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 our drug 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 covered entities, including 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) 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, and beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives;
- 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. 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.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which provides temporary relief from certain aspects of the Tax Cuts and Jobs Act that had imposed limitations on the utilization of certain losses, interest expense deductions, and minimum tax credits. We are currently in the process of assessing the tax-related provisions of the CARES Act and its potential impact on us.

As of December 31, 2020, we had aggregate U.S. net operating loss carryforwards of approximately $448.3 million, and aggregate U.S. federal and Texas state research and development credits of approximately $12.5 million and $5.3 million, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act and Cares Act, federal net operating losses incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal net operating losses generated in tax

years beginning after December 31, 2017 may be limited to 80% of current year taxable income for years beginning on or after January 1, 2021. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. 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, 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. Additionally, a company may not promote “off-label” uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product’s FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. 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 optimal dose and schedule 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. 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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began on February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed 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 possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges 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 of 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 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 unless additional Congressional action is taken. 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 attempted to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance 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 by the Biden administration until January 1, 2023. 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. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period, beginning January 1, 2021 and ending December 31, 2027. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN model interim final rule shall not commence earlier than sixty(60) days after publication of that regulation in the Federal Register. In addition, based on a recent executive order, the Biden administration expressed its intent to pursue policy initiatives to reduce drug prices. 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 in response to the COVID-19 pandemic.

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.

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. We are also aware of third-party patent applications having claims that may be considered as being directed to cellular therapy constructs utilizing a heterodimer domain for activation of caspase 9. We are monitoring these applications and if they are granted with the claims as drafted, they may be relevant to our potential dual-switch product candidates containing such a heterodimer activation domain.

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, or Nasdaq, that we were in breach of Listing Rule 5450(b)(2)(A), or the Market Value Rule, 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. In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have until November 1, 2021, to regain compliance with the Market Value Rule. To regain compliance, the market value of our listed securities must close at $35 million or more for a minimum of 10 consecutive business days any time prior to November 1, 2021.

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 The Nasdaq Capital Market, 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.

Prior to our December 2014 IPO, there was no public market for our common stock. 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.

As of December 31, 2019, we are no longer an "emerging growth company" and, as a result, are required to comply with increased disclosure and governance requirements.

As more than five fiscal years have passed since the December 18, 2014, listing of common stock listing on the Nasdaq, we ceased to be an "emerging growth company" as defined in the JOBS Act as of December 31, 2019. However, we currently qualify as a "Smaller Reporting Company" under applicable SEC rules, which limits some of the otherwise applicable public company requirements. Below are specific requirements to which we are now subject that did not previously apply to us. These requirements include the "say on pay" provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer.

Compliance with such requirements is expensive and time-consuming for management, as the loss of "emerging growth company" status and compliance with the additional requirements substantially increases our legal and financial compliance costs and makes some activities more time-consuming and costly.

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, warrants and related option fee proceeds.

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. Additionally, in connection with our August 2019 private placement we received option fee proceeds, or the Option Fee, which is accounted for as a liability. The value of the Option Fee is re-measured at each reporting period with changes in fair value recorded through earnings. 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, or the EIP. 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. Any such sales 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 are obligated to issue shares of Series 2 and Series 3 preferred stock in connection with the concurrent private placement, 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 and are obligated to issue up to 350,000 shares of Series 2 preferred stock and 250,000 shares of Series 3 preferred stock pursuant to the purchase agreement governing our August 2019 private placement.

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 and Series 2 preferred stock and $140.00 per share of Series 3 preferred stock, 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.

The issuance or sale of shares of our common stock, or rights to acquire shares of our common stock, including the issuance of our securities pursuant to our August 2019 private placement, could depress the trading price of our common stock.

Under the terms of the private placement transaction, we are obligated to issue (i) up to 350,000 shares of Series 2 preferred stock, at a purchase price of $100.00 per share, and related warrants to purchase up to 2,800,000 shares of our common stock at an exercise price of $10.00 per share, and (ii) 250,000 shares of Series 3 preferred stock, at a purchase price of $140.00 per share, and related warrants to purchase up to 875,000 shares of our common stock at an exercise price of $14.00 per share, for aggregate gross proceeds of up to $70,000,000, to certain institutional investors in two or more separate closings, each to occur at such investors' discretion. In addition, we may conduct future offerings of our common stock, preferred stock or other securities that are convertible into or exercisable for our common stock to finance our operations or fund acquisitions, or for other purposes. If we issue additional shares of our common stock or rights to acquire shares of our common stock, if any of our existing stockholders sells a substantial amount of our common stock, or if the market perceives that such issuances or sales may occur, then the trading price of our common stock, and, accordingly, the trading price of our common stock may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common stockholders.

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

Pursuant to the terms of the 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	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 the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 19, 2019).
3.3	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 December 23, 2014).
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 Annual Report on Form 10-K, filed with the SEC on March 14, 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).
10.1+	Bellicum Pharmaceuticals, Inc. 2019 Equity Incentive Plan, as amended (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 June 17, 2021).
10.2*	License Agreement by and between the Registrant and BioVec Pharma, Inc., dated as of June 4, 2015.
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
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and contained in Exhibit 101).
+	Indicates management contract or compensatory plan.
*	Certain portions of this exhibit (indicated by "[***]") have been excluded pursuant to Item 601(b)(10) of Regulation S-K because they are both not material and are the type that the Registrant treats as private or confidential

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: August 12, 2021

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

Date: August 12, 2021

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

Exhibit 10.1

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE BELLICUM PHARMACEUTICALS, INC. HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT BELLICUM PHARMACEUTICALS, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

LICENSE AGREEMENT

This LICENSE AGREEMENT (the "Agreement"), effective as of June 4, 2015 (the "Effective Date"), is made by and between Bellicum Pharmaceuticals, Inc., a Delaware corporation, having a place of business at 2130 Holcombe Boulevard, Suite 800, Houston, TX 77030, United States of America ("Bellicum"), and BioVec Pharma, Inc., a legally constituted corporation, having a principal place of business at 1201 rue du Capitaine Bernier, Québec, QC, Canada ("BioVec").

BACKGROUND

A. BioVec has developed and has rights to certain proprietary cell lines.

B. Bellicum desires to obtain a non-exclusive license to use the BioVec Products (as hereinafter defined) for producing gene therapy vectors for certain purposes, including, but not limited to, research, development (including human clinical trials), manufacturing and commercial uses and purposes; and

C. BioVec is willing to grant to Bellicum a non-exclusive license to use the BioVec Products under the terms and conditions set forth hereunder.

NOW, THEREFORE, for and in consideration of the covenants, conditions and undertakings hereinafter set forth, it is agreed by and between the Parties as follows:

ARTICLE 1
DEFINITIONS

As used herein, the following capitalized terms will have the meanings set forth below:

1.1 "Affiliate" means, with respect to a Party, any firm, corporation or other entity which directly or indirectly controls, is controlled by, or is under common control with, such Party. A Party shall be regarded as in control of another firm, corporation or other entity if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of such firm, corporation or other entity, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of such firm, corporation or other entity by any means whatsoever.

1.2 "Bellicum Intellectual Property" means the intellectual property and materials owned or Controlled by Bellicum and used for research, development, use and/or manufacturing of Licensed Products.

1.3 "Bellicum Licenses" has the meaning set forth in Section 3.2(a) hereof.

1.4 "BioVec Products" means the cell lines described on Exhibit A, as the same may be amended in writing by the Parties from time to time, as well as any modified versions or derivatives

thereof, including cell lines developed and characterized under GMP condition, in each case that are provided to Bellicum, its Affiliates, or Sublicensees (as defined hereinafter), in accordance with the terms of the Agreement.

1.5 "Clinical Phase" means a human clinical trial conducted in any country that is intended to evaluate the safety and/or pharmacological effect and/or efficacy of a Licensed Product in human subjects, or that would otherwise satisfy the requirements of 21 CFR 312.21, or its foreign equivalent.

1.6 "Combination Product" means a product that contains one or more active components which are Licensed Products, and wherein such Licensed Product components are sold in combination with other active components which are not Licensed Products.

1.7 "Competent Authority(ies)" means, collectively, (a) the governmental entities in each country or supranational organization that is responsible for the regulation of any Licensed Product intended for use in the Field (including without limitation the FDA and EMA), or (b) any other applicable regulatory or administrative agency in any country or supranational organization that is comparable to, or a counterpart of, the foregoing.

1.8 "Control" means the possession by a Party of the ability to grant access to, license or sublicense of intellectual property, in any case without violating the terms of any agreement binding on such Party.

1.9 "EMA" means the European Agency for the Evaluation of Medicinal Products of the European Union, or the successor thereto.

1.10 "FDA" means the Food and Drug Administration of the United States, or the successor thereto.

1.11 "Field" means all applications related to therapeutic, diagnostic, preventative, palliative and other uses of genetically modified cells, including, without limitation, genetically modified cells engineered to express suicide genes, chimeric antigen receptors and/or engineered or natural T-cell receptors, in the fields of oncology and infectious diseases.

1.12 "GAAP" means United States generally accepted accounting principles, consistently applied.

1.13 "GMP" means then-current good manufacturing standards, practices and procedures promulgated or endorsed by the FDA or other Competent Authorities relating to manufacturing, including but not limited to the principles detailed in the United States Current Good Manufacturing Practices (21 CFR Parts 200, 211 and 600), and all analogous guidelines promulgated by any Competent Authority (including the EMA and under the International Conference on Harmonisation (ICH)), the "Rules Governing Medicinal Product in The European Community - Volume IV Good Manufacturing Practice for Medicinal Products," and/or "Cooperative Manufacturing Arrangements for Licensed Biologics" FDA-CBER.

1.14 "Licensed IP Rights" means, collectively, the Licensed Know-How and the Licensed Patent Rights.

1.15 "Licensed Know-How" means all data, information, compositions and other technology (including, but not limited to, know-how, knowledge, trade secrets, practices, methods, formulae, procedures, protocols, techniques and results of experimentation and testing) which are disclosed to Bellicum by BioVec and are used by Bellicum to make, use, research, develop, sell, commercialize or seek regulatory approval to market a composition, or to practice any method or process, which relates to the BioVec Products, including any of the foregoing that may be provided to Bellicum under Section 2.2 or otherwise under this Agreement.

1.16 "Licensed Patent Rights" means (a) U.S. patent number [***] and CA application [***], (b) all divisions, continuations, continuations-in-part, continuing prosecution applications and provisionals that claim priority to, or common priority with, the patent and patent application described in sub-clause (a) above or the patent(s) resulting from the patent application described in sub-clause (a) above, and (c) all patents that have issued or in the future issue from any of the foregoing patent applications, including utility, model and design patents and certificates of invention, together with any reissues, renewals, re-examinations, extensions or additions thereto.

1.17 "Licensed Product" means a product or component of a product in the Field containing, derived from, or made using BioVec Products.

1.18 "Net Sales" means, with respect to any Licensed Product, the gross amount invoiced for sales of such Licensed Product by Bellicum, its Affiliates or Sublicensees to Third Parties who are not Affiliates or Sublicensees (or are Affiliates or Sublicensees, but are the end users of such Licensed Product) after deduction (if not already deducted in the amount invoiced) of the following items, but only to the extent that such items are actually paid or allowed in connection with such sale of Licensed Product and are consistent with GAAP: (a) **[***]**; (b) [***]; (c) [***]; (d) [***]; (e) [***]; and (f) [***].

For the avoidance of doubt, disposal of any Licensed Product for, or use of any Licensed Product in, (i) any clinical trial or other research and development activities without any form of consideration or charge, whether directly or indirectly related to Licensed Products, or (ii) compassionate use purposes, so long as such Licensed Product is provided without charge, if any, shall not result in any Net Sales.

For clarity, Net Sales shall not include sales by or among Bellicum and its Affiliates or Sublicensees for purposes of resale to Third Parties, provided that, upon resale of such Licensed Product by Bellicum or its Affiliate or Sublicensee, Net Sales shall include the amount received by Bellicum, its Affiliate or Sublicensee from Third Parties on the resale of such Licensed Product.

To the extent that Bellicum, its Affiliate or Sublicensee provides discounts or allowances that are applicable to the purchases of Licensed Product and one or more other products (such as in a "bundled sale" arrangement), such discounts and allowances shall be allocated between the Licensed Product (for purposes of the deductions used in calculating Net Sales as above) and such other products in a commercially reasonable manner that does not unfairly or inappropriately bias the level of discounting against the Licensed Product (as compared to the other products).

If a Licensed Product is sold as a Combination Product, then for purposes of determining Bellicum's payment obligations under Section 4.4, the following calculations shall apply:

(1) In the event one or more Licensed Products are sold as part of a Combination Product in a particular country, and all products contained in the Combination Product are sold separately in such country, the Net Sales of such Licensed Product component(s), for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country, during the applicable Net Sales reporting period, by [***], in each case during the applicable Net Sales reporting period.

(2) In the event one or more Licensed Products are sold as part of a Combination Product and are sold separately in such country, but the other product component(s) included in the Combination Product are not sold separately in such country, the Net Sales of the Licensed Product component(s), for the purposes of determining payments based on Net Sales, shall be determined by multiplying the Net Sales of the Combination Product in such country by [***], in each case during the applicable Net Sales reporting period.

(3) In the event that the Net Sales of the Licensed Product component(s) when included in a Combination Product cannot be determined using either of the methods described above, Net Sales of such Licensed Product component(s) for the purposes of determining payments based on Net Sales shall be determined by Bellicum in good faith, and reasonably agreed upon in good faith by the Parties, on the basis of the respective fair market values of the Licensed Product component(s) and all other product component(s) included in such Combination Product.

1.19 "Party" or "Parties" means, respectively, Bellicum or BioVec individually, or Bellicum and BioVec collectively.

1.20 "Registration(s)" means any and all permits, licenses, authorizations, registrations or regulatory approvals required and/or granted by any Competent Authority as a prerequisite to the development, manufacturing, packaging, marketing and selling of any Licensed Product in a given country or jurisdiction.

1.21 "Sublicense" has the meaning set forth in Section 3.1 hereof.

1.22 "Sublicensee" means a sublicensee under a Sublicense.

1.23 "Territory" means worldwide.

1.24 "Third Party" means any person or entity other than Bellicum, BioVec, and their respective Affiliates.

ARTICLE 2
SUPPLY

2.1 Supply. In consideration of the payment obligations of Bellicum set forth under Article 4, within [***] following the Effective Date, BioVec will deliver to Bellicum or its designee sufficient amounts of each BioVec Product to enable Bellicum to establish and maintain its own master and working cell banks of each BioVec Product. In the event that Bellicum is unable to establish its own master and working cell banks of each BioVec Product with the BioVec Products provided by BioVec under that first delivery (whether because any BioVec Product received from BioVec fails to grow, is contaminated or is lost, destroyed, damaged or otherwise compromised during transfer or otherwise), BioVec will deliver such additional amounts of each BioVec Product as may be required to enable Bellicum to establish and maintain its own master and working cell banks of each BioVec Product.

2.2 Technology and Data Transfer; Regulatory Support. Within [***] from the Effective Date, and periodically during the Term upon the reasonable request of Bellicum, BioVec shall transfer to Bellicum or its designee, without charge, such materials and documentation relating to the BioVec Products as are in BioVec's possession and Control and that are reasonably necessary to enable Bellicum or its designee (including a Third Party manufacturer designated by Bellicum) to use the BioVec Products to use, research, develop, conduct human clinical trials, manufacture and/or commercialize the Licensed Products (all such materials and documentation provided to Bellicum hereunder, the "BioVec Materials"), and BioVec shall provide reasonable assistance to enable the effective transfer of the foregoing to Bellicum. In addition, BioVec will use diligent efforts to assist Bellicum, its Affiliates and Sublicensees in preparation of regulatory information and packages related to Licensed Products.

2.3 Bellicum Service Providers. Bellicum may, without consent from BioVec, develop and produce, or engage one or more Third Party contract manufacturers, collaborators and/or services providers (collectively, "Bellicum Service Providers") to develop and produce, each (i) BioVec Product; (ii) any modified versions or derivatives of the BioVec Product cell lines, including cell lines developed and characterized by Bellicum, its Affiliates or Sublicensees; and (iii) any of the foregoing (i) or (ii) that contain any Bellicum materials or any other genetic materials or fall within the scope of Bellicum Intellectual Property, and such Bellicum Service Providers may use any of the foregoing (i-iii) to use, research, develop and manufacture Licensed Products; provided that each such Bellicum Service Provider shall be subject to a written agreement pursuant to which such Bellicum Service Provider agrees: (1) not to use any BioVec Products or BioVec Materials for any

purpose other than as permitted under this Agreement; (2) to use any BioVec Product that may be supplied to it by Bellicum solely in vitro and not in human subjects, in clinical trials, or for diagnostic purposes involving human subjects; and (3) not to sell, transfer, disclose or otherwise provide to any Third Party (other than to such Bellicum Service Provider's employees. consultants and agents who are performing such services for Bellicum and who are subject to confidentiality obligations no less protective of the BioVec Products and the BioVec Materials than those imposed under this Agreement) any BioVec Products or BioVec Materials. Bellicum shall submit to BioVec in writing the identity of such Bellicum Service Providers within [***] after BioVec Products have been delivered to them.

ARTICLE 3
GRANT

3.1 License. BioVec hereby grants to Bellicum and its Affiliates a non-exclusive, non-assignable and non-transferable (except in accordance with Section 11.3) license, with the right to grant and authorize sublicenses in accordance with Section 3.2 (each, a "Sublicense"), under the Licensed IP Rights to use BioVec Products in the Field solely to: conduct research and to develop, make, have made, use, offer for sale, sell, export, import and otherwise exploit Licensed Products in the Field in the Territory; provided that all commercialized Licensed Products also shall fall within the scope of Bellicum Intellectual Property and/or use or incorporate Bellicum materials or other genetic materials that were not provided by BioVec.

3.2 Sublicense. Bellicum shall have the right to grant Sublicenses; provided, however, that any such Sublicense shall bind the Sublicensee in writing to all the applicable terms and conditions of this Agreement; and further provided that a Sublicensee shall not have the right to grant further sublicenses without the written consent of BioVec, not to be unreasonably withheld, conditioned or delayed. Bellicum assumes full responsibility for the performance of all obligations imposed on Sublicensees by such Sublicenses. Furthermore, it is understood and agreed that Bellicum shall not have the right to sublicense all of its rights and obligations under this Agreement to a single Third Party unless such sublicense is granted within a transaction contemplated by Section 11.3(b) for which consent of the other Party is not required. The right to grant Sublicenses is also conditioned upon Bellicum complying with the following conditions:

(a) Such Sublicense is granted in connection with a license under Bellicum Intellectual Property and with respect to Licensed Products("Bellicum License");

(b) Without limiting the generality of the foregoing subclause (a), each Sublicensee shall be subject to obligations of confidentiality no less protective of the BioVec Products and the BioVec Materials than the obligations set forth in Section 2.3 and Article 6;

(c) Bellicum shall submit to BioVec a copy of each final executed Sublicense within [***] of its execution by the parties thereto, which Sublicense may be redacted to protect

information related to (i) any product other than the Licensed Product and (ii) any technology, know-how and intellectual property that is unrelated to the Licensed IP Rights;

(d) Each Sublicense shall contain disclaimers of representations, warranties, indemnities and liability on the part of BioVec consistent with such disclaimers set forth in this Agreement; and

(e) Each Sublicense shall not survive early termination of the Bellicum License.

3.3 Reserved Rights. BioVec retains title to or Control of Licensed IP Rights.

3.4 Limitations.

(a) Bellicum acknowledges and agrees that it does not acquire any rights hereunder to:

(1) transfer BioVec Products to any Third Party other than its Affiliates, Sublicensees or Bellicum Service Providers.

(2) sell or offer to sell BioVec Products to any Third Party.

(b) This Agreement shall not be interpreted or construed as granting to Bellicum or its Affiliates any rights, express or implied, by estoppel or otherwise, to any patents, patent applications, trademarks, copyrights, inventions, methods, technical information, confidential information, proprietary information, expertise, know-how, trade secrets or knowledge not specifically licensed under this Agreement, and all rights not expressly granted to Bellicum and its Affiliates by this Agreement are expressly reserved by BioVec.

(c) No license is granted hereunder to (i) use the Licensed IP Rights, BioVec Products or BioVec Materials in the development, making, using, offering for sale, selling, importation, exportation or distribution of products other than Licensed Products in the Field, or (ii) modify, manipulate, transform, make derivatives of or otherwise improve BioVec Products unless expressly permitted herein.

3.5 Other Licensees. While this Agreement is in effect, BioVec will not grant a license to any of its other licensees to use and exploit the BioVec Products and/or the BioVec Materials for the purpose of commercializing products that will compete with the Licensed Products without paying to BioVec a reasonable financial consideration. If Bellicum obtains evidence that (a) that BioVec has permitted such use and exploitation by such other licensee or has allowed an unlicensed Third Party to use and exploit the BioVec Products and/or the BioVec Materials for the purpose of commercializing products that will compete with the Licensed Products without requiring payment of such financial consideration to BioVec, or (b) that another of BioVec's licensees has violated the terms and conditions of its BioVec license agreement, with the result that a non-sublicensed Third Party is using or exploiting the BioVec Products and/or the BioVec Materials for the purpose of commercializing products that will compete with the Licensed Products without financial obligation

to such licensee (and indirectly to BioVec), then in the event that (a) or (b) occurs, Bellicum has the right to notify BioVec in writing of such circumstance detailing the evidence it has obtained and to demand that BioVec exercise its available rights and remedies against such other licensee and such unlicensed or non-sublicensed Third Party, with the objective of promptly terminating such unlicensed use and exploitation of the BioVec Products and/or the BioVec Materials or obtaining reasonable financial consideration. The Parties will reasonably discuss in good faith the steps that BioVec proposes to undertake to stop such unlicensed use and exploitation.

ARTICLE 4
PAYMENTS

4.1 License Fee. Within ten (10) business days after the Effective Date, Bellicum shall pay to BioVec the nonrefundable and noncreditable initial license fee of one hundred thousand U.S. dollars ($100,000 USD). Within ten (10) business days after the date of Bellicum's receipt of the first released GMP lot of Licensed Product, Bellicum shall pay to BioVec a second nonrefundable and noncreditable license fee of three hundred thousand U.S. dollars ($300,000 USD).

4.2 License Maintenance Fees. Within [***] after the date upon which the first of the following events occurs: an IND is submitted to the FDA in connection with a Licensed Product, and thirty (30) days (or such other period of time during which the FDA may be permitted to impose a clinical hold) following such IND submission has passed without the FDA imposing a clinical hold, thereby enabling Bellicum or its Affiliate or Sublicensee to lawfully initiate a first Phase I Clinical Phase in relation to such Licensed Product – or the foreign equivalent of the foregoing that enables a first Phase I Clinical Phase in relation to a Licensed Product outside of the United States -- (the "First IND Date"), Bellicum shall pay to BioVec a nonrefundable license maintenance fee of one hundred and fifty thousand U.S. dollars ($150,000 USD). On each anniversary of the First IND Date thereafter during the Term, Bellicum shall pay to BioVec a nonrefundable license maintenance fee of one hundred and fifty thousand U.S. dollars ($150,000 USD). Such license maintenance fees shall be fully creditable against any Royalties payable under Section 4.4, whether such Royalties are payable in the current anniversary year or in subsequent anniversary years described in this Section 4.2.

4.3 Milestone Payments. Bellicum shall pay BioVec the following milestone payments on the achievement by Bellicum, its Affiliates or Sublicensees of the following milestone events, with such milestone payments due within [***] after the applicable milestone event is achieved. For clarity, as used in the table below, the phrase "the first three (3) Licensed Products" refers to three distinctly different Licensed Products, wherein each is generated using a BioVec Product that contains a distinctly different retroviral construct.

Milestone Events & Milestone Payments
$250,000, payable upon the first administration of a Licensed Product to the first patient in a Clinical Phase, payable one time only for each of the first three (3) Licensed Products to enter into a Clinical Phase. In no event will the milestone payment with respect to this milestone event be paid more than three (3) times, even if additional Licensed Products subsequently achieve this milestone event.
$2,000,000, payable upon receipt of any Licensed Product Registration by the FDA or the EMA, payable one time only for each of the first three (3) Licensed Products to receive such Registration. In no event will the milestone payment with respect to this milestone event be paid more than three (3) times, even if additional Licensed Products subsequently achieve this milestone event.

4.4 Royalties. Bellicum shall pay to BioVec royalties of [***] percent ([***]%) on Net Sales in the Territory during the term of this Agreement (the "Royalties"). This royalty rate payable by Bellicum represents a [***].

ARTICLE 5
PAYMENTS; RECORDS

5.1 Payment Method. All payments due under this Agreement shall be made from a bank located in the United States by bank wire transfer in immediately available funds to a bank account designated by BioVec in writing. All payments hereunder shall be made in U.S. dollars. In the event that the due date of any payment subject to Article 4 is a Saturday, Sunday or national holiday, such payment may be paid on the following business day.

5.2 Taxes. If laws or regulations require that taxes be withheld from any amounts payable hereunder, Bellicum will: (a) deduct those taxes from the otherwise remittable payment; (b) timely pay the taxes to the proper taxing authority; and (c) notify BioVec and promptly furnish BioVec with copies of any documentation evidencing such withholding. Bellicum shall provide reasonable assistance to BioVec in order to allow BioVec to minimize or claim exemption from such deductions or withholdings under any present or future treaty against double taxation which may apply to such payments.

5.3 Payments and Reports. Royalty payments under this Agreement with respect to Net Sales of Licensed Products received by Bellicum, or Net Sales reported to Bellicum by its Affiliates and Sublicensees, in a given calendar quarter shall be made to BioVec or its designee [***] within [***] following the end of the applicable [***]. Each Royalty payment shall be accompanied by a report detailing, during the relevant calendar quarter: (i) units of Licensed Product sold, (ii) total gross amount invoiced for sales of the Licensed Product, (iii) calculation of the Net Sales (including the total amount of deductions utilized in determining Net Sales), and (iv) all other calculations made in determining the applicable Royalties payable on such Net Sales.

5.4 Currency Conversion. With respect to sales of Licensed Products invoiced in United States dollars, all such amounts shall be expressed in United States dollars. With respect to sales of Licensed Products invoiced in a currency other than United States dollars, all such amounts shall be expressed both in the currency in which the sale is invoiced and in the United States dollar equivalent. The United States dollar equivalent shall be calculated using the average of the exchange rates (local currency per US$1) published in [***] on the last business day of the third month in the applicable calendar year. All Royalties payable hereunder shall be calculated based on Net Sales expressed in United States dollars.

5.5 Books and Records; Accounting and Audits. Bellicum shall keep, and Bellicum shall cause its Affiliates and Sublicensees to keep, full, complete and proper records and accounts of Net Sales in sufficient detail to enable the Royalties payable under this Agreement to be determined by an independent audit. Bellicum shall permit an independent certified public accounting firm of nationally recognized standing, selected by BioVec and reasonably acceptable to Bellicum, and under an obligation of confidence, to have access upon reasonable prior written notice (which shall be no less than [***] prior written notice) during normal business hours of Bellicum and not more than once in each calendar year, to such records as may be reasonably necessary to verify the accuracy of the Royalties payments and reports hereunder. If BioVec's review of such records of Bellicum does not permit verification of Royalty payments payable for Affiliates' and/or Sublicensees' Net Sales, then BioVec may require Bellicum to conduct an audit of such Affiliate's and/or Sublicensee's records in order to provide BioVec with reasonably requested information and Bellicum shall have such an audit conducted promptly . A copy of the audit report shall be delivered promptly to Bellicum. Such audits shall be at BioVec's expense unless such audit determines that Royalties payments actually delivered to BioVec represent less than [***] percent ([***]%) of the amount determined to be due for any calendar year, in which case such audit shall be at Bellicum's expense. If such certified public accountant identifies an underpayment, and Bellicum does not have a good faith basis for disputing such finding, then Bellicum shall pay BioVec the amount of the discrepancy within [***] of the date BioVec delivers toBellicum (or Bellicum otherwise receives) such accountant's written report that identifies such underpayment. Bellicum shall preserve and maintain, and Bellicum shall cause its Affiliates and Sublicensees to preserve and maintain, all such Royalties payment records and accounts required for audit for a period of [***] after the [***] to which such records and accounts apply.

5.6 Interest. In the event that Bellicum does not pay to BioVec any undisputed amounts due under this Agreement within [***] after the applicable time period for payment set forth herein, such undisputed, overdue payment amount shall bear interest, to the extent

permitted by applicable law, at a rate of interest equal to the lesser of [***] percent ([***]%) per month, or the maximum interest rate permitted by applicable law.

5.7 Confidentiality. All financial information that is subject to review by BioVec or by BioVec's independent certified public accounting firm under this Article 5 (including all Royalties reports) shall be Bellicum's Confidential Information for purposes of this Agreement, and BioVec shall cause its independent certified public accounting firm to retain all such financial information in strict confidence.

ARTICLE 6
CONFIDENTIALITY

6.1 Confidential Information. During the term of this Agreement, and for a period of [***] following the expiration or earlier termination hereof, each receiving Party ("Recipient") shall maintain in confidence all confidential information of the other Party ("Disclosing Party") that is disclosed to the Recipient in connection with this Agreement, whether or not identified as, or acknowledged to be, confidential at the time of disclosure (the "Confidential Information"), and Recipient shall not use, disclose or grant the use of the Disclosing Party's Confidential Information except on a need-to-know basis to those of its or its Affiliates' directors, officers, affiliates, employees, permitted licensees, permitted assignees and agents, consultants, clinical investigators or contractors (collectively, "Representatives"), to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, the Recipient shall obtain written agreement of each such Representative to hold in confidence and not make use of the Disclosing Party's Confidential Information for any purpose other than those permitted by this Agreement. The Recipient shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information. Without limiting the generality of the foregoing, its is understood and agreed that, subject to Section 6.2, the Licensed Know-How constitutes Confidential Information of BioVec.

6.2 Exclusions. The confidentiality obligations contained in Section 6.1 shall not apply to the extent that (a) the disclosed information was public knowledge at the time of such disclosure to the Recipient, or thereafter became public knowledge, other than as a result of actions or inactions of the Recipient or its Representatives in violation hereof; (b) the disclosed information was known by the Recipient prior to the date of disclosure to the Recipient hereunder; (c) the disclosed information was rightfully disclosed to the Recipient on a non-confidential basis by a Third Party; or (d) the disclosed information was independently developed by the Recipient without use of or access to the Confidential Information of the Disclosing Party.

6.3 Permitted Use and Disclosures. Each Recipient may use or disclose Confidential Information of the Disclosing Party or the terms of this Agreement: (a) to the extent such use or disclosure is reasonably necessary in (i) filing or prosecuting patent applications in accordance with this Agreement, (ii) prosecuting or defending, or complying with discovery requests in, legal or

administrative actions related to this Agreement, (iii) complying with any applicable law, order, rule or regulation of any court or governmental body or governmental agency or otherwise submitting information to tax or other governmental authorities in connection with this Agreement, (iv) conducting clinical trials or obtaining approval to test or market a product pursuant to this Agreement, (v) making a permitted Sublicense or otherwise exercising its rights hereunder, or (vi) filings under applicable securities laws or regulations or per the rules of any securities exchange or similar organization; (b) to bona fide potential and actual acquirers, investors, underwriters and lenders, subject to reasonable non-use and non-disclosure requirements; and (c) to its and its Affiliates' respective Representatives, subject to reasonable non-use and non-disclosure requirements. The Recipient shall be responsible for the compliance of all such Representatives with this Article 6. If a Recipient is making a disclosure pursuant to subsection (a)(ii) or (a)(iii) above, such Recipient shall provide the Disclosing Party with prompt written notice of such planned disclosure prior to such disclosure (only to the extent prior notice is allowed under applicable laws, orders, rules or regulations) so that the Disclosing Party may seek to limit or avoid disclosure, or to seek a protective order or other appropriate relief. Subject to the foregoing sentence and the Recipient's compliance with its obligations under this Article 6, the Recipient may furnish the portion of the documents and information that it is legally compelled or it is otherwise required to disclose in connection therewith.

6.4 Terms of this Agreement. Except as otherwise provided in Section 6.2 or Section 6.3, neither Party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party. Notwithstanding anything to the contrary in the foregoing, prior to execution of this Agreement, the Parties have agreed upon the content and information that can be used to describe the terms of this transaction, and each Party may disclose such content and information, as modified by written mutual agreement of the Parties from time to time, without the other Party's consent.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES; LIABILITY

7.1 Bellicum. Bellicum represents and warrants that: (i) it has the legal power, authority and right to enter into this Agreement and to fully perform all of its obligations hereunder; (ii) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; (iii) the performance of its obligations hereunder do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligations of Bellicum.

7.2 BioVec. BioVec represents and warrants that: (i) it has the legal power, authority and right to enter into this Agreement and to fully perform all of its obligations hereunder; (ii) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; (iii) the performance of its obligations and the grant of rights hereunder do not conflict with, violate or breach or constitute a default or require any consent under, any contractual obligations of BioVec; (iv) all BioVec Products supplied to Bellicum under this Agreement shall conform with the applicable specifications therefor, which shall be agreed in writing between the Parties prior to

delivery thereof; (v) it shall reasonably support the transition of the BioVec Products listed in Exhibit A to full functionality in a serum free manufacturing environment; (vi) BioVec owns or Controls the Licensed IP Rights; and (vii) no Third Party claims have been asserted or threatened, nor are there any valid grounds for any claim of any such kind, challenging the inventorship, validity, enforceability, effectiveness, or ownership of the Licensed IP Rights.

7.3 No Consequential Damages. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, LOST PROFIT, EXPECTATION, PUNITIVE, EXEMPLARY, MULTIPLE OR INDIRECT DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, EVEN IF SUCH PARTY HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES, WHETHER GROUNDED IN TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY. CONTRACT, OR OTHERWISE ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT UNDER ANY THEORY OF LIABILITY; provided, however, that this Section 7.3 shall not limit either Party's indemnification obligations under Article 8.

ARTICLE 8
INDEMNIFICATION

8.1 Bellicum. Bellicum agrees to indemnify, defend and hold BioVec and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "BioVec Indemnitees") harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys' and professional fees and other expenses of litigation) (collectively, "Liabilities") arising, directly or indirectly, out of or in connection with Third Party claims, suits, actions, demands or judgments, relating to (a) the negligence or willful misconduct of Bellicum, its Affiliates or Sublicensees, (b) personal injury or death resulting from any Licensed Product developed, manufactured, used, sold or otherwise distributed by or on behalf of Bellicum, its Affiliates, Sublicensees or other designees; (c) any breach by Bellicum of its representations, warranties or covenants made in this Agreement, except, in each case, to the extent such Liabilities result from the matters described in Section 8.2 (a) or (b); and (d) the exercise by Bellicum, its Affiliates or Sublicensees of the rights granted herein.

8.2 BioVec. BioVec agrees to indemnify, defend and hold Bellicum and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "Bellicum Indemnitees") harmless from and against any Liabilities arising, directly or indirectly, out of or in connection with Third Party claims, suits, actions, demands or judgments, relating to (a) the negligence or willful misconduct of BioVec, or (b) any breach by BioVec of its representations, warranties and covenants made in this Agreement., except, in each case, to the extent such Liabilities result from the matters described in Section 8.1 (a) or (c) .

8.3 Indemnification Procedure. A Party that intends to claim indemnification (the "Indemnitee") under this Article 8 shall promptly notify the other Party (the "Indemnitor") in writing of any claim, complaint, suit, proceeding or cause of action with respect to which the Indemnitee

intends to claim such indemnification (for purposes of this Section 8.3, each a "Claim"), and the Indemnitor shall have sole control of the defense and/or settlement thereof; provided that the Indemnitee shall have the right to participate, at its own expense, with counsel of its own choosing in the defense and/or settlement of such Claim. The indemnification obligations of the Parties under this Article 8 shall not apply to amounts paid in settlement of any Claim if such settlement is effected by an Indemnitee without the written consent of the Indemnitor, which consent shall not be withheld, conditioned or delayed unreasonably. The failure to deliver written notice of a Claim to the Indemnitor within a reasonable time after the commencement of any such Claim, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 8, but the omission so to deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability to any Indemnitee otherwise than under this Article 8. The Indemnitee under this Article 8, and its employees, at the Indemnitor's request and expense, shall provide full information and reasonable assistance to Indemnitor and its legal representatives with respect to such Claims covered by this indemnification.

ARTICLE 9
DILIGENCE

9.1 Bellicum and its Affiliates shall use diligent efforts to develop at least one Licensed Product and to introduce at least one Licensed Product into the commercial market as soon as practicable and consistent with sound and reasonable business practice and judgment.

ARTICLE 10
TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date, and shall continue until termination of this Agreement in accordance with Section 10.2, 10.3 or 10.4.

10.2 Termination by Bellicum. Bellicum may terminate this Agreement, in its sole discretion, upon ninety (90) days prior written notice to BioVec.

10.3 Termination for Cause. Except as otherwise provided in Section 11.4, BioVec may terminate this Agreement upon or after the breach of any material provision of this Agreement by Bellicum, if Bellicum has not cured or discontinued such breach within sixty (60) days after receipt of express written notice delivered by BioVec to Bellicum describing such breach and demanding its cure. Except as otherwise provided in Section 11.4, Bellicum may terminate this Agreement upon or after the breach of any material provision of this Agreement by BioVec, if BioVec has not cured or discontinued such breach within sixty (60) days after receipt of express written notice delivered by Bellicum to BioVec describing such breach and demanding its cure.

10.4 Termination upon Insolvency. This Agreement may be terminated if a Party becomes insolvent, makes an assignment for the benefit of its creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has

such a petition filed against it and any such event shall have continued for sixty (60) days undismissed or undischarged. Such termination shall take effect only thirty (30) days after delivery of written notice of termination by the solvent Party to the insolvent Party.

10.5 Effect of Breach or Termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 5.5, 5.7, 7.3 and 10.5, and Articles 1, 6, 8, and 11 shall survive the expiration or termination of this Agreement. If this Agreement is terminated for any reason, any sublicensed rights granted by Bellicum to a Sublicensee under the license granted to Bellicum hereunder shall survive, and such Sublicensee's sublicensed rights hereunder shall automatically be converted to a direct license of such rights from BioVec; provided that each Sublicensee's financial obligations to BioVec which are payable as consideration for such directly licensed rights (i.e., the previously sublicensed rights) shall be equal to the amount that BioVec would have otherwise been entitled to receive from Bellicum as a result of such Sublicensee's activities under the previously sublicensed rights if this Agreement (and the Sublicense) had remained in effect; and further provided, for clarity, that the total amount of non-royalty payments owed to BioVec by all such Sublicensees shall not exceed the total amount of non-royalty payments that would have been owed by Bellicum to BioVec if this Agreement had remained in effect. If this Agreement expires or is terminated for any reason, Bellicum, its Affiliates or Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products in stock, provided that Bellicum shall remain obligated to make payment of Royalties to BioVec for such Licensed Products in accordance with Article 4. Bellicum shall, within thirty (30) days following the effective date of termination of this Agreement, cause itself, its Affiliates and Sublicensees to destroy all BioVec Products in its or in such Affiliates' or Sublicensees' possession, and shall provide written certification of such return or destruction in writing to BioVec.

ARTICLE 11
MISCELLANEOUS

11.1 Governing Laws. This Agreement shall be governed by, interpreted and enforced in accordance with the laws of the State of New York, without regard to principles of conflicts of laws. All disputes arising out of this Agreement shall be subject to the exclusive jurisdiction and venue of the federal courts located in the State of New York, and each Party hereby irrevocably consents to the personal and exclusive jurisdiction and venue thereof.

11.2 Independent Contractors. The relationship of the Parties under this Agreement is that of independent contractors. Neither Party shall be deemed to be an employee, agent, partner, franchisor, franchisee, joint venture or legal representative of the other Party for any purpose as a result of this Agreement or the transactions contemplated thereby, and neither Party shall have the right, power or authority to create any obligation or responsibility on behalf of the other Party.

11.3 Assignment. The Parties agree that neither this Agreement, nor their rights and obligations under this Agreement, shall be delegated, assigned or otherwise transferred to a Third

Party, in whole or part, whether voluntarily or by operation of law, including by way of sale of assets, merger or consolidation, without the prior written consent of the other Party. Notwithstanding anything to the contrary in the foregoing, a Party may, without such consent, assign this Agreement and its rights and obligations hereunder in their entirety (a) to an Affiliate, or (b) in connection with the bona fide sale, transfer, exclusive license, or other disposition, whether in a single transaction or series of related transactions, by such Party (or its Affiliates) to a Third Party of all or substantially ll the assets of such Party and its Affiliates related to this Agreement. Subject to the foregoing, this Agreement shall be binding on and inure to the benefit of the Parties and their permitted successors and assigns. Any attempted delegation, assignment or transfer in violation of the foregoing shall be null and void.

11.4 Force Majeure. If either Party is prevented from or delayed in the performance of any of its obligations hereunder by reason of acts of God, war, strikes, riots, storms, fires, earthquake, power shortage or failure, failure of the transportation system, or any other cause whatsoever beyond the reasonable control of the Party ("Force Majeure Event"), the Party so prevented or delayed shall be excused from the performance of any such obligation during a period that is reasonable in light of the Force Majeure Event, but no less than the duration of the Force Majeure Event itself.

11.5 Notices. Any notices required or permitted under this Agreement or required by law must be in writing and delivered by first class certified mail, return receipt requested, or by international express delivery service (such as FedEx or DHL), in each case properly posted and fully prepaid, to the applicable address below, or to such other address as a Party may substitute by written notice under this Section 11.5. Notice shall be deemed to have been given when delivered or, if delivery is not accomplished by reason or some fault of the addressee, when tendered.

If to BioVec: BioVec Pharma, Inc.
1201 rue du capitaine Bernier
Québec, QC, G1X 4Z1, Canada
Attention: Manuel Caruso, President and CEO

If to Bellicum: Bellicum Pharmaceuticals, Inc.
2130 Holcombe Boulevard, Suite 800
Houston, TX 77030, United States of America
Attention: Thomas J. Farrell, President and CEO

11.6 Interpretation. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless otherwise expressly specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement, and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a calendar day or year, unless otherwise expressly specified; (c) the word "notice" shall mean notice in writing

(whether or not specifically stated), but not by email unless otherwise expressly specified, and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement as a whole (including any Exhibits); (e) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or;”(f) provisions that require that a Party or the Parties “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; and (i) the word “law” (or “laws”) when used herein means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a government entity, together with any then-current modification, amendment and re-enactment thereof, and any legislative provision substituted therefor. The Parties and their respective counsel have had an opportunity to fully negotiate this Agreement. If any ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement. No prior draft of this Agreement shall be used in the interpretation or construction of this Agreement.

11.7 Compliance with Laws. Each Party shall furnish to the other Party any information reasonably requested or required by that Party during the term of this Agreement or any extensions hereof to enable that Party to comply with the requirements of any U.S. or foreign, state and/or government agency.

11.8 Further Assurances. At any time or from time to time on and after the date of this Agreement, BioVec shall at the written and reasonable request of Bellicum: (a) deliver to Bellicum such records, data or other documents consistent with the provisions of this Agreement; (b) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license; and (c) take or cause to be taken all such actions, as Bellicum may reasonably deem necessary or desirable in order for Bellicum to obtain the full benefits of this Agreement and the transactions contemplated hereby.

11.9 Use of Names and Marks. Neither Party shall use the name, logos, trade name, trademark or other designation of the other Party or its employees in connection with any products, promotion or advertising without the prior written permission of the other Party. For clarity, either Party may, without the other Party’s prior permission, reasonably utilize the other Party’s name or names of its employees in statements of fact, in legal proceedings, patent filings, and regulatory filings.

11.10 Severability. If any provision, or portion thereof, in this Agreement is held to be invalid or unenforceable to any extent, such provision of this Agreement shall be enforced to the maximum extent permissible by applicable law so as to effect the intent of the Parties, and the remainder of the Agreement shall remain in full force and effect. The Parties shall negotiate in good faith a valid and enforceable substitute provision for any invalid or unenforceable provision that

most nearly achieves the intent and economic effect of such invalid or unenforceable provision as if it were enforceable.

11.11 Waiver. Any waiver of any provision of this Agreement or of a Party's rights or remedies under this Agreement must be in writing to be effective. Failure, neglect, or delay by a Party to enforce the provisions of this Agreement or its rights or remedies at any time, shall not be construed as a waiver of such Party's rights under this Agreement, and shall not in any way affect the validity of the whole or any part of this Agreement or prejudice such Party's right to take subsequent action. No exercise or enforcement by a Party of any right or remedy under this Agreement shall preclude the enforcement by such Party of any other right or remedy under this Agreement or that such Party is entitled by law to enforce.

11.12 Entire Agreement; Modification. This Agreement (including the Exhibits and any amendments hereto signed by both Parties) constitutes the entire understanding and agreement between the Parties with respect to the subject matter hereof, and supersedes any and all prior and contemporaneous negotiations, representations, agreements, and understandings, written or oral, that the Parties may have reached with respect to the subject matter hereof. Except as set forth in Section 10.13, this Agreement may not be altered, amended or modified in any way except by a writing (excluding email or similar electronic transmissions) signed by the authorized representatives of both Parties.

11.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Once signed, any reproduction of this Agreement made by reliable means (e.g., pdf, photocopy, facsimile) is considered an original.

[*signature page follows*]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed by their authorized representatives and delivered as of the Effective Date.

BELLICUM PHARMACEUTICALS, INC. **BIOVEC PHARMA, INC.**

By: /s/ Thomas J. Farrell By: /s/ Manuel Caruso

Name: Thomas J. Farrell Name: Manuel Caruso

Title: President & CEO Title: President and CEO

EXHIBIT A

BioVec Products

The following packaging cell lines will be provided by BioVec:

- [***]
- [***]
- [***]

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: August 12, 2021

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 June 30, 2021 (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)
August 12, 2021

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.