

**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 September 30, 2023

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

(State or other jurisdiction of incorporation or organization)

20-1450200

(I.R.S. Employer Identification No.)

3730 Kirby Drive, Suite 1200, Houston, TX
(Address of principal executive offices)

77098
(Zip code)

(281) 454-3424

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 November 9, 2023, there were 9,716,931 outstanding shares of Bellicum's common stock, par value, \$0.01 per share.

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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,909	\$ 21,837
Accounts receivable, interest and other receivables	15	—
Prepaid expenses and other current assets	924	1,964
Total current assets	6,848	23,801
Property and equipment, net	5	22
Total assets	\$ 6,853	\$ 23,823
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 526	\$ 486
Accrued expenses and other current liabilities	1,205	2,477
Warrant derivative liability	518	809
Total liabilities	2,249	3,772
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 September 30, 2023 and December 31, 2022; 452,000 shares issued and outstanding at September 30, 2023 and December 31, 2022	31,618	18,036
Stockholders' (deficit) equity:		
Common stock, \$0.01 par value; 160,000,000 shares authorized at September 30, 2023 and December 31, 2022; 9,784,677 shares issued and 9,716,931 shares outstanding at September 30, 2023; 8,682,447 shares issued and 8,614,701 shares outstanding at December 31, 2022	98	87
Treasury stock: 67,746 shares held at September 30, 2023 and December 31, 2022	(5,056)	(5,056)
Additional paid-in capital	569,904	582,763
Accumulated other comprehensive loss	(354)	(354)
Accumulated deficit	(591,606)	(575,425)
Total stockholders' (deficit) equity	(27,014)	2,015
Total liabilities, redeemable preferred stock and stockholders' equity	\$ 6,853	\$ 23,823

See accompanying notes, which are an integral part of these unaudited condensed 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		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenues				
Supply agreement	\$ —	\$ —	\$ 8	\$ —
License revenue	1,000	1,000	1,000	1,000
Revenue-supply agreement	\$ 1,000	\$ 1,000	1,008	1,000
Operating expenses				
Research and development	263	6,850	12,286	16,425
General and administrative	1,511	1,315	5,208	4,216
Total operating expenses	1,774	8,165	17,494	20,641
Other operating expense (income)				
Gain on disposal of fixed assets, net	(1)	—	(1)	—
Total other operating income	(1)	—	(1)	—
Loss from operations	(773)	(7,165)	(16,485)	(19,641)
Other income (expense):				
Interest income	2	11	10	38
Change in fair value of warrant derivative liability	5	(59)	291	827
Other income	3	—	3	—
Total other income (expense)	10	(48)	304	865
Net loss	\$ (763)	\$ (7,213)	\$ (16,181)	\$ (18,776)
Net loss attributable to common stockholders	(763)	(7,213)	(16,181)	(18,776)
Net loss per common share attributable to common stockholders, basic and diluted				
	\$ (0.02)	\$ (0.23)	\$ (0.52)	\$ (0.61)
Weighted-average shares outstanding, basic and diluted				
	30,904,808	30,831,161	30,858,466	30,826,683
Net loss	\$ (763)	\$ (7,213)	\$ (16,181)	\$ (18,776)
Other comprehensive loss:				
Foreign currency translation adjustment	—	(10)	—	(15)
Comprehensive loss	\$ (763)	\$ (7,223)	\$ (16,181)	\$ (18,791)

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

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

Nine Months Ended September 30, 2023

	Series 1 Preferred		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2022	452,000	\$ 18,036	8,682,447	\$ 87	(67,746)	\$ (5,056)	\$ 582,763	\$ (575,425)	\$ (354)	\$ 2,015
Share-based compensation	—	\$ —	—	\$ —	—	\$ —	\$ 559	\$ —	\$ —	\$ 559
Issuance of common stock upon vesting of restricted stock units	—	—	1,597	—	—	—	—	—	—	—
Issuance of common stock upon exercise of pre-funded warrants	—	—	430,000	4	—	—	(4)	—	—	—
Accretion of Series 1 preferred stock redemption	—	4,528	—	—	—	—	(4,528)	—	—	(4,528)
Comprehensive loss	—	—	—	—	—	—	—	(8,066)	—	(8,066)
Balance, March 31, 2023	452,000	\$ 22,564	9,114,044	\$ 91	(67,746)	\$ (5,056)	\$ 578,790	\$ (583,491)	\$ (354)	\$ (10,020)
Share-based compensation	—	\$ —	—	\$ —	—	\$ —	\$ 59	\$ —	\$ —	\$ 59
Issuance of common stock upon exercise of pre-funded warrants	—	—	450,000	5	—	—	(5)	—	—	—
Accretion of Series 1 preferred stock redemption	—	4,527	—	—	—	—	(4,527)	—	—	(4,527)
Comprehensive loss	—	—	—	—	—	—	—	(7,352)	—	(7,352)
Balance, June 30, 2023	452,000	\$ 27,091	9,564,044	\$ 96	(67,746)	\$ (5,056)	\$ 574,317	\$ (590,843)	\$ (354)	\$ (21,840)
Share-based compensation	—	\$ —	—	\$ —	—	\$ —	\$ 116	\$ —	\$ —	\$ 116
Issuance of common stock upon vesting of restricted stock units	—	—	220,633	2	—	—	(2)	—	—	—
Accretion of Series 1 preferred stock redemption	—	4,527	—	—	—	—	(4,527)	—	—	(4,527)
Comprehensive loss	—	—	—	—	—	—	—	(763)	—	(763)
Balance, September 30, 2023	452,000	\$ 31,618	9,784,677	\$ 98	(67,746)	\$ (5,056)	\$ 569,904	\$ (591,606)	\$ (354)	\$ (27,014)

Nine Months Ended September 30, 2022

	Series 1 Preferred		Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2021	452,000	\$ 18,036	8,497,025	\$ 85	(67,746)	\$ (5,056)	\$ 580,156	\$ (550,452)	\$ (338)	\$ 24,395
Share-based compensation	—	—	—	—	—	—	599	—	—	599
Issuance of common stock upon vesting of restricted stock units	—	—	122,928	1	—	—	(1)	—	—	—
Issuance of common stock upon exercise of pre-funded warrants	—	—	56,950	1	—	—	(1)	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(7,562)	(3)	(7,565)
Balance, March 31, 2022	452,000	\$ 18,036	8,676,903	\$ 87	(67,746)	\$ (5,056)	\$ 580,753	\$ (558,014)	\$ (341)	\$ 17,429
Share-based compensation	—	—	—	—	—	—	611	—	—	611
Issuance of common stock upon vesting of restricted stock units	—	—	2,116	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	—	—	(4,001)	(2)	(4,003)
Balance, June 30, 2022	452,000	\$ 18,036	8,679,019	\$ 87	(67,746)	\$ (5,056)	\$ 581,364	\$ (562,015)	\$ (343)	\$ 14,037
Share-based compensation	—	\$ —	—	\$ —	—	\$ —	\$ 685	\$ —	\$ —	\$ 685
Issuance of common stock upon vesting of restricted stock units	—	\$ —	1,668	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —
Comprehensive income (loss)	—	\$ —	—	\$ —	—	\$ —	—	\$ (7,213)	\$ (10)	\$ (7,223)
Balance, September 30, 2022	452,000	\$ 18,036	8,680,687	\$ 87	(67,746)	\$ (5,056)	\$ 582,049	\$ (569,228)	\$ (353)	\$ 7,499

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

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (16,181)	\$ (18,776)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	734	1,895
Depreciation and amortization expense	7	9
Gain on disposal of fixed assets, net	(1)	—
Change in fair value of warrant derivative liability	(291)	(827)
Changes in operating assets and liabilities:		
Accounts receivable, interest and other receivables	(15)	(795)
Prepaid expenses and other assets	1,040	(241)
Accounts payable	40	624
Accrued liabilities and other	(1,272)	(761)
Net cash used in operating activities	(15,939)	(18,872)
Cash flows from investing activities:		
Purchases of property and equipment	(4)	(14)
Proceeds from sale of fixed Asset	15	—
Net cash provided by (used in) investing activities	11	(14)
Effect of exchange rate changes on cash	—	(15)
Net change in cash, cash equivalents, and restricted cash	(15,928)	(18,901)
Cash, cash equivalents and restricted cash at beginning of period	21,837	47,657
Cash, cash equivalents and restricted cash at end of period	\$ 5,909	\$ 28,756

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

Bellicum Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

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

Organization

Bellicum Pharmaceuticals, Inc. (“Bellicum”) is a clinical stage biopharmaceutical company that has discovered and developed novel, controllable cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors.

As of September 30, 2023, Bellicum has one wholly-owned subsidiary, Bellicum Pharma GmbH, a private limited liability company organized under German law. It was formed for the purpose of developing product candidates in Europe. Bellicum and Bellicum Pharma GmbH are collectively referred to herein as the “Company.” All intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in conformity with the authoritative U.S. generally accepted accounting principles (“GAAP”) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, the accompanying unaudited condensed consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto in the Company’s Annual Report on Form 10-K (“Annual Report”) for the fiscal year ended December 31, 2022, as filed with the SEC on March 31, 2023.

The Company has experienced net losses from operations since its inception and as of September 30, 2023 and December 31, 2022, the Company had an accumulated deficit of \$591.6 million and \$575.4 million, respectively, and at September 30, 2023, the Company had cash and cash equivalents of approximately \$5.9 million. 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 financial statements are issued. The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern, and do not include any adjustments that may result from the outcome of this uncertainty. 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.

In March 2023, the Company announced its decision to discontinue its ongoing Phase 1/2 clinical trials evaluating the safety and preliminary efficacy of its GoCAR-T cell product candidates in combination with rimiducid in heavily pre-treated cancer patients. The trials for BPX-601 and BPX-603 are being discontinued following the Company’s assessment of the risk/benefit profile of BPX-601 in combination with rimiducid. An evaluation of the Company’s strategic alternatives is underway. The strategic alternatives include, but are not limited to, a merger, sale, or other business combination, a strategic partnership with one or more parties, or the licensing, sale, or divestiture of our programs. Despite undertaking this process, the Company may not be successful in completing a transaction, and even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits. If the Company does not successfully consummate a strategic alternative, its board of directors may decide to pursue a dissolution and liquidation of the Company. Even if the Company is successful in consummating one or more such strategic alternatives, it may cease operations as a result and its board or directors may choose to dissolve the Company and distribute the proceeds of such strategic alternative, if any, and any remaining assets to its stockholders.

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.

Revenue Recognition

The Company's sources of revenue during the nine months ended September 30, 2023 include the sale of a proprietary reagent to a third party, which resulted in recognized revenue of \$8.0 thousand during the first quarter of 2023. Additionally, in the third quarter of 2023, the Company received an annual maintenance fee of \$1.0 million as specified in the 2021 MD Anderson Option and License Agreement executed in August 2021.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 2023, 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 on Form 10-K for the fiscal year ended December 31, 2022.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other liabilities consist of the following:

<i>(in thousands)</i>	September 30, 2023	December 31, 2022
Accrued payroll	\$ 89	\$ 264
Accrued patient treatment costs	2	675
Accrued clinical research costs	494	841
Accrued manufacturing costs	105	434
Accrued professional services	373	207
Accrued other	142	56
Total accrued expenses and other current liabilities	<u>\$ 1,205</u>	<u>\$ 2,477</u>

Net (Loss) Income and Net (Loss) Income per Share of Common Stock Attributable to Common Stockholders

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

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

	September 30, 2023	September 30, 2022
Anti-dilutive common stock equivalents:		
	Number of Shares	
Redeemable convertible series 1 preferred stock	4,520,000	4,520,000
Warrants to purchase common stock	5,750,000	5,750,000
Options to purchase common stock	215,206	3,658,489
Unvested shares of restricted stock units	397,987	225,633
Total anti-dilutive common stock equivalents	<u>10,883,193</u>	<u>14,154,122</u>

NOTE 2 - FAIR VALUE MEASUREMENTS AND INVESTMENT SECURITIES

Fair Value of Financial Instruments

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a fair value hierarchy has been established that prioritizes the inputs used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

These inputs are classified into the following hierarchy:

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

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

Level 3 Inputs - unobservable inputs for the assets.

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

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

Investment Securities

The following table presents the Company's investment securities (including, if applicable, those classified on the Company's balance sheet as cash equivalents) that are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022:

<i>(in thousands)</i>	Fair Value at September 30, 2023			Fair Value at December 31, 2022		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Cash equivalents:						
Money market funds	\$ 4,532	\$ —	\$ —	\$ 20,024	\$ —	\$ —
Total cash equivalents	\$ 4,532	\$ —	\$ —	\$ 20,024	\$ —	\$ —

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

Warrant Derivative Liability

The Company's financial liabilities recorded at fair value on a recurring basis include the fair values of the warrant derivative liability. The Company estimates the fair value (Level 3) of the warrants using the Black-Scholes valuation technique, which utilizes assumptions including (i) the fair value of the underlying stock relative to the warrant exercise price at the valuation measurement date, (ii) volatility of the price of the underlying stock, (iii) the expected term of the warrants, and (iv) risk-free interest rates.

The fair value of the warrant derivative liability is classified as current liability in the accompanying condensed consolidated balance sheets. This liability is classified as current liability on the balance sheet because the exercisability of such warrants is outside of the Company's control, and the Company does not have the unconditional right to defer settlement beyond 12 months.

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

	September 30, 2023	December 31, 2022
Risk-free interest rate	4.80%	4.1%
Volatility	143.00%	102.00%
Expected term (years)	2.88	3.63

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

(in thousands)	Fair Value at September 30, 2023			Fair Value at December 31, 2022		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant derivative liability	\$ —	\$ —	\$ 518	\$ —	\$ —	\$ 809

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 - PUBLIC OFFERING AND PRIVATE PLACEMENT

December 2021 Private Placement

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

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

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

November 2020 Underwritten Offering

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

August 2019 Public Offering

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

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

The following table reflects the fair value roll forward reconciliation of the Public Warrants liabilities for the period ended September 30, 2023:

<i>(in thousands)</i>	Warrant Derivative Liability	
Balance, December 31, 2022	\$	809
Change in fair value		(291)
Balance, September 30, 2023	\$	518

Private Placement

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

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

A summary of warrants outstanding and exercisable as of September 30, 2023 is as follows:

Year Issued	Warrants Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price (per share)
2019	5,750,000	2.88	\$ 13.00
2020	4,149,378	2.10	\$ 6.50
2020 ¹	1,659,752	—	\$ —
2021	2,055,920	5.19	\$ 1.69
2021 ²	19,679,210	—	\$ —
	<u>33,294,260</u>		

NOTE 4 - REDEEMABLE CONVERTIBLE PREFERRED STOCK

On August 21, 2019, the Company sold Series 1 Preferred Stock pursuant to the Offering. The Company has 10,000,000 authorized shares of Preferred Stock with a par value of \$0.01 per share, of which the Company has designated 1,517,500 shares as Series 1 Preferred Stock, 350,000 shares as Series 2 Preferred Stock and 250,000 shares as Series 3 Preferred Stock. There were 452,000 shares of Series 1 Preferred Stock and no shares of Series 2 or Series 3 Preferred Stock issued and outstanding as of September 30, 2023. The Series 1 Preferred Stock, Series 2 Preferred Stock and Series 3 Preferred Stock is referred to collectively as the Preferred Stock.

¹ The pre-funded warrants issued on November 2, 2020 do not have an expiration date.

² The pre-funded warrants issued on December 7, 2021 do not have an expiration date.

As of September 30, 2023, the Company classified the Series 1 Preferred Stock as mezzanine equity, because the Series 1 Preferred Stock is redeemable at the option of the holders upon passage of time, which is outside of the Company's control to prevent. Subsequent adjustment of the amount presented in mezzanine equity to its redemption amount is necessary unless it is probable that the instrument will not become redeemable.

The Series 1 Preferred Stock is not redeemable at September 30, 2023, and is only redeemable upon a fundamental change or, at the option of the holder, on or after August 21, 2024, if certain Conditions have not been met (described below) before that date.

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

A subsequent adjustment of the amount presented within mezzanine equity to its redemption amount is necessary if it is probable that the instrument will become redeemable. The Company does not believe a fundamental change is considered probable until it occurs. However, as of December 31, 2022, the Company concluded that it was probable that the Conditions will not be met before August 21, 2024. Therefore, the Company will prospectively accrete the Series 1 Preferred Stock to its redemption amount of \$45.2 million over the future reporting periods until the earliest redemption date. As of September 30, 2023, the Series 1 Preferred Stock has been remeasured to \$31.6 million.

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 August 21, 2024, all or any portion of the Preferred Stock is redeemable at the option of the holder. The redemption price of the Series 1 Preferred Stock, which is the only series of Preferred Stock outstanding, is \$100.00 per share. 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 above) is met.

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 5- SHARE-BASED COMPENSATION PLANS

Share-Based Compensation Plans

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

Share-Based Compensation Expense

Share-based compensation expense by classification for the three and nine months ended September 30, 2023 and 2022 are as follows:

<i>(in thousands)</i>	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Research and development	\$ (9)	\$ 334	\$ 96	\$ 921
General and administrative	125	351	638	974
Total	\$ 116	\$ 685	\$ 734	\$ 1,895

At September 30, 2023, total compensation cost not yet recognized was \$0.1 million and the weighted-average period over which this amount is expected to be recognized is 0.2 years.

NOTE 6 - COMMITMENTS AND CONTINGENCIES

License Agreement - Baylor

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

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

As the Company has no active efforts or plans to pursue the licensed technologies under two 2016 license agreements, the Company terminated both license agreements effective December 20, 2022.

License Agreement - Agensys, Inc.

On December 10, 2015, the Company and Agensys, Inc. (“Agensys”), entered into a license agreement (the “Agensys Agreement”), pursuant to which (i) Agensys granted the Company, within the field of cell and gene therapy of diseases in humans, an exclusive, worldwide license and sublicense to its patent rights directed to prostate stem cell antigen 1 (“PSCA”) and related antibodies, and (ii) the Company granted Agensys a non-exclusive, fully paid license to the Company’s patents directed to inventions that were made by the Company in the course of developing the Company’s licensed products, solely for use with Agensys therapeutic products containing a soluble antibody that binds to PSCA or, to the extent not based upon the Company’s other proprietary technology, to non-therapeutic applications of antibodies not used within the field. As consideration for the rights granted to the Company under the Agreement, the Company agreed to pay to Agensys a non-refundable upfront fee of \$3.0 million, which was included in license fee expense. The Company is also required to make aggregate milestone payments to Agensys of up to (i) \$5.0 million upon the first achievement of certain specified clinical milestones for its licensed products, (ii) \$50.0 million upon the achievement of certain specified clinical milestones for each licensed product, and (iii) \$75.0 million upon the achievement of certain sales milestones for each licensed product. The Agreement additionally provides that the Company will pay to Agensys a royalty that ranges from the mid to high single digits based on the level of annual net sales of licensed products by the Company, its affiliates or permitted sublicensees. The royalty payments are subject to reduction under specified circumstances. These milestone and royalty payments will be expensed as incurred. Under the Agreement, Agensys also was granted the option to obtain an exclusive license, on a product-by-product basis, from the Company to commercialize in Japan each licensed product developed under the Agensys Agreement that has completed a phase 2 clinical trial. As to each such licensed product, if Agensys or its affiliate, Astellas Pharma, Inc., exercises the option, the Agensys Agreement provides that the Company will be paid an option exercise fee of \$5.0 million. In addition, the Agensys Agreement provides that the Company will be paid a royalty that ranges from the mid to high single digits based on the level of annual net sales in Japan of each such licensed product. If the option is exercised, the aggregate milestone payments payable by the Company to Agensys, described above with respect to each licensed product, would be reduced by up to an aggregate of \$65.0 million upon the achievement of certain specified clinical and sales milestones. The Agensys Agreement will terminate upon the expiration of the last royalty term for the products covered by the Agensys Agreement, which is the earlier of (i) the date of expiration or abandonment of the last valid claim within the licensed patent rights covering any licensed products under the Agreement, (ii) the expiration of regulatory exclusivity as to a licensed product, and (iii) 10 years after the first commercial sale of a licensed product. Either party may terminate the Agensys Agreement upon a material breach by the other party that remains uncured following 60 days after the date of written notice of such breach (or 30 days if such material breach is related to failure to make payment of amounts due under the Agensys Agreement) or upon certain insolvency events. In addition, Agensys may terminate the Agensys Agreement immediately upon written notice to the Company if the Company or any of its affiliates or permitted sublicensees commences an interference proceeding or challenges the validity or enforceability of any of Agensys’ patent rights.

License Agreement - BioVec

On June 10, 2015, the Company and BioVec Pharma, Inc. (“BioVec”) entered into a license agreement (the “BioVec Agreement”) pursuant to which BioVec agreed to supply the Company with certain proprietary cell lines and granted to the Company a non-exclusive, worldwide license to certain of its patent rights and related know-how related to such proprietary cell lines. As consideration for the products supplied and rights granted to the Company under the BioVec Agreement, the Company agreed to pay to BioVec an upfront fee of \$100,000 within ten business days of the effective date of the BioVec Agreement and a fee of \$300,000 within ten business days of its receipt of the first release of GMP lot of the products licensed under the BioVec Agreement. In addition, the Company agreed to pay to BioVec an annual fee of \$150,000, commencing 30 days following the first filing of an Investigational New Drug Application (an IND filing), or its foreign equivalent, for a product covered by the license; with such annual

fees being creditable against any royalties payable by the Company to BioVec under the BioVec Agreement. The Company also is required to make a \$250,000 milestone payment to BioVec for each of the first three licensed products to enter into a clinical phase trial and one-time milestone payments of \$2.0 million upon receipt of a registration granted by the Federal Drug Administration or European Medicines Agency on each of the Company's first three licensed products. The BioVec Agreement additionally provides that the Company will pay to BioVec a royalty in the low single digits on net sales of products covered by the BioVec Agreement. The Company may also grant sublicensees under the licensed patent rights and know-how to third parties for limited purposes related to the use, sale and other exploitation of the products licensed under the BioVec Agreement. The BioVec Agreement will continue until terminated. The BioVec Agreement may be terminated by the Company, in its sole discretion, at any time upon 90 days written notice to BioVec. Either party may terminate the BioVec Agreement in the event of a breach by the other party of any material provision of the BioVec Agreement that remains uncured on the date that is 60 days after written notice of such failure or upon certain insolvency events that remain uncured following the date that is 30 days after the date of written notice to a party regarding such insolvency event. On October 3, 2023, an amendment to the BioVec Agreement was made in which the Company and BioVec agreed to extend the payment date of the 2023 annual license maintenance fee until there is clarity if the license will be needed for further GoCAR-T development, currently forecasted to be in the first quarter of 2024. All annual license maintenance fees for years subsequent to 2023 shall remain unchanged.

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, 2022, filed with the SEC on March 31, 2023, 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

Until recently, we were a clinical stage biopharmaceutical company that has discovered and developed novel, controllable cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors. Our proprietary Chemical Induction of Dimerization, or CID, technology platform is designed to enable control of components of the immune system in real time. By incorporating our CID platform into cellular immunotherapies, their efficacy and safety may be enhanced.

In March 2023, we announced our decision to discontinue our ongoing Phase 1/2 clinical trials evaluating the safety and preliminary efficacy of our GoCAR-T cell product candidates (including BPX-601 and BPX-603) in combination with rimiducid in heavily pre-treated cancer patients following our assessment of the risk/benefit profile of BPX-601 in combination with rimiducid.

We received an email notification on July 18, 2023 and a letter on August 7, 2023 from the Food and Drug Administration, or FDA, notifying us that they have placed the BPX-601 Investigational New Drug Application (IND) on clinical hold. As the Phase 1/2 clinical trial of BPX-601 has already been discontinued, we do not expect a material impact on our operations from this regulatory action.

We are evaluating and exploring a variety of strategic and financing alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of our programs. Despite undertaking this process, we may not be successful in completing a strategic transaction, and, even if a transaction is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value. If we do not successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company. Even if we are successful in consummating one or more such strategic alternatives, we may still cease operations and our board or directors may choose to dissolve our company.

Additionally, the certificate of designations for our Series 1 preferred stock provides that if we liquidate, dissolve or wind up our company, or effect a deemed liquidation involving the sale of a majority of our common stock or all or substantially all of our assets, the holders of our Series 1 preferred stock will have a liquidation preference which, as of September 30, 2023, would entitle them to receive an aggregate of \$45,200,000 before any payments are made to holders of our common stock. This liquidation preference amount would likely exceed the amount of any proceeds we would receive in any strategic transaction or transactions or any liquidation, deemed liquidation, dissolution or winding up of our company. As a result, holders of our common stock may not receive any amounts even if we are successful in consummating one or more strategic transactions or if our board of directors liquidates, dissolves, or winds up our company (whether in connection with a strategic transaction or not).

We are no longer pursuing further clinical development of our product candidates at this time. The disclosures throughout this Quarterly Report include discussions regarding our historical operations.

Historical research overview

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 can 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:

- The inducible MyD88/CD40 (iMC) activation switch that was incorporated into our GoCAR product candidates is designed to enhance CAR-based cell therapies by augmenting multiple mechanisms of action, including: 1) boosting effector cell proliferation; 2) enhancing functional persistence by resisting exhaustion and inhibitory signals found in the tumor microenvironment; and 3) stimulating the cancer patient’s own immune system to intensify tumor killing. Unlike other CAR therapies that can behave unpredictably due to their autonomous activity, GoCAR antitumor effects are controlled through scheduled administration of rimiducid. In the event of severe side effects, GoCAR activity can be attenuated by extending the interval between rimiducid doses or suspending further rimiducid administration.
- Our CaspaCIDE™ safety switch (also known as inducible Caspase-9, or iC9) is designed to be inactive unless the patient experiences a serious side effect (e.g., cytokine release syndrome, or CRS, neurologic toxicities or off-tumor / on-target toxicities). In that event, rimiducid or temsirolimus is administered to induce Caspase-9 and eliminate the cells, with the goal of attenuating the therapy and resolving the serious side effect.
- “Dual-switch” GoCARs 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 developed GoCAR product candidates we advanced to Phase 1/2 clinical trials:

- **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.
- **BPX-603** is an autologous dual-switch GoCAR-T product candidate containing both the iMC activation and CaspaCIDE safety switches. BPX-603 is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen, or HER2.

Results of Operations

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

(in thousands)	Three Months Ended			Nine Months Ended		
	September 30, 2023	September 30, 2022	Change	September 30, 2023	September 30, 2022	Change
Revenues						
Supply agreement	—	—	—	8	—	8
License revenue	\$ 1,000	\$ 1,000	\$ —	\$ 1,000	\$ 1,000	\$ —
Revenue-supply agreement	\$ 1,000	\$ 1,000	\$ —	1,008	1,000	8
Operating expenses:						
Research and development	263	6,850	(6,587)	12,286	16,425	(4,139)
General and administrative	1,511	1,315	196	5,208	4,216	992
Total operating expenses	1,774	8,165	(6,391)	17,494	20,641	(3,147)
Other operating (income) expense:						
Gain on sale of fixed asset, net	(1)	—	(1)	(1)	—	(1)
Total other operating income:	(1)	—	(1)	(1)	—	(1)
Loss from operations	(773)	(7,165)	6,392	(16,485)	(19,641)	3,156
Other income (expense):						
Interest income	2	11	(9)	10	38	(28)
Change in fair value of warrant derivative liability	5	(59)	64	291	827	(536)
Other income (expense)	3	—	3	3	—	3
Total other income (expense)	10	(48)	58	304	865	(561)
Net loss	\$ (763)	\$ (7,213)	\$ 6,450	\$ (16,181)	\$ (18,776)	\$ 2,595

Revenues

The increase in revenues for the nine months ended September 30, 2023, compared to the same period in 2022, primarily resulted from our sale of a small amount of a proprietary reagent to a third party during the first quarter of 2023. During the third quarter of 2023, we also earned an annual maintenance fee of \$1.0 million per the 2021 MD Anderson Option and License Agreement executed in August 2021.

Research and Development Expenses (R&D)

The decrease in R&D expenses for the three months ended September 30, 2023, compared to the same period in 2022, was due to reduced expenses of \$2.5 million in consulting and other technical operations expenses as a result of contract terminations following the discontinuation of our BPX-601 and BPX-603 trials in March 2023. Additionally, there was a decrease of \$2.5 million related to clinical and other site costs, as a result of final reconciliations with our clinical sites and vendors. Lastly, there was a decrease of \$1.5 million in personnel costs as a result of terminations of R&D employees.

The decrease in R&D expenses for the nine months ended September 30, 2023, compared to the same period in 2022, was primarily due to a decrease of \$2.4 million in consulting and stock-based compensation expenses as a result of terminations of R&D employees and consultants. Additionally, there was a decrease of \$1.7 million of clinical trial expenses due to the discontinuation of our BPX-601 and BPX-603 trials and final reconciliations with our clinical sites and vendors.

General and Administrative Expenses (G&A)

The increase in G&A expenses for the three months ended September 30, 2023, compared to the same periods last year, were primarily due to an increase of \$0.5 million in personnel related and consulting costs, offset by an increase of \$0.7 million attributable to legal fees related to our evaluation of strategic alternatives.

The increase in G&A expenses for the nine months ended September 30, 2023, compared to the same periods last year, was primarily due to a decrease of \$0.1 million in personnel related and consulting costs, offset by an increase of \$1.1 million attributable to legal fees related to our evaluation of strategic alternatives.

Other Income (Expense)

Other income (expense) primarily consists of interest income, offset by changes in fair value of our warrant derivative liability, which is remeasured at each reporting period. Due to the nature of the inputs in the model used to assess the fair value of the warrant derivative liability, 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.

The increase in other income (expense) for the three months ended September 30, 2023, compared to the same period last year, was primarily due to changes in fair value of our warrant liability. During the three months ended September 30, 2023, we recognized a gain from the change in fair value of \$5 thousand, compared to a loss of \$59 thousand during the same period last year.

The decrease in other income (expense) for the nine months ended September 30, 2023, compared to the same period last year, was primarily due to changes in fair value of our warrant liability. During the nine months ended September 30, 2023, we recognized a gain from the change in fair value of \$0.3 million, compared to a gain of \$0.8 million during the same period last year.

Liquidity and Capital Resources

Going Concern and Management's Plans

As of September 30, 2023, we had cash and cash equivalents of \$5.9 million, and net cash used in operations for the nine months ended September 30, 2023 was approximately \$15.9 million.

The accompanying unaudited condensed consolidated financial statements have been prepared on the basis that we will continue as a going concern, and do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of our assets and the satisfaction of our 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 we be unable to continue as a going concern. We have experienced net losses since our inception and as of September 30, 2023, we have an accumulated deficit of \$591.6 million. We believe that there is substantial doubt that our 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 financial statements are issued.

Subject to the terms of our certificate of incorporation, at any time on or after August 21, 2024, all of our outstanding shares of Series 1 preferred stock will be redeemable at the option of the holder, and, if this were to occur, we may be required to pay an aggregate redemption price of up to \$45,200,000. We may not have sufficient cash or other capital resources available at such time to effect any such redemption.

In March 2023, we announced our decision to discontinue our ongoing Phase 1/2 clinical trials evaluating the safety and preliminary efficacy of our GoCAR-T cell product candidates in combination with rimiducid in heavily pre-treated cancer patients. The trials for BPX-601 and BPX-603 are being discontinued following our assessment of the risk/benefit profile of BPX-601 in combination with rimiducid. We are communicating with clinical trial sites and regulatory agencies regarding our decision to discontinue our ongoing clinical trials, and an evaluation of our strategic alternatives is underway.

Based on our current status, we are evaluating strategic alternatives, including, but not limited to, a merger, sale, or other business combination, a strategic partnership with one or more parties, or the licensing, sale, or divestiture of our programs. Despite undertaking this process, we may not be successful in completing a transaction, and, even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits. If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. If we are successful in consummating one or more such strategic alternatives, we may cease operations as a result and our board or directors may choose to dissolve our company.

Cash Flows

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2023 was \$15.9 million compared to \$18.9 million from the same period in 2022. The primary operating activities were (1) \$16.2 million of net losses, (2) a 0.2 million decrease from changes in operating assets and liabilities, and (3) a non-cash gain of \$0.3 million recognized from the change in the fair value of the warrant derivative liability. These activities were partially offset by the share-based compensation changes of \$0.7 million.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2023, was less than \$0.1 million as compared to the \$0.1 million net cash used in 2022. Our cash provided by investing activities during the nine months ended September 30, 2023 was primarily related to the sale of a fixed asset, offset by the purchase of computer equipment.

Financing Activities

There was no cash used in or provided by financing activities during the nine months ended September 30, 2023 and 2022.

As of September 30, 2023, we do not have any short-term or long-term lease liabilities, debt obligations or other material capital commitments. The expected capital expenditures for the next 12 months are minimal.

Critical Accounting Policies and Estimates

There have been no material changes to the Company's critical accounting policies and use of estimates from those disclosed in the Company's Form 10-K for the year ended December 31, 2022. 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, 2022.

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

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

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2023. 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 an issuer that are designed to ensure that information required to be disclosed by the issuer 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 an issuer 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 officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance 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 September 30, 2023, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are involved in various legal proceedings arising in the ordinary course of business. We are not currently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, cash flows, or financial condition. Defending any such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

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.

- Our activities to evaluate and pursue strategic alternatives may not result in any definitive transaction or enhance stockholder value.
- We have incurred net losses from operations in every year since our inception and anticipate that we will continue to incur net losses in the future.
- Adverse side effects or other safety risks associated with our product candidates have caused us to discontinue our clinical trials and could, if we, or an acquiror, pursues clinical development in the future, cause a suspension or discontinuance of future clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- 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.
- Our principal stockholders own a significant percentage of our stock and can exert significant control over matters subject to stockholder approval.
- Our common stock trades on the OTCBK Market instead of a national securities exchange, which may make it more difficult for stockholders to sell their shares.

Risk Factors

Our business and results of operations are subject to a number of risks and uncertainties. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk () those risk factors that have changed since the issuance of our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 31, 2023, or our Annual Report.*

Risks Related to Our Business and Industry

Our activities to evaluate and pursue strategic alternatives may not result in any definitive transaction or enhance stockholder value.*

Following the discontinuation of our Phase 1/2 clinical trials to evaluate the safety and preliminary efficacy of our GoCAR-T cell product candidates (including BPX-601 and BPX-603) in combination with rimiducid in heavily pre-treated cancer patients, we have begun evaluating and exploring a variety of strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of our programs. Our ability to successfully execute on a strategic alternative is dependent on a number of factors and we may not be able to execute upon a transaction or other strategic alternative upon favorable terms within an advantageous timeframe and recognize significant value for these assets, if at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative may be costly and time-consuming. Any executed strategic alternative may not result in anticipated savings or other economic benefits, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

The current market price of our common stock may reflect a market assumption that a strategic alternative will occur, and a failure to complete a strategic alternative could result in negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives. There can be no certainty that any strategic alternative will be completed, be on attractive terms, enhance stockholder value or deliver the anticipated benefits, and successful integration or execution of the strategic alternatives will be subject to additional risks. In addition, potential strategic alternatives that require stockholder approval may not be approved by our stockholders. If we do not successfully consummate a strategic alternative, our board of directors may decide to pursue a dissolution and liquidation of our company. Even if we are successful in consummating one or more such strategic alternatives, we may still cease operations and our board or directors may choose to dissolve our company. In the event of any liquidation, deemed liquidation (including the sale of a majority of our common stock or all or substantially all of our assets), dissolution or winding up of our company, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such event, the amount of cash that will need to be reserved for commitments and contingent liabilities, and the payment of the liquidation preference applicable to our Series 1 preferred stock in connection with such events which, as of June 30, 2023, would entitle our preferred stockholders to receive an aggregate of \$45,200,000 before any payments are made to holders of our common stock. This liquidation preference amount would likely exceed the amount of any proceeds we would receive in any strategic transaction or transactions or any liquidation, deemed liquidation, dissolution or winding up of our company.

Because of these factors, and particularly the liquidation preference applicable to our Series 1 preferred stock, the amount available for distribution to our common stockholders could be as low as \$0.00 and result in a total loss of investment to our common stockholders.

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

Until recently, we were a clinical-stage biopharmaceutical company that had no products approved for commercial sale and had incurred significant losses since our inception in 2004. To date, we have financed our operations primarily through equity and debt financings. As of September 30, 2023, we had an accumulated deficit of \$591.6 million. We expect to continue to incur significant losses from operations for the foreseeable future.

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.

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. Based on our Phase 1 results of BPX-601 and rimiducid, we believe further optimization of the clinical dose and schedule of GoCAR-T cells and rimiducid or further engineering of the CID platform may be needed to achieve favorable outcomes, 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 which would adversely affect its value.

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, including:

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

Our current product candidates were recently in early stage clinical trials, and, if an acquiror, reinitiates these trials or initiates additional clinical trials, they may experience unfavorable results in the future.

We have recently discontinued the Phase 1/2 clinical trial for BPX-601 for the treatment of prostate cancer, and the Phase 1/2 clinical trial for BPX-603 in HER2-positive solid tumors, following our assessment of the risk/benefit profile of BPX-601 in combination with rimiducid. We are communicating with clinical trial sites and regulatory agencies regarding our decision to discontinue our ongoing clinical trials, and have begun evaluating a variety of strategic and financing alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, or other business combination, a strategic partnership with one or more parties, or the licensing, sale or divestiture of our programs. As these product candidates are in early stages of development, there is significant uncertainty regarding whether they will be effective and safe in human patients, and the results from preclinical studies, such as in vitro and in vivo studies, of BPX-601 and BPX-603 may not be indicative of the results of clinical trials of these product candidates. Additionally, the most recent patient treated in the Phase 1/2 trial of BPX-601 in mCRPC experienced serious immune-mediated adverse events including Grade 4 CRS, the second dose-limiting toxicity observed in this cohort of dose escalation. 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 submission of our product candidates for approval. To the extent that the results of 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 significant additional resources may be required to conduct additional clinical trials in support of potential approval of our product candidates.

We have in the past relied on third parties to conduct clinical trials.

While we are not currently conducting any clinical development and do not have plans to initiate any additional clinical trials, we have in the past depended upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct preclinical and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to development timelines and increased costs. We would expect to rely heavily on these third parties over the course of clinical trials, and would control only certain aspects of their activities. Nevertheless, we would be responsible for ensuring that each study is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and reliance on third parties would not relieve us of regulatory responsibilities. We and these third parties would be required to comply with 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 failed 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, any future clinical trials with our product candidates would be required to 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 clinical protocols or regulatory requirements or for other reasons, the 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.

Switching or adding third parties to conduct 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.

There may be difficulties enrolling patients in future clinical trials of our product candidates, resulting in clinical development delays.

While we are not currently conducting any clinical trials and do currently have plans to initiate any further clinical trials in the future, should our product candidates be acquired and developed by others, there may be difficulties in patient enrollment in clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the 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;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to obtain and maintain patient consents;
- 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 future clinical trials could 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. If we, or a third party, wanted to continue the development of our product candidates, any future 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, because some patients who might have opted to enroll in the clinical trials may instead opt to enroll in a trial being conducted by a competitor. Further, since the number of qualified clinical investigators is limited, we expect future clinical trials could be conducted at the same clinical trial sites that competitors use, which will reduce the number of patients who are available at these clinical trial sites. Moreover, because our CAR-T therapies 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 future clinical trials for our product candidates. Patients may also be unwilling to participate in clinical trials because of negative publicity from adverse events in the biotechnology or gene therapy industries.

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 the value of our CID platform.

Rimiducid and CaspaCIDE-containing cell therapy constructs are being used by third parties in clinical trials which are completely independent of our previous development programs. 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 additional clinical trials as a condition to marketing approval. If a product candidate receives regulatory approval 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 the product. In addition, treating physicians may be less willing to administer a product due to concerns over such adverse events.

Adverse side effects or other safety risks associated with our product candidates have caused us to discontinue our clinical trials and could, if we, or an acquiror, pursues clinical development in the future, cause a suspension or discontinuance of future clinical trials, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Adoptive cell therapy with autologous T cells is associated with a range of potentially severe immune-mediated adverse effects. In third party clinical trials involving CAR-T cells, the most prominent acute toxicities included symptoms thought to be associated with the release of cytokines, such as fever, low blood pressure and kidney dysfunction. Some patients also experienced toxicity of the central nervous system, such as confusion, cranial nerve dysfunction and speech impairment. Adverse side effects attributed to CAR-T cells were severe and life-threatening in some patients. The life-threatening events were related to kidney dysfunction and toxicities of the central nervous system. Severe and life-threatening toxicities occurred primarily in the first two weeks after cell infusion and generally resolved within three weeks. In the past, 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, have resulted in, and could, in the future, result in the delay, suspension or termination of clinical trials for our product candidates, the FDA or other regulatory authorities for a number of reasons. In addition, because the patients in clinical trials involving CAR-T cells are typically suffering from life-threatening diseases, are often suffering from multiple complicating conditions and are in a position of extreme immune deficiency at the time that they receive therapy, it may be difficult to accurately assess the relationship between our product candidates and adverse events experienced by very ill patients. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue.

We are highly dependent on our key personnel, and if we are not successful in 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 business, our ability to retain key personnel and may be distracting to management.*

On June 30, 2023, the employment of Richard Fair, President and Chief Executive Officer, and Charity Scripture, Chief Development Officer, officially terminated, and we entered into consulting agreements with Mr. Fair and Ms. Scripture providing for their continued service in their officer capacities as consultants. As of September 30, 2023, we have no employees, and have entered into consulting arrangements with certain former employees, including Mr. Fair and Ms. Scripture, to perform services for the Company substantially similar to those provided during their prior employment with the Company.

Despite our efforts to retain valuable personnel, any of our consultants, including Mr. Fair and Ms. Scripture, may terminate their engagement with us on short notice. Our ability to pursue and complete strategic transactions and/or an orderly wind-down of the Company depends on our ability to retain these key consultants. The loss of the services of any of our consultants could substantially harm our business prospects.

Furthermore, we may identify deficiencies in our internal controls 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.

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

In August 2019, we entered into an agreement with certain institutional investors providing for a private placement. Pursuant to the terms of the 2019 securities purchase agreement for the private placement transaction, the investors in the private placement transaction have consent rights over certain significant matters of our business. These include decisions to authorize or issue equity securities that are senior or pari passu to the Series 1 preferred stock with respect to liquidation preference, the occurrence of indebtedness in excess of \$1,000,000, the sale or license of certain of our technology and the payment of dividends. As a result, these stockholders, acting together, will have significant influence over certain matters affecting our business. The investors in the private placement may not consent to us seeking additional funds through debt or other equity financings or the sale or license of our technology. Further, in the event of a liquidation, dissolution, winding up or deemed liquidation, holders of the Series 1 preferred will receive a payment equal to the per share purchase price of their Series 1 preferred stock before any proceeds are distributed to the holders of common stock and this could mean that there is little to no consideration available for distribution to the holders of common stock in the case of a strategic transaction or the liquidation of the Company. As of September 30, 2023, the liquidation preference

applicable to our Series 1 preferred stock in connection with any liquidation, deemed liquidation, dissolution or winding up of the Company would entitle our preferred stockholders to receive an aggregate of \$45,200,000 before any payments are made to holders of our common stock, and this liquidation preference amount would likely exceed the amount of any proceeds the Company would receive in connection with any such transaction or transactions. In addition, any potential investors in the Company or potential strategic partners or acquirors may decline to invest in, or acquire, the Company 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.

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

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

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 business operations.

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

Our operations, and those of our 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.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the U.S., our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalties law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health and Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals, as well as require certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by or are in conflict with HIPAA, including the European Union General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018, and which imposes privacy and security obligations on any entity that collects and/or processes health data from individuals located in the European Union. Under the GDPR, fines of up to 20 million euros or up to 4% of the annual global turnover of the infringer, whichever is greater, could be imposed for significant non-compliance. As well as complicating our compliance efforts, non-compliance with these laws could result in penalties or significant legal liability. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects.

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

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

If product liability lawsuits are brought against us, we may incur substantial liabilities.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates. 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 or manufacturing. 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. 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. 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:

- injury to our reputation;
- 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;
- exhaustion of any available insurance and our capital resources; and
- a decline in our share price.

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

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

As of December 31, 2022, we had aggregate U.S. federal net operating loss carryforwards of approximately \$499.0 million, and aggregate U.S. federal and Texas state research and development credits of approximately \$14.0 million and \$5.1 million, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. U.S. federal net operating loss carryforwards generated in taxable years beginning before January 1, 2018, may be carried forward only 20 years to offset future taxable income, if any. Under current U.S. federal income tax law, U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of current year taxable income. It is uncertain if and to what extent various states will conform to federal law.

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

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, our suppliers, manufacturers, or our customers, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and

lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. In addition, beginning in 2022, taxpayers are required to capitalize and amortize certain research and development expenditures over five years if incurred in the United States and fifteen years if incurred in foreign jurisdictions, rather than deducting them currently. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming.

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 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.

There will also be delays in completing the clinical development of our product candidates if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, or recommended for termination by the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. The termination of, or delays in the completion of, any clinical trial of our product candidates, will harm the commercial prospects for our product candidates. In addition, any delays in completing clinical trials will increase costs, slow down product development and approval process and jeopardize the 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.

Even if our product candidates receive regulatory approval, they will be subject to ongoing regulatory obligations and continued regulatory review.

Any regulatory approvals received 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 are conducted post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with 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.

Foreign legislative changes may also affect the 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 our product candidates obtain regulatory approval, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

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

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

In addition, although our product candidates 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.

Even if our products achieve market acceptance, they 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.

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 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. 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.

There have been executive judicial and Congressional challenges to other aspects of the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the PPACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". 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. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and any additional healthcare reform measures will impact the PPACA.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018 and subsequent legislation, will remain in effect until 2032, unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers.

Further, recently there has been heightened governmental scrutiny in the United States over the manner in which drug manufacturers set prices for their marketed products, in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that

outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. 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.

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

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

The 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. Obtaining adequate levels of reimbursement will impact the ability to successfully market and sell our product candidates. 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 the 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.

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.

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 BioVec Pharma Inc. with respect to making retrovirus for all of our programs.

Any termination of these agreements, or other agreements to which we are a party could result in the loss of significant rights.

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 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.

Our efforts to protect the proprietary nature of our technologies may not be adequate, and 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. 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.

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

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, or an acquiror's, ability to develop and commercialize the product candidate without 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.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our, or an acquiror's, 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. 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. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we, or an acquiror, would be unable to further develop and commercialize our product candidates.

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, and in such instances, we have sought, and will continue to seek, measures to protect our intellectual property. However, if disputes related to intellectual property relevant to our product candidates arise, we may not be able to resolve such disputes in a satisfactory manner.

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 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.

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.

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. 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

Our common stock trades on the OTCPK Market instead of a national securities exchange, which may make it more difficult for stockholders to sell their shares.*

Our common stock is currently quoted on the OTC Market Group's OTCPK Market quotation system under the ticker symbol "BLCM." The OTC Markets are regulated quotation services that display real-time quotes, last sale prices and volume limitations in over-the-counter securities. Trading in shares quoted on the OTCPK is often thin, meaning that the number of persons interested in purchasing stock at or near bid prices at any given time may be relatively small or non-existent, and characterized by volatility in trading prices. This volatility may be caused by a variety of factors, including the lack of readily available price quotations, the absence of consistent administrative supervision of bid and ask quotations, lower trading volume and market conditions. As a result, there may be wide fluctuations in the market price of the shares of our common stock for reasons unrelated to operating performance, and this volatility, when it occurs, may have a negative effect on the market price of our common stock. Moreover, the OTCPK is not a stock exchange, and trading of securities on it is often more sporadic than the trading of securities listed on a national quotation system or stock exchange. Accordingly, our stockholders may not be able to realize a fair price for their shares when they determine to sell them or may have to hold them for a substantial period of time until the market for our common stock improves. If we are unable to list our common stock on a national securities exchange, the trading price of our common stock could suffer, the trading market for our common stock may be less liquid and our common stock price may be subject to increased volatility. In addition, the stock markets in general, including in the industry in which we operate, have experienced extreme volatility that has, in some cases, been unrelated to the operating performance of the issuer. Accordingly, these broad market and industry factors may also seriously harm the market price of our common stock, regardless of our operating performance.

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

As previously disclosed, on July 10, 2023, the Nasdaq Stock Market LLC, or Nasdaq, filed a Form 25 with the SEC in accordance with Rule 12d2-2 promulgated under the Exchange Act, which removed our common stock from listing and registration on Nasdaq. Effective July 20, 2023, our common stock commenced trading on the OTCPK marketplace under the symbol "BLCM." We do not intend to appeal Nasdaq's determination.

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:

- additions or departures of key personnel;
- 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 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.

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

The terms of our 2019 private placement 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.

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 stockholders were to choose to act together, they would have the ability to significantly influence all matters requiring stockholder approval. For example, these stockholders may be able to significantly influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Accounting rules and interpretations for certain aspects of our operations are highly complex and involve significant assumptions and judgment. These complexities could lead to a delay in the preparation and dissemination of our financial statements. Furthermore, changes in accounting rules and interpretations or in our accounting assumptions and/or judgments, such as asset impairments, could significantly impact our financial statements. In some cases, we could be required to apply a new or revised standard retroactively,

resulting in restating prior period financial statements. Any of these circumstances could have a material adverse effect on our business, prospects, liquidity, financial condition and results of operations.

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

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

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

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

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

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

We issued 575,000 shares of Series 1 Preferred Stock in connection with our August 2019 public offering. Subject to the terms of our certificate of designations for our Preferred Stock, at any time on or after August 21, 2024, some or all of our outstanding shares of Series 1 Preferred Stock, which is the only series of Preferred Stock currently outstanding, will be redeemable at the option of the holder at a redemption price of \$100.00 per share upon delivery of an irrevocable written notice to us. If a holder of Series 1 Preferred Stock requests redemption we will be required to redeem such shares of Series 1 Preferred Stock. However, we may be unable to redeem such Series 1 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 Series 1 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. 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.

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 acquirors 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.

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 and the Third Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 12, 2022).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on December 23, 2014).
3.3	Certificate of Designations, Preferences and Rights of Series 1 Redeemable Convertible Non-Voting Preferred Stock, Series 2 Redeemable Convertible Non-Voting Preferred Stock and Series 3 Redeemable Convertible Non-Voting Preferred Stock of Bellicum Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's report on Form 8-K, filed with the SEC on August 19, 2019).
4.1	Reference is made to Exhibits 3.1 , 3.2 and 3.3 .
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-200328), originally filed with the SEC on November 18, 2014).
4.3	Registration Rights Agreement by and among the Registrant and Baker Brothers Life Sciences, LP, and two of its affiliated funds, dated January 15, 2016 (incorporated by reference to Exhibit 4.4 to Registrant's Registration Statement on Form S-3 (File No. 333-209012), filed with the SEC on January 15, 2016).
4.4	Form of Warrant issued in public offering (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.5	Form of Warrant issued in private offering (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.6	Securities Purchase Agreement, dated August 16, 2019, by and among the Company and the institutional investors named therein, (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on August 19, 2019).
4.7	Form of pre-funded warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on November 2, 2020).
4.8	Form of warrant to purchase common stock (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No.001-36783), filed with the SEC on November 2, 2020).
4.9	Form of Pre-Funded Warrant issued in private placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
4.10	Form of Accompanying Common Warrant issued in private placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-36783), filed with the SEC on December 6, 2021).
10.1	Amendment to Consulting Agreement, dated as of September 26, 2023, by and between the Registrant and Charity Scripture.
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
104.1	Inline XBRL Cover Page Interactive Data File

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: November 14, 2023

/s/ Richard A. Fair

Richard A. Fair

Principal Executive and Financial Officer

Date: November 14, 2023

/s/ Charles S. Grass

Charles S. Grass

Principal Accounting Officer

**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: November 14, 2023

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

**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 third quarter ended September 30, 2023 (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.

Date: November 14, 2023

/s/ Richard A. Fair

Richard A. Fair

President and Chief Executive Officer

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.