Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2019

OR

o 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	**2836**	**20-1450200**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2130 W. Holcombe Blvd., Ste. 800
Houston, TX 77030
(832) 384-1100
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**BLCM**	**The Nasdaq Global Market**

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

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** x **No** o

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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	x
Emerging growth company	x		

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. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** o **No** x
As of July 31, 2019, there were 46,254,163 outstanding shares of Bellicum's common stock, par value, $0.01 per share.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,857	$ 43,695
Investment securities, available for sale - short-term	13,709	49,304
Accounts receivable, interest and other receivables	537	909
Prepaid expenses and other current assets	2,001	1,387
Total current assets	59,104	95,295
Right-of-use assets	5,589	—
Property and equipment, net	17,870	20,878
Restricted cash	3,984	4,973
Other assets	3,158	355
TOTAL ASSETS	$ 89,705	$ 121,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,039	$ 3,774
Accrued expenses and other current liabilities	12,560	8,589
Current maturity of long-term debt	5,000	—
Current portion of lease liabilities	1,432	40
Current portion of deferred revenue	1,075	2,983
Current portion of deferred rent	—	418
Total current liabilities	22,106	15,804
Long-term liabilities:		
Long-term debt, net of deferred financing costs	31,271	35,832
Long-term lease liabilities	6,020	91
Deferred rent	—	1,296
TOTAL LIABILITIES	59,397	53,023
Commitments and contingencies: (Note 13)		
Stockholders' equity:		
Preferred stock: $0.01 par value; 10,000,000 shares authorized: no shares issued and outstanding	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized at June 30, 2019 and December 31, 2018, 46,931,626 shares issued and 46,254,163 shares outstanding at June 30, 2019; 44,242,059 shares issued and 43,564,596 shares outstanding at December 31, 2018	469	442
Treasury stock: 677,463 shares held at June 30, 2019 and December 31, 2018	(5,056)	(5,056)
Additional paid-in capital	507,013	493,784
Accumulated other comprehensive loss	(106)	(144)
Accumulated deficit	(472,012)	(420,548)
Total stockholders' equity	30,308	68,478
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 89,705	$ 121,501

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

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

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2019	**2018**	**2019**	**2018**
REVENUES				
Grants	$ 1,391	$ 362	$ 1,907	$ 516
Total revenues	1,391	362	1,907	516
OPERATING EXPENSES				
Research and development	19,859	18,412	36,677	34,948
License fees	173	150	203	180
General and administrative	7,518	5,367	15,054	11,059
Total operating expenses	27,550	23,929	51,934	46,187
Loss from operations	(26,159)	(23,567)	(50,027)	(45,671)
OTHER INCOME (EXPENSE):				
Interest income	311	437	721	704
Interest expense	(1,088)	(1,045)	(2,158)	(2,048)
Total other expense	(777)	(608)	(1,437)	(1,344)
NET LOSS	$ (26,936)	$ (24,175)	$ (51,464)	$ (47,015)
Net loss per common share attributable to common shareholders, basic and diluted	$ (0.58)	$ (0.60)	$ (1.14)	$ (1.27)
Weighted-average shares outstanding, basic and diluted	46,052,348	40,605,953	45,153,118	37,050,949
Net loss	$ (26,936)	$ (24,175)	$ (51,464)	$ (47,015)
Other comprehensive income (loss):				
Unrealized gain (loss) on investment securities	5	36	56	(22)
Foreign currency translation adjustment	(46)	—	(18)	—
Comprehensive loss	$ (26,977)	$ (24,139)	$ (51,426)	$ (47,037)

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

Bellicum Pharmaceuticals, Inc.
Condensed Consolidated Statements of Stockholders' Equity
Three and Six Months Ended June 30, 2019 and 2018

Six months ended June 30, 2019 (amounts in thousands, except share data)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2018	44,242,059	$ 442	$ (677,463)	$ (5,056)	$ 493,784	$ (420,548)	$ (144)	$ 68,478
Share-based compensation	—	—	—	—	2,136	—	—	2,136
Exercise of stock options	27,647	—	—	—	70	—	—	70
Issuance of common stock upon vesting of restricted stock units	22,702	—	—	—	—	—	—	—
Issuance of common stock in open market transactions, net of issuance costs	1,350,652	14	—	—	4,611	—	—	4,625
Comprehensive loss	—	—	—	—	—	(24,528)	79	(24,449)
Balance, March 31, 2019	45,643,060	$ 456	$ (677,463)	$ (5,056)	$ 500,601	$ (445,076)	$ (65)	$ 50,860
Share-based compensation	—	—	—	—	1,996	—	—	1,996
Exercise of stock options	2,206	—	—	—	6	—	—	6
Issuance of common stock - Employee Stock Purchase Plan	40,000	1	—	—	70	—	—	71
Issuance of common stock upon vesting of restricted stock units	5,857	—	—	—	—	—	—	—
Issuance of common stock in open market transactions, net of issuance costs	1,240,503	12	—	—	4,340	—	—	4,352
Comprehensive loss	—	—	—	—	—	(26,936)	(41)	(26,977)
Balance, June 30, 2019	46,931,626	$ 469	$ (677,463)	$ (5,056)	$ 507,013	$ (472,012)	$ (106)	$ 30,308

Six months ended June 30, 2018 (amounts in thousands, except share data)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2017	33,962,640	$ 340	$ (677,463)	$ (5,056)	$ 411,922	$ (322,512)	$ (46)	$ 84,648
Share-based compensation	—	—	—	—	3,605	—	—	3,605
Exercise of stock options	311,258	3	—	—	825	—	—	828
Issuance of common stock upon vesting of restricted stock units	12,658	—	—	—	—	—	—	—
Comprehensive loss	—	—	—	—	—	(22,840)	(58)	(22,898)
Balance, March 31, 2018	34,286,556	$ 343	$ (677,463)	$ (5,056)	$ 416,352	$ (345,352)	$ (104)	$ 66,183
Share-based compensation	—	—	—	—	3,572	—	0	3,572
Exercise of stock options	521,348	5	—	—	2,153	—	—	2,158
Issuance of common stock - Employee Stock Purchase Plan	13,779	—	—	—	99	—	—	99
Issuance of common stock in a public offering, net of issuance costs	9,200,000	92	—	—	64,573	—	—	64,665
Comprehensive loss	—	—	—	—	—	(24,175)	36	(24,139)
Balance, June 30, 2018	44,021,683	$ 440	$ (677,463)	$ (5,056)	$ 486,749	$ (369,527)	$ (68)	$ 112,538

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

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

	Six months ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (51,464)	$ (47,015)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	4,132	7,178
Depreciation and amortization expense	3,742	3,165
Amortization of (discount) premium on investment securities, net	(28)	127
Amortization of right-of-use assets	636	—
Accretion of lease liability	355	(127)
Amortization of deferred financing costs	439	442
Changes in operating assets and liabilities:		
Accounts receivable, interest and other receivables	372	(24)
Prepaid expenses and other assets	(2,336)	(129)
Accounts payable	(1,735)	(1,805)
Accrued liabilities and other	1,747	1,003
Deferred revenue	(1,907)	(516)
NET CASH USED IN OPERATING ACTIVITIES	(46,047)	(37,701)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of investment securities	—	(32,457)
Proceeds from sale of investment securities	35,679	37,810
Purchases of property and equipment	(551)	(1,055)
NET CASH PROVIDED BY INVESTING ACTIVITIES	35,128	4,298
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock offering, net of offering costs	8,977	64,665
Proceeds from issuance of stock from employee stock purchase plan	71	99
Proceeds from exercise of stock options	76	2,985
Payment on financing lease obligations	(14)	(15)
NET CASH PROVIDED BY FINANCING ACTIVITIES	9,110	67,734
EFFECT OF EXCHANGE RATE CHANGES ON CASH	(18)	—
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(1,827)	34,331
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF PERIOD	48,668	45,029
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 46,841	$ 79,360
SUPPLEMENTAL CASH FLOW INFORMATION:		
Interest paid	$ 1,722	$ 1,336
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchases of property and equipment in accounts payables and accrued liabilities	$ —	$ 22

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

NOTE 1 - ORGANIZATION AND BUSINESS DESCRIPTION

Bellicum Pharmaceuticals, Inc., or Bellicum, was incorporated in Delaware in July 2004 and is based in Houston, Texas. Bellicum is a clinical stage biopharmaceutical company focused on discovering and developing novel cellular immunotherapies for various forms of cancer, including both hematological cancers and solid tumors, as well as orphan inherited blood disorders. Bellicum is devoting substantially all of its present efforts to developing next-generation product candidates in some of the most important areas of cellular immunotherapy, including CAR-T and hematopoietic stem cell transplantation.

In 2017, Bellicum formed two wholly-owned subsidiaries, Bellicum Pharma Limited, a private limited company organized under the laws of the United Kingdom, and Bellicum Europe GmbH, a private limited liability company organized under Swiss law. In 2018, Bellicum formed Bellicum Pharma GmbH, a wholly-owned private limited liability company organized under German law. All were formed for the purpose of developing product candidates in Europe. Bellicum, Bellicum Pharma Limited, Bellicum Europe GmbH and Bellicum Pharma GmbH are collectively referred to herein as the “Company”.

NOTE 2 - BASIS OF PRESENTATION

The interim condensed consolidated financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain necessary funding to continue operations. As of June 30, 2019, the Company has incurred an accumulated deficit of $472.0 million since inception and has not yet generated any revenue from operations. Additionally, the Company continues to expend cash to continue its research and development efforts. Management anticipates that its cash on hand as of June 30, 2019, grants and other cash inflows will be insufficient to fund its operations within one year from the financial statement issuance date and therefore, substantial doubt about the entity’s ability to continue as a going concern exists. These consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, and follow the requirements of the U.S. Securities and Exchange Commission, or the SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been omitted. In management’s opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments necessary for the fair presentation of the Company’s financial position and its results of operations and its cash flows for the periods presented. All such adjustments are normal and recurring in nature. These statements should be read in conjunction with the Company's Annual Report on Form 10-K filed for the fiscal year ended December 31, 2018, or the Annual Report. A copy of the Annual Report is available on the SEC’s website, www.sec.gov, under the Company’s ticker symbol “BLCM” or on Bellicum’s website, www.bellicum.com. The results for the interim periods are not necessarily indicative of the results expected for the full fiscal year or any other interim period. Any reference in these footnotes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or the FASB.

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

NOTE 3 - SIGNIFICANT ACCOUNTING POLICIES

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.

Consolidation

All financial information presented includes the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Revenue Recognition

The Company has not yet generated any revenue from product sales. The Company's source of revenue for the three and six months ended June 30, 2019 and 2018 has been from grants. When grant funds are received after costs have been incurred, the Company accrues revenue and records a grant receivable. Cash received from grants in advance of incurring qualifying costs is recorded as deferred revenue and recognized as revenue when qualifying costs are incurred.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments with maturity of three months or less from the date of purchase to be cash equivalents.

Investment Securities

Consistent with its investment policy, the Company invests its cash allocated to fund its short-term liquidity requirements with prominent financial institutions in bank depository accounts and institutional money market funds. The Company invests the remainder of its cash in corporate debt securities and municipal bonds rated at least A quality or equivalent, U.S. Treasury notes and bonds and U.S. and state government agency-backed securities.

The Company determines the appropriate classification of investment securities based on whether they represent the investment of funds available for current operations, as defined in ASC 210-10-45-1 and ASC 210-10-45-2. The Company reevaluates its classification as of each balance sheet date. All investment securities owned are classified as available-for-sale. The cost of securities sold is based on the specific identification method. Investment securities are recorded as of each balance sheet date at fair value, with unrealized gains and, to the extent deemed temporary, unrealized losses reported as accumulated other comprehensive gain (loss), a separate component of stockholders' equity. Interest and dividend income on investment securities, accretion of discounts and amortization of premiums and realized gains and losses are included in interest income in the statements of operations and comprehensive income (loss).

An investment security is considered to be impaired when a decline in fair value below its cost basis is determined to be other than temporary. The Company evaluates whether a decline in fair value of an investment security is below its cost basis is other than temporary using available evidence. In the event that the cost basis of the investment security exceeds its fair value, the Company evaluates, among other factors, the amount and duration of the period that the fair value is less than the cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, and operational and financing cash flow factors, overall market conditions and trends, the Company's intent to sell the investment security and whether it is more likely than not the Company would be required to sell the investment security before its anticipated recovery. If a decline in fair value is determined to be other than temporary, the Company records an impairment charge in the statement of operations and comprehensive loss and establishes a new cost basis in the investment.

Property and Equipment

Leasehold improvements, furniture, equipment and software are recorded at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets, which range from three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life or the remaining lease term.

Intangible Assets

Non-refundable upfront payments related to a supply agreement with future benefits have been capitalized as an intangible asset, presented in other assets on the balance sheet and amortized over the term of the agreement. The amortization of the intangible asset is included in operating expenses.

Debt Issuance Costs

Costs related to debt issuance are presented in the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts and are amortized using the effective interest method. Amortization of debt issuance costs are included in interest expense.

Operating Leases

Operating leases are recognized as right-of-use, or ROU, assets and operating lease liabilities on the balance sheet. Any lease incentives received are deferred and recorded as a reduction of the ROU asset and amortized over the term of the lease. Rent expense, comprised of amortization of the ROU asset and the implicit interest accreted on the operating lease liability, is recognized on a straight-line basis over the lease term.

Fair Value of Financial Instruments

Accounting standards include disclosure requirements around fair values used for certain financial instruments and establish a fair value hierarchy. The three-tier hierarchy prioritizes valuation inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market, as described further in Note 5.

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

Financial Instruments and Credit Risks

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

Equity Issuance Costs

Equity issuance costs represent costs paid to third parties in order to obtain equity financing. These costs have been netted against the proceeds of the equity issuances.

Licenses and Patents

Licenses and patent costs for technologies that are utilized in research and development and have no alternative future use are expensed as incurred. Costs related to the license of patents from third parties and internally developed patents are classified as research and development expenses. Legal costs related to patent applications and maintenance are classified as general and administrative expenses.

Clinical Trials

The Company estimates its clinical trial expense accrual for a given period based on the number of patients enrolled at each site, estimated cost per patient, and the length of time each patient has been in the trial, less amounts previously billed. These accruals are recorded in accrued expenses and other current liabilities, and the related expense is recorded in research and development expense.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of laboratory supplies, manufacturing expenses, fees paid to third parties and other outside expenses.

Research and development costs are expensed as incurred. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the clinical trial or project and the invoices received from its external service providers. The Company estimates depend on the timeliness and accuracy of the data provided by the vendors regarding the status of each project and total project spending. The Company adjusts its accrual as actual costs become known. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone events are achieved.

Collaboration Agreements

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as a deduction to the research and development expenses. The Company also recognizes, as research and development expenses in the period when its collaborator incurs development expenses, the portion of the collaborator's development expenses that the Company is obligated to reimburse.

Contract Manufacturing Services

Contract manufacturing services are expensed as incurred. Prepaid expenses are capitalized and amortized as services are performed.

Share-Based Compensation

The Company accounts for its share-based compensation in accordance with ASC 718, *Compensation - Stock Compensation*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors to be recognized in the financial statements, based on their fair value. The Company measures share-based compensation to consultants in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees*, and recognizes the fair value of the award over the period the services are rendered.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock option awards. The fair value is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award on a straight-line basis.

Comprehensive Loss

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period, from transactions, and other events and circumstances from non-owner sources. Components of comprehensive income (loss) includes, among other items, unrealized gains and losses on the changes in fair value of investments. These components are added, net of their related tax effect, to the reported net income (loss) to arrive at comprehensive income (loss). The components of accumulated other comprehensive loss at June 30, 2019 and December 31, 2018, on the Company’s balance sheet was comprised of the net unrealized holding gains and losses on the Company’s investment securities and unrealized gains or losses arising from fluctuations in foreign currency exchange rates related to foreign operations. See Note 5 for further detail of the unrealized holding gains and losses on the Company’s investment securities.

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

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period without consideration for common stock equivalents.

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

	As of June 30,	
	2019	**2018**
Common Stock Equivalents:	**Number of shares**	
Options to purchase common stock	7,665,330	5,265,521
Unvested shares of restricted stock units	215,937	217,186
Unvested shares of restricted stock	—	14,707
Total common stock equivalents	7,881,267	5,497,414

Application of New Accounting Standards

In the first quarter of 2019, the Company adopted ASU 2016-02, "Leases (Topic 842)," ("ASC 842") which requires companies that lease assets to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. ASC 842 provides for a modified retrospective transition approach requiring lessees to recognize and measure leases on the balance sheet at the beginning of either the earliest period presented or as of the beginning of the period of adoption with the option to elect certain practical expedients. The Company has elected to apply ASC 842 as of the beginning of the period of adoption (January 1, 2019) and has not restated comparative periods.

The Company has elected the 'package of practical expedients', which permit it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use of hindsight practical expedient. The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify.

NOTE 4 - CASH, CASH EQUIVALENTS AND RESTRICTED CASH

As of June 30, 2019, and December 31, 2018, respectively, the Company maintained $4.0 million and $5.0 million as restricted cash.

During 2017, $4.2 million was received from the Cancer Prevention and Research Institute of Texas, or "CPRIT", and the unreleased balance is being held in a separate account to be used for costs solely related to the CPRIT grant. Release of the CPRIT funds are subject to the terms of the grant agreement and requirements therein and require the authorization of CPRIT. To-date, CPRIT authorized the release of $1.7 million of restricted funds from the CPRIT account, leaving a balance of $2.5 million at June 30, 2019. For more information about the CPRIT grant, see Note 10.

The remaining $1.5 million of restricted cash as of June 30, 2019 is held in escrow to cover specific construction of manufacturing improvement costs related to the facility lease. The release of the escrowed funds is subject to the terms of the escrow agreement and requirements therein including approval by both the Company and the landlord based on authorized completion of certain aspects of the manufacturing improvements.

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

	June 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents [(1)]	$ 42,857	$ 43,695
Restricted cash, noncurrent	3,984	4,973
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	$ 46,841	$ 48,668

[(1)] As of June 30, 2019, and December 31, 2018, the Company invested approximately $33.6 million and $25.0 million, respectively, in cash equivalent instruments.

NOTE 5 - FAIR VALUE MEASUREMENTS AND INVESTMENT SECURITIES

Fair Value Measurement

The Company follows ASC, Topic 820, *Fair Value Measurements and Disclosures*, or ASC 820, for application to financial assets. ASC 820 defines fair value, provides a consistent framework for measuring fair value under GAAP and requires fair value financial statement disclosures. ASC 820 applies only to the measurement and disclosure of financial assets that are required or permitted to be measured and reported at fair value under other ASC topics (except for standards that relate to share-based payments such as ASC Topic 718, *Compensation - Stock Compensation*).

The valuation techniques required by ASC 820 may be based on either observable or unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, and unobservable inputs reflect the Company's market assumptions.

These inputs are classified into the following hierarchy:

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

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

Level 3 Inputs - unobservable inputs for the assets.

The following tables present the Company's investment securities (including, if applicable, those classified on the Company's balance sheet as cash equivalents) that are measured at fair value on a recurring basis as of June 30, 2019 and December 31, 2018:

		Fair Value Measurements at Reporting Date Using		
	Balance at June 30, 2019	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(in thousands)			
Cash Equivalents:				
Money market funds	$ 33,590	$ 33,590	$ —	$ —
Total Cash Equivalents	$ 33,590	$ 33,590	$ —	$ —
Investment Securities:				
U.S. government agency-backed securities	$ 4,002	$ —	$ 4,002	$ —
Corporate debt securities	9,707	—	9,707	—
Total Investment Securities	$ 13,709	$ —	$ 13,709	$ —

		Fair Value Measurements at Reporting Date Using		
	Balance at December 31, 2018	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
	(in thousands)			
Cash Equivalents:				
Money market funds	$ 24,953	$ 24,953	$ —	$ —
Total Cash Equivalents	$ 24,953	$ 24,953	$ —	$ —
Investment Securities:				
U.S. government agency-backed securities	$ 7,383	$ —	$ 7,383	$ —
Corporate debt securities	41,921	—	41,921	—
Total Investment Securities	$ 49,304	$ —	$ 49,304	$ —

U.S. Treasury, U.S. government agency-backed securities and corporate debt securities are valued based on various observable inputs such as benchmark yields, reported trades, broker/dealer quotes, benchmark securities and bids.

Investment securities, all classified as available-for-sale, consisted of the following as of June 30, 2019 and December 31, 2018:

June 30, 2019	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Estimated Fair Value
	(in thousands)			
Investment Securities:				
U.S. government agency-backed securities	$ 3,996	$ 6	$ —	$ 4,002
Corporate debt securities	9,702	5	—	9,707
Total Investment Securities	$ 13,698	$ 11	$ —	$ 13,709

December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Estimated Fair Value
	(in thousands)			
Investment Securities:				
U.S. government agency-backed securities	$ 7,382	$ 2	$ (1)	$ 7,383
Corporate debt securities	41,968	—	(47)	41,921
Total	$ 49,350	$ 2	$ (48)	$ 49,304

The Company's investment securities as of June 30, 2019, will reach maturity between July 2019 and November 2019, with a weighted-average maturity date in August 2019.

NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Estimated Useful Lives	June 30, 2019	December 31, 2018
		(in thousands)	
Leasehold improvements	5 Years	$ 21,633	$ 21,633
Lab equipment	5 Years	8,854	8,471
Office furniture	5 Years	1,704	1,704
Manufacturing equipment	5 Years	1,891	1,890
Computer and office equipment	3 to 5 Years	1,738	1,606
Equipment held under financing leases	5 Years	270	204
Software	3 Years	394	361
Total		36,484	35,869
Less: accumulated depreciation		(18,614)	(14,991)
Property and equipment, net		$ 17,870	$ 20,878

During the six months ended June 30, 2019 and 2018, the Company recorded $3.7 million and $3.2 million of depreciation expense, respectively. Leasehold improvements as of June 30, 2019 and December 31, 2018 includes $2.5 million related to costs incurred by the landlord.

NOTE 7 - LEASES

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

The Company entered into a lease agreement for office space and equipment in South San Francisco, California commencing in April 2019 and expiring in 2022. The Company recorded right-of-use assets of $1.2 million and leased assets of $0.2 million for the real estate and equipment components of the lease, respectively, and a corresponding lease liability of $1.4 million upon lease commencement.

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

	Three Months Ended June 30, 2019	Six months ended June 30, 2019
	(in thousands)	
Operating lease cost[1]	$ 547	$ 993
Short-term lease cost	$ 12	$ 47

(1) Includes right-of-use asset amortization of $325,000 and $636,000 for the three and six months ended June 30, 2019, respectively.

Supplemental cash flow information and non-cash activity related to the Company's operating leases are as follows:

	Six months ended June 30, 2019
	(in thousands)
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	$ 1,095
Non-cash activity:	
Right-of-use assets obtained in exchange for lease obligations	$ 1,259

Weighted-average remaining lease term and discount rate for operating leases are as follows:

	June 30, 2019
Weighted-average remaining lease term	5.9 years
Weighted-average discount rate	12.1%

Maturities of lease liabilities by year for leases are as follows (in thousands):

	Operating Leases	Financing Leases
2019[1]	$ 1,301	$ 47
2020	1,620	96
2021	1,579	90
2022	1,418	39
2023	1,143	—
2024 and beyond	3,250	—
Total lease payments	10,311	272
Less: Imputed interest	(3,084)	(47)
Present value of lease liabilities	$ 7,227	$ 225

(1) Excluding the 6 months ended June 30, 2019.

As of December 31, 2018, minimum lease payments under non-cancelable leases by period were expected to be as follows:

Year	Operating Leases	Capital Leases
	(in thousands)	
2019	$ 2,087	$ 68
2020	1,112	68
2021	1,055	43
2022	1,094	—
2023	1,133	—
Thereafter	3,222	—
Total minimum rentals	$ 9,703	179

NOTE 8 – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other liabilities consist of the following:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued construction costs	$ 457	$ 457
Accrued payroll	2,854	3,430
Accrued patient treatment costs	2,167	2,053
Accrued manufacturing costs	1,239	546
Accrued professional services	1,450	235
Accrued obligations under material supply agreements	1,137	—
Accrued other	3,256	1,868
Total accrued expenses and other current liabilities	$ 12,560	$ 8,589

NOTE 9 - DEBT

On December 21, 2017, or the Oxford Closing Date, the Company entered into a loan and security agreement, or the Oxford Loan Agreement, with Oxford Finance LLC, as the collateral agent and a lender, pursuant to which the Company borrowed $35.0 million in a single term loan, or the Oxford Loan on the Oxford Closing Date. For additional information about the Oxford Loan Agreement, see Note 8 to the audited financial statements contained in the Annual Report.

The Company paid expenses related to the Oxford Loan Agreement of $0.1 million, which, along with the final facility charge of $3.0 million, have been recorded as deferred financing costs, and are included in long-term debt on the Company's balance sheet. The deferred financing costs are being amortized over the term of the loan as interest expense. Interest expenses included amortization of deferred financing costs of $0.2 million during each of the three-month periods ended June 30, 2019 and 2018 and $0.4 million during each of the six-month periods ended June 30, 2019 and 2018.

Management believes that the carrying value of the debt facility approximates its fair value, as the Company's debt facility bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics. The fair value of the Company's debt facility is determined under Level 2 in the fair value hierarchy.

NOTE 10 - GRANT REVENUE

Cancer Research Grant Contract

On August 9, 2017, the Company entered into a Cancer Research Grant Contract with CPRIT, pursuant to which CPRIT awarded a grant of approximately $16.9 million to the Company to fund development of rivo-cel for hematologic cancer, or the CPRIT Award. The CPRIT Award is contingent upon funds being available during the term of the grant agreement and subject to CPRIT’s ability to perform its obligations under the grant agreement. For additional information about the grant agreement, see Note 9 to the audited financial statements in the Annual Report.

During the three and six-month periods ended June 30, 2019, the Company recognized expenses and accrued revenue of $1.4 million and $1.9 million , respectively, for work performed under the CPRIT grant. During the three and six-month period

ended June 30, 2018, the Company recognized expenses and accrued revenue of $0.4 million and $0.5 million, respectively for work performed under the CPRIT grant.

NOTE 11 - STOCKHOLDERS' EQUITY

On April 20, 2018, the Company completed an underwritten public offering of 9,200,000 shares of its common stock, or Common Stock, at a price of $7.50 per share, for an aggregate offering size of $69.0 million, pursuant to a registration statement on Form S-3. The net proceeds to the Company, after deducting underwriting discounts, and commissions and offering expenses was approximately $64.7 million.

On October 5, 2018, the Company entered into an Open Market Sale Agreement[SM] with Jefferies LLC, or Jefferies, as sales agent, or the Jefferies Agreement, pursuant to which the Company may offer and sell, from time to time, through Jefferies, shares of the Company's common stock having an aggregate offering price of up to $60.0 million. The shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3. During the six months ended June 30, 2019, the Company received $9.0 million in proceeds, net of discounts and offering expenses totaling $0.3 million, and issued 2,591,155 shares of common stock pursuant to the Jefferies Agreement.

NOTE 12 - SHARE-BASED COMPENSATION

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

For a description of each of the plans in existence as of December 31, 2018, or the Prior Plans, refer to Note 11 to the audited financial statements included the Annual Report.

2019 Equity Incentive Plan

The 2019 Equity Incentive Plan, or the 2019 Plan, is designed to secure and retain the services of the Company's employees and directors, provide incentives for employees and directors to exert maximum efforts for the success of the Company and its affiliates, and provide a means by which employees and directors may be given an opportunity to benefit from increases in the value of the Company's common stock. The 2019 Plan is successor to and continuation of the 2014 Equity Incentive Plan, as amended, or the 2014 Plan, and no additional awards may be issued from the 2014 Plan.

Subject to adjustment for certain changes in the Company's capitalization, the aggregate number of shares of Common Stock that may be issued under the 2019 Plan, or the Share Reserve, will not exceed the sum of (i) 2,500,000 new shares and (ii) the Prior Plans' Returning Shares, as defined in the 2019 Plan documents, in an amount not to exceed 6,005,401 shares, including any stock award granted under the 2014 Plan, 2011 Stock Option Plan, as amended, or 2006 Stock Option Plan, as amended, that were outstanding as of the date the 2019 Plan was approved by the Company's stockholders, as such shares become available from time to time.

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

The following shares of Common Stock will not become available again for issuance under the 2019 Plan: (i) any shares that are reacquired or withheld (or not issued) by the Company to satisfy the exercise, strike or purchase price of a stock award granted under the 2019 Plan or any Prior Plan (including any shares subject to such award that are not delivered because such award is exercised through a reduction of shares subject to such award); (ii) any shares that are reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with a stock award granted under the 2019 Plan or any Prior Plan; (iii) any shares repurchased by the Company on the open market with the proceeds of the exercise, strike or purchase price of a stock award granted under the 2019 Plan or any Prior Plan; and (iv) in the event that a stock appreciation right granted under the 2019 Plan or any Prior Plan is settled in shares, the gross number of shares subject to such award.

The number of shares of Common Stock available for issuance under the 2019 Plan will be reduced by: (i) one share for each share issued pursuant to a stock option or stock appreciation right with an exercise price that is at least 100% of the fair market value of Common Stock on the date of grant, or an Appreciation Award. granted under the 2019 Plan; and (ii) 1.25 shares for each share issued pursuant to a stock award that is not an Appreciation Award, or a Full Value Award, granted under the 2019 Plan.

The number of shares of Common Stock available for issuance under the 2019 Plan will be increased by: (i) one share for each Prior Plans' Returning Share or 2019 Plan Returning Share subject to an Appreciation Award; and (ii) 1.25 shares for each Prior Plans' Returning Share or 2019 Plan Returning Share subject to a Full Value Award.

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

The following table summarizes the stock option activity for all stock plans during the six months ended June 30, 2019:

	Options and Inducement awards
Outstanding at December 31, 2018	5,759,246
Granted	2,697,305
Exercised	(2,206)
Forfeited	(789,015)
Outstanding at June 30, 2019	7,665,330
Exercisable at June 30, 2019	2,664,476

The following table summarizes the stock award activity for all stock plans during the six months ended June 30, 2019:

	Restricted Stock Awards and Units
Outstanding at December 31, 2018	246,155
Granted	30,000
Vested	(47,281)
Forfeited	(12,937)
Outstanding at June 30, 2019	215,937

2014 Employee Stock Purchase Plan

The 2014 Employee Stock Purchase Plan, or the ESPP, provides for eligible Company employees, as defined by the ESPP, to be given an opportunity to purchase the Company's common stock at a discount, through payroll deductions, with stock purchases being made upon defined purchase dates. The ESPP authorizes the issuance of up to 550,000 shares of the Company's common stock to participating employees and allows eligible employees to purchase shares of common stock at a 15% discount from the lesser of the grant date or purchase date fair market value. During the six-month periods ended June 30, 2019 and 2018 there were 40,000 and 13,779 shares purchased by the ESPP, respectively. As of June 30, 2019, there were 374,637 shares available for issuance under the ESPP.

A summary of activity within the ESPP follows:

	Six months ended June 30,	
	2019	2018
	(amounts in thousands)	
Deductions from employees	$ 48	$ 101
Share-based compensation expense recognized	$ 57	$ 73
Remaining share-based compensation expense	$ 135	$ 304

Share-Based Compensation Expense

The valuation of the share-based compensation awards is a significant accounting estimate that requires the use of judgments and assumptions that are likely to have a material impact on the financial statements. The fair value of option grants is determined using the Black-Scholes option-pricing model. Expected volatilities utilized in the model are based on historical volatility of the Company's common stock. Similarly, the dividend yield is based on historical experience and the estimate of future dividend yields. The risk-free interest rate is derived from the U.S. Treasury yield curve in effect at the time of grant. The expected term of the options is based on the average period the stock options are expected to remain outstanding. As the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior, the expected term is calculated as the midpoint between the weighted-average vesting term and the contractual expiration period also known as the simplified method.

The fair value of the option grants has been estimated, with the following weighted-average assumptions:

	Six months ended June 30,	
	2019	**2018**
Risk-free interest rate	2.25%	2.47%
Volatility	72.1%	71.3%
Expected life (years)	6.08	6.08
Expected dividend yield	—%	—%

Share-based compensation expense by classification for the three and six months ended June 30, 2019 and 2018 are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(in thousands)		**(in thousands)**	
Research and development	$ 959	$ 1,623	$ 2,024	$ 3,292
General and administrative	1,037	1,950	2,108	3,886
Total	$ 1,996	$ 3,573	$ 4,132	$ 7,178

At June 30, 2019, total compensation cost not yet recognized was $14.9 million and the weighted-average period over which this amount is expected to be recognized is 2.51 years.

NOTE 13 - COMMITMENTS AND CONTINGENCIES

Miltenyi Supply Agreement

On March 27, 2019, Bellicum entered into a strategic, long-term supply agreement with Miltenyi Biotec GmbH, or Miltenyi, for the supply of Miltenyi's CliniMACS tubing set, reagents and disposables for the manufacture of Bellicum's programmed T cell therapies for preclinical and clinical use and, if approved, for commercial use, as well as support services. Under the supply agreement, Bellicum is required to make non-refundable upfront payments totaling €2,000,000, which have been capitalized as an intangible asset and will be amortized over the 10-year term of the agreement. The annual amortization will be approximately $0.2 million for each of the next five years.

Under the supply agreement, Bellicum will provide Miltenyi with regularly scheduled rolling forecasts of anticipated purchase requirements on a product-by-product and country-by-country basis. Within the rolling forecasts, there is a period of time referred to as the "Firm Zone" in which Bellicum is obligated to purchase, and Miltenyi has agreed to provide, the number of products Bellicum has specified for that period, subject to specified conditions and limitations.

Litigation

On February 6, 2018, a purported securities class action complaint captioned *Nipun Kakkar v. Bellicum Pharmaceuticals, Inc., Rick Fair and Alan Musso* was filed against the Company, and certain of its officers in the U.S. District Court for the Southern District of Texas, Houston Division. A second substantially similar class action was filed on March 14, 2018 by plaintiff Frances Rudy against the same defendants in the same court. The lawsuits purport to assert class action claims on behalf of purchasers of the Company's securities during the period from May 8, 2017 through January 30, 2018. The complaints allege that the defendants violated the Securities Exchange Act of 1934, as amended, or the Exchange Act, by making materially false and misleading statements concerning the Company's clinical trials being conducted in the U.S. to assess rivo-cel (rivogenlecleucel, formerly known as BPX-501) as an adjunct T-cell therapy administered after allogeneic hematopoietic stem cell transplantation. The complaints purport to assert claims for violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaints seek, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief. On April 9, 2018, the District Court consolidated the two lawsuits under the Kakkar action. On March 26, 2019, the court appointed lead plaintiffs to represent the putative class and on May 15, 2019, plaintiffs filed an amended class action complaint. On July 5, 2019, defendants filed a motion to dismiss the amended complaint.

On July 19, 2018, a purported shareholder derivative complaint captioned *Seung Paik v. Richard A. Fair, et al*. was filed against the Company's directors and certain of the Company's officers in the U.S. District Court for the Southern District of Texas, Houston Division. The lawsuit purports to seek damages on behalf of the Company against the individual defendants for breach of fiduciary duty, waste, unjust enrichment and violations of Section 14(a) of the Exchange Act. The complaint alleges that the defendants caused or allowed the Company to disseminate misstatements regarding the clinical trials for rivo-cel and to make false or misleading statements in the proxy materials for the Company's 2017 annual meeting of stockholders. On October 3, 2018, the District Court granted the Company's motion to stay the *Paik* derivative cause of action until reinstated on motion of the parties.

On July 8, 2019, another purported shareholder derivative complaint captioned *Scott Ludovissy and Ann Gordon Trammell v. Richard A. Fair, et al.* was filed against the same defendants in the same court. The *Ludovissy* complaint includes substantially similar factual allegations as the class action case and seeks to hold the defendants liable for allegedly causing the Company to make material misstatements.

On May 29, 2019, Bellicum was served with a second amended complaint indicating that the Company had been added as an additional defendant in an ongoing civil tort lawsuit, captioned *Kelly v. Children's Hospital of Los Angeles et al.*, filed in the Los Angeles County Superior Court, Case No. BC681477. On July 10, 2019, a third amended complaint was filed, which alleges claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability - failure to warn, breach of express warranty and products liability design or manufacturing defect. Plaintiffs are seeking unspecified monetary damages including punitive damages.

NOTE 14 - SUBSEQUENT EVENTS

On July 30, 2019, the Company exercised the first of its renewal options to extend its lease of office and laboratory space at its Houston, Texas facility for an additional year, commencing February 1, 2020. As a result of the lease renewal, the Company will record a ROU asset and lease liability of approximately $1.0 million in the third quarter of 2019.

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, 2018, filed with the SEC on March 12, 2019, or our Annual Report, as well as our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q, or this Quarterly Report.

Forward-Looking Statements

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

Overview

We are a clinical stage biopharmaceutical company focused on discovering and developing novel cellular immunotherapies by modulating T cell function via controllable molecular switches. We are focused on developing treatments for various forms of cancer, including both hematological cancers and solid tumors, as well as orphan inherited blood disorders. We are using our proprietary Chemical Induction of Dimerization, or CID, technology platform to engineer our product candidates with switch technologies that are designed to control components of the immune system in real time. By incorporating our CID platform, our product candidates may offer better efficacy and safety outcomes than are seen with current cellular immunotherapies.

We are developing next-generation product candidates in some of the most important areas of cellular immunotherapy, including chimeric antigen receptor T cell therapy, or CAR-T and hematopoietic stem cell transplantation, or HSCT. CAR-T cell therapies are an innovative approach in which a patient's T cells are genetically modified to carry chimeric antigen receptors, or CARs. While high objective response rates have been reported in some hematological malignancies, CAR-T cells have shown limited clinical efficacy in solid tumors due to limited proliferation and persistence of these cells and to immune suppressive factors found in the tumor microenvironment. Patients treated with CAR-T cell therapies can have serious and sometimes fatal toxicities, which include instances in which the CAR-T cells have caused high levels of cytokines due to over-activation, referred to as "cytokine release syndrome," or CRS, neurologic toxicities and cases in which CAR-T cells have attacked healthy organs. In each case, these toxicities have sometimes resulted in death. HSCT, also known as bone marrow transplantation, has for decades been curative for many patients with hematological cancers or orphan inherited blood disorders. However, adoption of HSCT to date has been limited by the risks of transplant-related morbidity and mortality from graft-versus-host-disease, or GvHD, and the potential for serious infections or cancer recurrence due to the lack of an effective immune system following a transplant.

Our proprietary CID platform is designed to address these challenges. Events inside a cell are 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 include these molecular switches in the appropriate immune cells and deliver the cells to the patient in the manner of conventional cellular immunotherapy. We have developed two such switches: an "activation switch," designed to stimulate activation, proliferation and persistence of the immunotherapy cells and provide other immunomodulatory benefits, and a "safety switch," designed to initiate programmed cell death, or apoptosis, of the immunotherapy cells. Each of our product candidates incorporates one or both of these switches, for enhanced, real time control of efficacy and safety:

- Our iMC activation switch (also known as inducible MyD88/CD40) incorporated into our GoCAR-T™ product candidates is designed to deliver enhanced efficacy versus 1st and 2nd generation CAR-T therapies through multiple mechanisms of action, including: 1) inducible activation, proliferation and persistence of the T cells; 2) modulation of the tumor microenvironment, overriding common inhibitory pathways like PD-1, PGE2, and TGF-β; and 3) enhancing host immune activity by inducing pro-inflammatory cytokines and chemokines to modulate the tumor microenvironment and recruit host immune cells. These effects are designed to be controlled through the scheduled administration of a course of rimiducid infusions that may continue until the desired patient outcome is achieved. In the event of emergence of side effects, the level of activation of the GoCAR-T cells is designed to be attenuated by extending the interval between rimiducid doses, potentially reducing the dosage per infusion, or suspending further rimiducid administration.

- Our CaspaCIDe™ safety switch (also known as inducible Caspase-9, or iC9) is incorporated into our rivo-cel product candidate, where it is inactive unless the patient experiences a serious side effect. In that event, a

small molecule dimerizer (e.g., rimiducid or temsirolimus) is administered to induce Caspase-9 and eliminate a majority of the cells, with the goal of attenuating the therapy and resolving the serious side effect.

- In addition, we have an active research effort to develop other advanced molecular switch approaches, including a "dual-switch" GoCAR-T that is designed to provide a user-controlled system for managing proliferation, persistence and safety of tumor antigen-specific CAR-T cells by incorporating both our iMC and CaspaCIDe switches, respectively.

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

- **Rivo-cel (rivogenlecleucel, formerly known as BPX-501)** is a product candidate intended to improve HSCT outcomes in the treatment of hematologic malignancies, including leukemias, lymphomas, and inherited blood disorders. Rivo-cel, which contains our proprietary CaspaCIDe safety switch, is an allogeneic polyclonal T cell therapy that is designed to improve transplant outcomes following an HSCT procedure, including enhancing the recovery of the donor immune system, providing protection against infections, and in the case of malignancies, protection against disease relapse. In cases of severe or uncontrolled GvHD (the primary risk of donor T cell infusions), elimination of a portion of the infused rivo-cel product is possible through the activation of the CaspaCIDe safety switch.

  The European Commission has granted orphan drug designations to rivo-cel for treatment in HSCT, and for activator agent rimiducid for the treatment of GvHD. Additionally, rivo-cel and rimiducid have received orphan drug status from the U.S. Food and Drug Administration, or the FDA, as a combination replacement T cell therapy for the treatment of immunodeficiency and GvHD after allogeneic HSCT.

  Based on interactions with the European Medicines Agency, or the EMA, we believe that data from the European arm of our BP-004 trial could form the basis of Marketing Authorisation Applications, or MAAs, for rivo-cel and rimiducid for the treatment of pediatric patients with high-risk hematological cancers or certain orphan inherited blood disorders. In addition, the EMA's Committee for Medicinal Products for Human Use, or the CHMP, has agreed that review and approval under "exceptional circumstances" may be suitable, recognizing that a randomized trial may not be feasible in the pediatric haploidentical HSCT setting. In place of a randomized trial, we are collecting data from the C/CP-004 study, a concurrent observational study in pediatric patients receiving a matched unrelated donor HSCT. In July 2019 we announced that the primary endpoint of event-free survival at 180 days in our BP-004 European registration trial for rivo-cel has been achieved. In addition, based on recent EMA feedback we are also planning to compare our BP-004 results to similar patients registered in the European Bone Marrow Transplant (EBMT) registry. We expect to file MAAs for European marketing approvals in late 2019 or early 2020.

  We recently initiated a pivotal randomized Phase 2/3 global clinical trial, called THRIVE, for rivo-cel in adult and adolescent patients 12 years and older with intermediate and high-risk acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). The trial will compare the primary endpoint of overall survival in patients receiving a haplo-transplant with rivo-cel versus the standard post-transplant cyclophosphamide haplo-transplant regimen. We submitted and reviewed the protocol with the FDA during a Type C meeting and began screening patients for the trial in December of 2018.

- **BPX-601** is an autologous GoCAR-T product candidate containing our proprietary iMC activation switch, designed to treat solid tumors expressing prostate stem cell antigen, or PSCA. We believe iMC enhances T cell proliferation and persistence, enhances host immune activity, and modulates the tumor microenvironment to improve the potential to treat solid tumors compared to traditional CAR-T therapies. A Phase 1/2 clinical trial, called BP-012, in patients with pancreatic, gastric, or prostate cancers expressing PSCA is ongoing and we expect to report updated data from this clinical trial in late 2019 or early 2020.

- **BPX-603** is a dual-switch GoCAR-T product candidate containing both the iMC activation and CaspaCIDe safety switches. BPX-603 is Bellicum's first controllable dual-switch GoCAR-T product candidate and is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen, or HER2.
  We expect IND clearance for BPX-603 in late 2019.

- **BPX-802** is a dual-switch GoCAR-T product candidate containing both the iMC and CaspaCIDe switches. BPX-802 is designed to target an antigen expressed in hematological malignancies. We expect to submit an IND for BPX-802 in late 2019.

We have developed efficient and scalable processes to manufacture genetically modified T cells of high quality, which are currently being used to produce rivo-cel and BPX-601 for our clinical trials. We are leveraging this know how in combination with our proprietary cellular control technologies, resources, capabilities and expertise for the manufacture of CAR-T product candidates to create and develop first and best-in-class product candidates.

We have established in-house cell manufacturing and vector production capabilities at our headquarters facility in Houston, Texas. We completed the facility build-out in early 2018, and we expect that our facilities will meet our U.S. clinical trial and early commercialization requirements. For the European market, we plan to continue working with established contract manufacturers.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2019 and 2018

The following table sets forth our results of operations for the three and six month periods ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
Total revenues	$ 1,391	$ 362	$ 1,029	$ 1,907	$ 516	$ 1,391
Operating expenses:						
Research and development	19,859	18,412	1,447	36,677	34,948	1,729
License fees	173	150	23	203	180	23
General and administrative	7,518	5,367	2,151	15,054	11,059	3,995
Total operating expenses	27,550	23,929	3,621	51,934	46,187	5,747
Loss from operations	(26,159)	(23,567)	(2,592)	(50,027)	(45,671)	(4,356)
Other income (expense):						
Interest income	311	437	(126)	721	704	17
Interest expense	(1,088)	(1,045)	(43)	(2,158)	(2,048)	(110)
Total other expense	(777)	(608)	(169)	(1,437)	(1,344)	(93)
Net loss	$ (26,936)	$ (24,175)	$ (2,761)	$ (51,464)	$ (47,015)	$ (4,449)

Grant Revenues

We recognized grant revenue of $1.4 million and $0.4 million, respectively, in the three months ended June 30, 2019 and 2018 from the CPRIT grant. We recognized grant revenue of $1.9 million and $0.5 million, respectively, in the six months ended June 30, 2019 and 2018 from the CPRIT grant. The increase in grant revenues was due to the initiation of additional clinical sites in 2019.

Research and Development Expenses

Research and development expenses increased $1.4 million in the three months ended June 30, 2019, compared with the three months ended June 30, 2018. The overall increase was due to increases in costs related to our GoCAR-T program, including expenses related to the filing of an IND for BPX-603 and increased expenses related to BPX-601 related to initiation of additional clinical sites. Expenditures related to rivo-cel and general research and development expenses were comparable in the three months ended June 30, 2019 and 2018.

Research and development expenses increased $1.7 million in the six months ended June 30, 2019, compared with the six months ended June 30, 2018. The overall increase was due to increases in costs related to our GoCAR-T program, including expenses related to the filing of an IND for BPX-603 and increased expenses related to BPX-601 related to initiation of additional clinical sites. Expenditures related to rivo-cel and general research and development expenses were comparable in the six months ended June 30, 2019 and 2018.

License Fees

We incur license fees under the terms of our various license agreements for intellectual property. License fees were comparable in the three and six months ended June 30, 2019 and 2018. See Note 12 to the audited financial statements in our Annual Report for additional information about our license agreements.

General and Administrative Expenses

General and administrative expenses increased $2.2 million in the three-month periods ended June 30, 2019, compared to the same periods in 2018. The increase is primarily due to an increase in personnel costs as well as increased commercialization activities.

General and administrative expenses increased $4.0 million in the six-month periods ended June 30, 2019, compared to the same periods in 2018. The increase is primarily due to an increase in personnel costs as well as increased commercialization activities.

Other Expense

Other expense consists of interest expense partially offset by interest income. Other expenses increased $0.2 million in the three months ended June 30, 2019 compared to the same period in 2018. Other expenses increased $0.1 million in the six months ended June 30, 2019 compared to the same period in 2018. In each case, the increase is primarily the result of higher interest costs on our debt, and lower investment income as a result of a reduced portfolio of investment securities. See Note 9 to the unaudited interim financial statements for additional information about debt obligations. See Note 5 to the unaudited interim financial statements for additional information about our investments in marketable securities. See Note 11 to the unaudited interim financial statements for additional information about the public offerings of our common stock.

Liquidity and Capital Resources

Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. At June 30, 2019 we had a significant accumulated deficit of approximately $472.0 million and working capital of approximately $37.0 million. During the six months ended June 30, 2019, we had a net loss of approximately $51.5 million and negative cash flows from operations of approximately $46.0 million. Our cash resources are primarily consumed by operating activities. Based on our research and development plans and our timing expectations related to the progress of our programs, we believe there is substantial doubt that our cash, cash equivalents, restricted cash and investment securities of $60.6 million as of June 30, 2019 will be sufficient to fund our operating expenses and capital expenditure requirements through one year from the financial statement issuance date.

We have had and will continue to have negative cash flows from operations, at least into the near future. We have previously funded, and plan to continue funding, our losses primarily through the sale of common stock, debt financings and grants. However, we cannot be certain that we will be able to obtain such funds required for our operations at terms acceptable to us or at all.

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

In August 2018, we filed a registration statement on Form S-3 for the offer and sale by the Company of its securities in one or more offerings for up to an aggregate maximum offering price of $150.0 million. The registration statement became effective August 23, 2018. We intend to obtain additional funding through the sale of our securities in one or more offerings, however we cannot assure you that we will be able to do so on favorable terms. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

On October 5, 2018, we entered into an Open Market Sale Agreement^{SM} with Jefferies LLC, as sales agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of the Company's common stock having an aggregate offering price of up to $60.0 million. The shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3. During the six months ended June 30, 2019, we received $9.0 million in net proceeds from the sale of 2,591,155 shares of our common stock in the open market. See Note 11 to the unaudited interim financial statements.

We may also consider new collaborations or selectively partnering our technology. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

Funding Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, facility costs and general overhead costs.

The successful development of any of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of rivo-cel, our GoCAR-T program or our other current and future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of product candidates.

C***ash Flows***

Our liquid assets, consisting of cash, restricted cash and investments in marketable securities declined $37.4 million in the six months ended June 30, 2019. We used $46.0 million to fund our operating activities, and $0.6 million to fund purchases of equipment, partially funding our uses of liquid resources with $0.1 million in proceeds from stock option exercises and the sale of common stock to the ESPP and $9.0 million in net proceeds from sales of our common stock through the Open Market Sale Agreement with Jefferies LLC.

In the comparable six months ended June 30, 2018, our liquid assets increased $28.8 million. We used $37.7 million to fund our operating activities, and $1.1 million to fund purchases of equipment, partially funding our uses of liquid resources with proceeds of $64.7 million from a public offering of our common stock, and from stock option exercises and the sale of common stock to the ESPP of $3.1 million.

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles requires us to make judgments, estimates and assumptions in the preparation of our consolidated financial statements and accompanying notes. Actual results could differ from those estimates. On January 1, 2019, we adopted ASC 842 “Leases,” which requires companies that lease assets to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. See Note 3 and Note 7 to the unaudited financial statements included in this Quarterly Report.

Recent Accounting Pronouncements

See Note 3 of the unaudited financial statements included in this Quarterly Report.

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

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to realize income from our investments without assuming significant risk. To achieve our objectives, we invest our cash allocated to fund our short-term liquidity requirements with prominent financial institutions in bank depository accounts and institutional money market funds. We invest the remainder of our cash in corporate debt securities and municipal bonds rated at least A quality or equivalent, U.S. Treasury notes and bonds and U.S. and state government agency-backed securities. As of June 30, 2019, we had cash, cash equivalents, restricted cash and investment securities of $60.6 million.

A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

We are exposed to changes in foreign currency exchange rates. We have contracts with entities in areas outside the U.S. that are denominated in a foreign currency. Most of our assets are located within the U.S. and are not subject to changes in foreign currency exchange rates, however a portion of our operating expense is denominated in foreign currencies, primarily pounds sterling and euros. We do not engage in any hedging transactions to mitigate the effect of changes in foreign currency exchange rates. While the effect of changes in foreign currency exchange rates has not had a material effect on our financial results or financial condition to date, we cannot assure you that fluctuations in foreign currency exchange rates will not have a material effect on our future results.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer, our Principal Financial Officer and our Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Principal Executive, Principal Financial and Principal Accounting Officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2019, our Principal Executive Officer, Principal Financial Officer and Principal Accounting 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

On February 6, 2018, a purported securities class action complaint captioned *Nipun Kakkar v. Bellicum Pharmaceuticals, Inc., Rick Fair and Alan Musso* was filed against us, and certain of our officers in the U.S. District Court for the Southern District of Texas, Houston Division. A second substantially similar class action was filed on March 14, 2018 by plaintiff Frances Rudy against the same defendants in the same court. The lawsuits purport to assert class action claims on behalf of purchasers of our securities during the period from May 8, 2017 through January 30, 2018. The complaints allege that the defendants violated the Exchange Act by making materially false and misleading statements concerning our clinical trials being conducted in the U.S. to assess rivo-cel as an adjunct T-cell therapy administered after allogeneic hematopoietic stem cell transplantation. The complaints purport to assert claims for violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaints seek, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief. On April 9, 2018, the District Court consolidated the two lawsuits under the *Kakkar* action. On March 26, 2019, the court appointed lead plaintiffs to represent the putative class and on May 15, 2019, plaintiffs filed an amended class action complaint. On July 5, 2019, defendants filed a motion to dismiss the amended complaint.

On July 19, 2018, a purported shareholder derivative complaint captioned *Seung Paik v. Richard A. Fair, et al.* was filed against the Company's directors and certain of the Company's officers in the U.S. District Court for the Southern District of Texas, Houston Division. The lawsuit purports to seek damages on behalf of the Company against the individual defendants for breach of fiduciary duty, waste, unjust enrichment and violations of Section 14(a) of the Exchange Act. The complaint alleges that the defendants caused or allowed the Company to disseminate misstatements regarding the clinical trials for rivo-cel and to make false or misleading statements in the proxy materials for the Company's 2017 annual meeting of stockholders. On October 3, 2018, the District Court granted the Company's motion to stay the *Paik* derivative cause of action until reinstated on motion of the parties.

On July 8, 2019, another purported shareholder derivative complaint captioned *Scott Ludovissy and Ann Gordon Trammell v. Richard A. Fair, et al.* was filed against the same defendants in the same court. The *Ludovissy* complaint includes substantially similar factual allegations as the class action case and seeks to hold the defendants liable for allegedly causing the Company to make material misstatements.

On May 29, 2019, Bellicum was served with a second amended complaint indicating that the Company had been added as an additional defendant in an ongoing civil tort lawsuit, captioned *Kelly v. Children's Hospital of Los Angeles et al.*, filed in the Los Angeles County Superior Court, Case No. BC681477. On July 10, 2019, a third amended complaint was filed, which alleges claims for wrongful death, negligence, breach of fiduciary duty, fraud, medical battery on decedent, medical battery on individual plaintiffs, products liability - failure to warn, breach of express warranty and products liability design or manufacturing defect. Plaintiffs are seeking unspecified monetary damages including punitive damages.

Item 1A. Risk Factors

Our business and results of operations are subject to a number of risks and uncertainties. You should carefully consider the following risk factors, as well as the other information in this report, and in our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect additional risk factors since the issuance of our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the Securities and Exchange Commission on March 12, 2019, or our Annual Report.

Risks Related to Our Business and Industry

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

We are a clinical stage biopharmaceutical company with a limited operating history. We are not profitable, have no products approved for commercial sale and have incurred significant losses since our inception in 2004. To date, we have financed our operations primarily through equity and debt financings. For the six months ended June 30, 2019 and 2018, we reported a net loss of $51.5 million and $47.0 million, respectively. As of June 30, 2019, we had an accumulated deficit of $472.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

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

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require significant funding to complete the development and commercialization of our product candidates. If we fail to obtain additional financing, we may have to delay, reduce or eliminate our development programs or commercialization efforts.

This report includes disclosures stating that our existing cash resources and our accumulated stockholders' deficit raise substantial doubt about our ability to continue as a going concern. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates and other research and development programs.

As of June 30, 2019, we had cash, restricted cash and cash equivalents of approximately $46.9 million and total investments in marketable securities of $13.7 million. We maintain our cash, cash equivalents, and marketable securities with high quality, accredited financial institutions. These amounts at times may exceed federally insured limits. Cash, restricted cash and cash equivalents and investments in marketable securities, or a total of $60.6 million, may not be sufficient to fund our operating expenses and capital expenditure requirements through one year from the financial statement issuance date. Our cash position, together with our short-term debt obligations and anticipated operating losses due to increased effort on commercialization and research and development projects raises substantial doubt about our ability to continue as a going concern.

We expect to finance future cash needs through public or private equity offerings, debt financings, strategic partnerships and alliances or licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Subject to limited exceptions, our loan agreement with Oxford Finance prohibits us from incurring indebtedness without the prior written consent of Oxford. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we will need to significantly delay, scale back or discontinue the development or commercialization of our product candidates. We also could be required to:

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

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common shares to decline. In the event that sufficient additional funds are not obtained through public or private equity offerings, debt financings, strategic partnerships and/or alliances or licensing arrangements on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our development programs, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will continue to have substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders.

The EMA and/or FDA may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our business and future success depends, in part, on our ability to obtain regulatory approval of and then successfully commercialize rivo-cel and our other clinical product candidates. All of our product candidates, including rivo-cel, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, and access to sufficient commercial manufacturing capacity and significant marketing efforts before we can expect to generate any revenue from product sales.

Rivo-cel and our other product candidates could fail to receive regulatory approval for many reasons, including the following:

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

We plan to initially seek approval for rivo-cel and rimiducid from the EMA for the treatment of pediatric patients undergoing haploidentical (partially matched) hematopoietic stem cell transplants, or HSCT, and to submit the MAAs for this indication in 2019. While we expect that the European arm of our BP-004 trial could serve as the registrational trial for these MAAs, this clinical trial was not originally designed for that purpose. We cannot be certain that our preclinical and clinical trial package for the MAAs will be sufficient for approval of rivo-cel for multiple reasons including issues related to trial conduct and analysis; limitations of data available from pre-clinical and Phase 1/2 studies; or issues related to CMC efforts to date. We have sought to avoid or remediate potential issues but we cannot be sure that such efforts will be effective or sufficient. Further, we cannot assure you that the EMA or any other regulatory agency will agree that rivo-cel provides a clinically meaningful and differentiated therapeutic benefit or that the side effects experienced in our clinical trials yield an acceptable benefit/risk ratio in the opinion of the EMA or other regulatory agencies. If the MAAs for rivo-cel are deficient, we will incur additional expense to address the deficiencies, which may require additional clinical trials, and the commercialization of rivo-cel will be delayed. This would adversely affect our business, results of operations and prospects.

We are currently conducting a pivotal randomized Phase 2/3 global clinical trial, called THRIVE, for rivo-cel in adult and adolescent patients 12 years and older with intermediate and high-risk AML or MDS. This trial is intended to provide the basis for approval of rivo-cel in the U.S. and expansion of the label in Europe. However, the general approach for FDA approval of a new biologic or drug is to require dispositive data from two adequate and well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that a single Phase 3 clinical trial strategy is warranted given the limited alternatives for patients for whom rivo-cel therapy is potentially beneficial, but the FDA may ultimately require more than one Phase 3 clinical trial and may limit clinical trial designs allowed to serve as a registration trial.

In addition, because rivo-cel is our most advanced product candidate, and because many of our other product candidates are based on similar technology, if rivo-cel encounters safety or efficacy problems, developmental delays, regulatory issues or other problems, our development plans and business for our other product candidates would be significantly harmed.

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

We have devoted substantially all of our financial resources and efforts to developing our proprietary CID technology platform, identifying potential product candidates and conducting preclinical studies and clinical trials. We are in the early stages of developing our product candidates, and we have not completed development of any products. Our ability to generate revenue

and achieve profitability depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of products for the foreseeable future. Our ability to generate future revenues from product sales depends heavily on our success in:

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

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

Our CID technology is novel and largely unproven.

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

T cell therapies are novel and present significant challenges.

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

- obtaining regulatory approval, as the EMA, FDA and other regulatory authorities have limited experience with commercial development of T-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 T cells into the patient;
- educating medical personnel regarding the potential safety benefits, as well as the challenges, of incorporating our product candidates into their treatment regimens;
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and
- the availability of coverage and adequate reimbursement from third-party payors for our novel and personalized therapy.

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

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

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

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

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

Phase 1 clinical trials are ongoing for BPX-601 for the treatment of pancreatic, gastric, and prostate cancers and BPX-701 for the treatment of refractory or relapsed AML/MDS. We have not initiated clinical trials for any additional preclinical product candidates and we may not be able to commence clinical trials on the time frames we expect. As these product candidates are in early stages of development, we face significant uncertainty regarding how effective and safe they will be in human patients and the results from preclinical studies, such as *in vitro* and *in vivo* studies, of BPX-601 and BPX-701 and our other preclinical programs may not be indicative of the results of clinical trials of these product candidates. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

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

We believe that our CID platform, which serves as the foundation of our CaspaCIDe and GoCAR-T technologies, can be further leveraged to discover other novel technologies, therapeutic applications and market opportunities. For example, we are developing new molecular switches and dual-switch systems to provide greater control over cellular immunotherapy. We are at

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

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

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, and strategic partners to conduct our preclinical and clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP 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 cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

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

- the patient eligibility criteria defined in the protocol;

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

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

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

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

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

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

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

Undesirable side effects observed in our clinical trials, whether or not they are caused by our product candidates, could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities for a number of reasons. In addition, because the patients in our clinical trials are suffering from life-threatening diseases, are often suffering from multiple complicating conditions and, in the case of transplant patients, are in a position of extreme immune deficiency at the time that they receive our therapy, it may be difficult to accurately assess the relationship between our product candidates and adverse events experienced by very ill patients. For example, in January 2018, we announced that we had received notice from the FDA that a clinical hold had been placed on our U.S. clinical trials of rivo-cel following three cases of encephalopathy deemed as possibly related to rivo-cel. In April 2018, we announced that the FDA had lifted the clinical hold following consultation between us and the FDA and agreement on amendments to the study protocols, including guidance on monitoring and management of certain neurologic adverse events. The FDA or foreign regulatory authorities, including in Europe, could in the future take similar actions, which would harm our business. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

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

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

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

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

Specifically, genetically engineering T cells faces significant competition from multiple companies, including

Adaptimmune, Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Autolus Therapeutics plc, bluebird bio, Inc., Celgene Corporation, Cellectis SA, Cell Medica Limited, Celyad S.A., Fate Therapeutics Inc., GlaxoSmithKline plc, Intrexon Corporation, Immune Design Corp., Gilead Sciences, Inc., Iovance Biotherapeutics, Inc., Kiadis Pharma B.V., Lyell Immunopharma, Inc., Medigene AG, MolMed S.p.A., Mustang Bio, Inc., Novartis AG, Poseida Therapeutics, Precision Biosciences, Inc., Unum Therapeutics, and Ziopharm Oncology.

Our rivo-cel product candidate is designed to improve HSCT outcomes by addressing risks of disease relapse, infections and GVHD control. Other companies are developing product candidates to improve the outcome of HSCT, including Kiadis Pharma Netherlands B.V., Magenta Therapeutics, Inc., MolMed S.p.A., and Gamida Cell Ltd. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price

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

Rivo-cel and rimiducid have received orphan drug designation, but we may be unable to maintain or receive the benefits associated with orphan drug status, including market exclusivity.

The FDA or EMA grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in that jurisdiction a drug or biologic for a disease or condition will be recovered from sales in that jurisdiction for that drug or biologic. If a product that has orphan drug designation subsequently receives the first FDA or EMA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA or EMA may not approve any other applications, including a full authorization to market the same biologic for the same indication for seven years in the U.S. and for 10 years in Europe, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

The EMA has granted orphan drug designations to rivo-cel for treatment following HSCT, and for the activator agent, rimiducid for the treatment of GvHD. Additionally, rivo-cel and rimiducid have received orphan drug designation from the FDA, as a combination replacement T-cell therapy for the treatment of immunodeficiency and GvHD after allogeneic HSCT. However, in each case, exclusive marketing rights may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the EMA or FDA, as applicable, later determines that the request for designation was materially defective or if we are unable to assure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Although the respective designations may provide seven years of market exclusivity in the U.S. and ten years of market exclusivity in Europe, the designations are subject to certain limited exceptions. Therefore, even though we have obtained orphan drug designation for certain indications, we may be unable to obtain orphan drug designation for our future product candidates and we may not be the first to obtain marketing approval for any particular orphan indication.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

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

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and restricted stock units, or RSUs, that vest over time. The value to employees of stock options and RSUs that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled scientific and medical personnel.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, including the preparations for a potential launch of rivo-cel in Europe, we expect to need additional managerial, medical, operational, sales, marketing, market access financial and other personnel. Future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures.

There are a small number of individuals with experience in cell therapy and the competition for these individuals is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. The services of independent organizations, advisors and consultants may not continue to be available to us on a timely basis when needed, and we may not be able to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. We may not be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates, and, accordingly, may not achieve our research, development and commercialization goals.

The terms of our debt facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the debt facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

In December 2017, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, that is secured by a lien covering substantially all of our assets, excluding intellectual property, but including proceeds from the sale, license, or disposition of our intellectual property, under which we have borrowed $35.0 million. The loan and security agreement governing the debt facility requires us to comply with a number of covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; transfer a material portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions. Our intellectual property also is subject to customary negative covenants. In addition, subject to limited exceptions, Oxford could declare an event of default upon the occurrence of any event that it interprets as having a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the loan and security agreement or upon the collateral or Oxford's liens on the collateral under the agreement, thereby requiring us to repay the loan immediately, together with a prepayment charge of up to 3% of the then outstanding principal balance and an end-of-term charge. Although, in and of itself, the occurrence of adverse results or delays in any clinical study or the denial, delay or limitation of approval of or taking of any other regulatory action by the FDA or another governmental entity will not constitute a material adverse effect under our loan and security agreement with Oxford, Oxford may determine that such an event together with contemporaneous events or circumstances constitutes a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the loan and security agreement. If we default under the facility, Oxford may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, Oxford could take control of our pledged assets and we could immediately cease operations. If we were to renegotiate our agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, Oxford's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Oxford of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness under the loan and security agreement with Oxford. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

If the London Inter-Bank Offered Rate, or LIBOR, is discontinued, interest payments under our credit agreement may be calculated using another reference rate.

In July 2017, the Chief Executive of the United Kingdom Financial Conduct Authority, or FCA, which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR by the end of 2021. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index

calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. U.S. dollar LIBOR is used as a benchmark rate in our credit agreement with Oxford Finance LLC, and such credit agreement does not provide fallback language for all circumstances in which U.S. dollar LIBOR ceases to be published. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not known. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including our credit agreement with Oxford Finance LLC, or difficult and costly processes to amend such documentation. As a result, our ability to refinance our credit agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which would adversely affect the operations of our business.

We need to oversee manufacturing of a complex supply chain of cellular therapy product candidates, viral vectors and small molecule drugs. We expect to rely on third parties to manufacture a substantial portion of our clinical cell therapy product candidates, viral vectors and small molecule supplies in Europe.

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

We do not currently own a European facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture supplies and process our product candidates, which is and will need to be done on a patient-by-patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale. We may not be able to scale patient-by-patient manufacturing and processing to satisfy clinical or commercial demands for any of our product candidates. In addition, our anticipated reliance on a limited number of third-party manufacturers for manufacturing in Europe exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and any replacement contractor must be approved by the EMA. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory approval, if any.
- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by regulatory agencies to ensure strict compliance with cGMP and other government regulations and standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party manufacturers could breach or terminate their agreement with us.

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

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

The United Kingdom is currently negotiating the terms of its exit from the European Union, often referred to as "Brexit", which is scheduled for October 2019. In November 2018, the United Kingdom and the European Union agreed upon a draft withdrawal agreement, including a transition period to allow time for a future trade agreement to be agreed. To date, withdrawal

agreements have been rejected by the U.K. Parliament, creating significant uncertainty about the terms under which the United Kingdom will leave the European Union. If no agreement can be reached and the United Kingdom leaves the European Union with no agreement, there will be a period of considerable uncertainty, particularly with respect to the free movement of goods, services, people, data and capital between the United Kingdom and the European Union. We may also face new regulatory costs and challenges that could have a material adverse effect on our operations. In this regard, the EMA has already issued a notice reminding marketing authorization holders of centrally authorized medicinal products for human and veterinary use of certain legal requirements that need to be considered as part of Brexit. Examples of the impact Brexit could have on our business, financial condition or results of operations include:

- regulatory uncertainty, notably United Kingdom legal entities (like our subsidiary Bellicum Pharma Limited) will no longer be eligible to apply for or hold centralized drug applications such as orphan drug designations and Marketing Authorization Applications;

- legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws and directives to replace or replicate, or where previously implemented by enactment of United Kingdom laws or regulations, to retain, amend or repeal; and

- various geopolitical forces that may impact the global economy and our business, including, for example, other E.U. member states in which we have operations proposing referendums to, or electing to, exit the European Union.

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

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

We have begun limited in-house manufacturing at our own manufacturing facility for supply of U.S. clinical product candidate requirements, and anticipated using this facility to meet US commercial cell therapy product requirements. This will require significant resources and expertise and we may fail to successfully complete or grow our manufacturing capabilities as planned, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We have completed the buildout of manufacturing space at our leased headquarters in Houston, Texas and have begun in-house clinical supply manufacturing. We also rely on outside vendors to manufacture clinical supplies and process intermediates to support our clinical trials. Internal manufacturing for clinical trial and future commercial use will rely upon finding personnel with appropriate background and training to staff and operate the facility on a daily basis. Should we be unable to find these individuals, we may need to rely on external contractors longer than anticipated, and train additional personnel to fill the needed roles. There are a small number of individuals with experience in cell therapy and the competition for these individuals is high.

Specifically, the operation of a cell-therapy manufacturing facility is a complex endeavor requiring knowledgeable individuals who have successful previous experience in cleanroom environments. Cell therapy facilities, like other biological agent manufacturing facilities, require appropriate commissioning and validation activities to demonstrate that they operate as designed. Additionally, each manufacturing process must be proven through the performance of process validation runs to guarantee that the facility, personnel, equipment, and process work as designed. While we have developed our own manufacturing processes using an in-house team, there is timing risk associated with increased in-house product manufacture.

The manufacture of our product candidates is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in our manufacturing facilities, the manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. It is possible that stability or other issues relating to the manufacture of our product candidates could occur in the future.

Our product candidates currently are and will continue to be manufactured on a patient-by-patient basis. We have not yet manufactured our clinical trial product candidates on a large scale, nor on a commercial scale, and may not be able to achieve large scale clinical trial or commercial manufacturing and processing on our own to satisfy expected clinical trial or commercial demands for any of our product candidates. While we believe that our current manufacturing and processing approaches are appropriate to support our clinical product development, we have limited experience in managing the T cell engineering process, and our processes may be more difficult or more expensive than anticipated. The manufacturing processes employed by us may not result in product candidates that will be safe and effective.

Our manufacturing operations will be subject to review and oversight by the FDA upon commencement of the manufacturing of our product candidates for our planned Phase 3 clinical trials. We will have to complete facility validation, and must obtain approval from the FDA prior to licensure to manufacture our product candidates for these trials. Even if approved, we will continue to be subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with current good manufacturing practices and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

We do not yet have sufficient information to reliably estimate the cost of commercial manufacturing and processing of our product candidates. The actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

We also may fail to manage the logistics of collecting and shipping patient material to our manufacturing site and shipping the product candidate back to the patient. Logistical and shipment delays and problems, whether or not caused by us or our vendors, could prevent or delay the delivery of product candidates to patients.

In addition, it is possible that we could experience manufacturing difficulties in the future due to resource constraints or because of labor disputes. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients could be materially adversely affected.

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

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

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

We currently have a limited commercial organization and as a company have no experience in marketing cell therapy products. If we are unable to enhance our market access, marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have established a European subsidiary, Bellicum Pharma Limited, that is focused on preparations for potential commercialization of rivo-cel in Europe, if approved. We have hired an experienced General Manager with commercial and operational experience and are hiring additional professionals experienced in market access, marketing and sales of pharmaceutical and biotechnology products. This team has very little experience in commercializing cell therapy products such as rivo-cel and the Company has never successfully commercialized any product candidate. We intend to expand and enhance our in-house marketing organization and plan to recruit a sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and marketing, sales and other commercial personnel.

If we are unable or decide not to expand our internal sales, marketing, market access and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We may not be able to expand our in-house market access, marketing, sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in Europe or the U.S.

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our operations, and those of our clinical investigators, contractors and consultants, could be subject to power shortages, telecommunications failures, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient by patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

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;

- 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 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, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as require certain manufacturers and group purchasing organizations to report annually ownership and investment interests held by 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, Brexit could lead to further legislative and regulatory changes. While the Data Protection Act of 2018, that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under the GDPR. We may incur liabilities, expenses, costs, and other operational losses under the GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

Additionally, we are subject to state and foreign equivalents of each of the 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, individual imprisonment, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop, alone or with corporate collaborators. We currently carry $10.0 million of 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.

Comprehensive tax reform could adversely affect our business and financial condition.

On December 22, 2017, the president of the United States signed into law the Tax Cuts and Jobs Act which significantly revises the Internal Revenue Code of 1986, as amended. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. The impact of the Tax Cuts and Jobs Act on holders of our securities is likewise uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our securities.

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

As of December 31, 2018, we had aggregate U.S. and U.K. net operating loss carryforwards of approximately $303.0 million and $2.4 million, respectively, and aggregate U.S. federal and Texas state research and development credits of approximately $8.9 million and $4.7 million, respectively. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, federal net operating losses incurred in taxable years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal net operating losses generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced one or more ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Government Regulation

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

We have not previously submitted an MAA or a BLA to the EMA or FDA, or similar approval filings to other foreign authorities. An MAA/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, the FDA has limited experience with commercial development of T cell therapies for cancer. In addition, the cell and gene therapy office of the FDA has limited experience with combination products that include a small molecule component. Approval of our product candidates, including rivo-cel, will require this FDA office to consult with another division of the FDA, which may result in further challenges in obtaining regulatory approval, including in developing final product labeling. The regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

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

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

For example, in January 2018 we announced that we had received notice from the FDA that a clinical hold had been placed on our U.S. clinical trials of rivo-cel following three cases of encephalopathy deemed as possibly related to rivo-cel. In April 2018, we announced that the FDA had lifted the clinical hold following consultation between us and the FDA and agreement on amendments to the study protocols, including guidance on monitoring and management of certain neurologic adverse events.

Also, before a clinical trial can begin at an NIH-funded institution, that institution's independent institutional review board, or IRB, and its Institutional Biosafety Committee must review the proposed clinical trial to assess the safety of the trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, the Data Monitoring Committee for such clinical trial, or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

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

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

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

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The EMA and 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 EMA, 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 cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the EMA or 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 EMA's, 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 Europe, the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

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

The use of engineered T cells as a potential cancer treatment 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. We expect physicians in the large bone marrow transplant centers to be particularly influential and we may not be able to convince them to use our product candidates for many reasons. 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 EMA, FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the EMA, 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 availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness and ability of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- confusion or lack of understanding regarding the effects of rimiducid and the timing and size of dosing of rimiducid after immune cell therapy; and
- the effectiveness of our sales and marketing efforts.

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

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

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

Market acceptance and sales of our product candidates will depend in large part on global reimbursement policies and may be affected by future healthcare reform measures, both in the United States and other key international markets. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, successful commercialization of our products will depend in part on the availability of governmental and third-party payor reimbursement for the cost of our product candidates and/or payment to the physician for administering our product candidates. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. One third-party payor's decision to cover a particular medical product or service does not assure that other payors will also provide coverage for the medical product or service, or to provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained. Further, a third-party payor's decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. The market for our product candidates will depend significantly on access to third-party payors' formularies or lists of treatments for which third-party payors provide coverage and reimbursement. Third party payors may also have difficulty in determining the appropriate coverage of our product candidates, if approved, including rivo-cel, 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 product candidates like rivo-cel and our other product candidates. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for treatments based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the EEA and other significant or potentially significant markets for our product candidate, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in Canada and the EEA will put additional pressure on product pricing, coverage, reimbursement and utilization, which may adversely affect our product sales and results of operations. These pressures can arise from policies and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, coverage and reimbursement policies and pricing in general. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following: (i) an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs; (ii) an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively; (iii) a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (iv) extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (v) expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability; (vi) expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; (vii) expansion of health care fraud and abuse laws, including the federal civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance; and (viii) a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment there have been judicial and Congressional challenges to other aspects of the PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by 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, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress may consider other legislation to replace elements of the PPACA. We continue to evaluate the potential effect of the possible repeal and replacement of the PPACA may have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA. 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 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers.

Further, recently there has been heightened governmental scrutiny in the United States over the manner in which drug manufacturers set prices for their marketed products, in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal and state healthcare reform measures will be adopted in the future, any of which could result in reduced demand for our products or other adverse effects on our business.

In the EU, the success of rivo-cel and our other product candidates, if approved, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use therapies that are not reimbursed by the government. Negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the EEA have increased the amount of discounts required on pharmaceutical products and other therapies, and we expect these discounts to continue as countries attempt to manage healthcare expenditures, especially in light of current economic conditions. As a result of these pricing practices, it may become difficult to achieve profitability or expected rates of growth in revenue or results of operations. Any shortfalls in revenue could adversely affect our business, prospects, financial condition and results of operations.

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

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

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

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

We are subject to 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 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 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. When it becomes effective on January 1, 2020, the CCPA will require 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. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. 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 U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

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

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

Any termination of these agreements, or other agreements to which we are a party could result in the loss of significant rights and could harm our ability to commercialize our product candidates. See "Item 1. Business—Our License Agreements" in our Annual Report on Form 10-K for the year ended December 31, 2018 for additional information regarding our license agreements.

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

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

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

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

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

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

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

- if and when patents will issue;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

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

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

Patent coverage on the dimerization molecule rimiducid, expired in February 2016. Therefore, any additional barriers to entry for competitors to use rimiducid may not be effective in preventing such use. There remain significant questions regarding how the FDA will interpret the ‘biosimilar’ provisions recently added to the PHSA as applied to complex biological products such as our investigational products. Depending on how the FDA ultimately interprets these provisions, if our investigational products incorporating rimiducid receive FDA approval through a combination product BLA, then a biosimilar of these combination products could be approved by the FDA twelve years from the date that we receive FDA approval for our application. In addition, if a third party were able to obtain FDA approval of a new drug application for rimiducid on its own, then it is possible that other third parties could later seek approval of an abbreviated new drug application for rimiducid.

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

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

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

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

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

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

We are aware of third-party patents having claims that may be considered as being directed to single-chain antibody fragments that bind to PSCA and these patents may be considered relevant to BPX-601 and related technologies we are developing. We currently are evaluating whether or not we need to obtain rights to these patents under a license, and if it is determined that we need to obtain such rights, whether these rights can be obtained. We are also aware of third-party patent applications having claims that may be considered as being directed to cellular therapy constructs utilizing a heterodimer domain for activation of iC9. We are monitoring these applications and if they are granted with the claims as drafted they may be relevant to our potential dual-switch product candidates containing such a heterodimer activation domain.

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

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

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

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

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

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

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. It also is possible that a competitor we sue for patent infringement could countersue us for allegedly infringing one or more of their own patents or one or more patents they licensed from another entity. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

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

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

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us, and (2) patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

We are subject to securities litigation, which is expensive and could divert management attention.

Our share price has been and may continue to be volatile. Companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We are a target of this type of litigation. For example, on February 6, 2018, a purported securities class action complaint captioned *Nipun Kakkar v. Bellicum Pharmaceuticals, Inc., Rick Fair and Alan Musso* was filed against us, and certain of our officers in the U.S. District Court for the Southern District of Texas, Houston Division. A second substantially similar class action was filed on March 14, 2018 by plaintiff Frances Rudy against the same defendants in the same court. The lawsuits purport to assert class action claims on behalf of purchasers of our securities during the period from May 8, 2017 through January 30, 2018. The complaints allege that the defendants violated the Exchange Act by making materially false and misleading statements concerning our clinical trials being conducted in the U.S. to assess rivo-cel as an adjunct T-cell therapy administered after allogeneic hematopoietic stem cell transplantation. The complaints purport to assert claims for violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaints seek, on behalf of the purported class, an unspecified amount of monetary damages, interest, fees and expenses of attorneys and experts, and other relief. On April 9, 2018, the District Court consolidated the two lawsuits under the *Kakkar* action. On March 26, 2019, the court appointed lead plaintiffs to represent the putative class and on May 15, 2019, the plaintiffs filed an amended class action complaint. On July 5, 2019, defendants filed a motion to dismiss the amended complaint.

On July 19, 2018, a purported shareholder derivative complaint captioned *Seung Paik v. Richard A. Fair, et al.* was filed against the Company's directors and certain of the Company's officers in the U.S. District Court for the Southern District of Texas, Houston Division. The lawsuit purports to seek damages on behalf of the Company against the individual defendants for breach of fiduciary duty, waste, unjust enrichment and violations of Section 14(a) of the Exchange Act. The complaint alleges that the defendants caused or allowed the Company to disseminate misstatements regarding the clinical trials for rivo-cel and to make false or misleading statements in the proxy materials for the Company's 2017 annual meeting of stockholders. On October 3, 2018, the District Court granted the Company's motion to stay the derivative cause of action until reinstated on motion of the parties.

On July 8, 2019, another purported shareholder derivative complaint captioned *Scott Ludovissy and Ann Gordon Trammell v. Richard A. Fair, et al.* was filed against the same defendants in the same court. The *Ludovissy* complaint includes substantially similar factual allegations as the class action case and seeks to hold the defendants liable for allegedly causing the Company to make material misstatements.

Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

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

Prior to our December 2014 IPO, there was no public market for our common stock. The trading price of our common stock is likely to continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including market conditions in general and a limited trading volume for our shares. In addition to the factors discussed in this "Risk Factors" section and elsewhere in our Annual Report, these factors include:

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

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

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

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of our loan and security agreement with Oxford restrict our ability to declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

As of July 31, 2019, our executive officers, directors and 5% stockholders beneficially owned approximately 17.0% of our outstanding voting shares. Therefore, these stockholders may have the ability to significantly influence us through this ownership position. These stockholders may be able 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.

We are an emerging growth company and a smaller reporting company and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company through 2019, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (a) December 31, 2019, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, or (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We expect to continue to take advantage of some, but not all, of the available exemptions. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, or SRC, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues *and* (2) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles, or US GAAP, or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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.

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

Certain holders of our outstanding shares of common stock, are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or 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 2014 Equity Incentive Plan, as amended, or the EIP. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

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

We expect that significant additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts for rivo-cel, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including pursuant to our shelf registration statement on Form S-3 that we filed with the SEC. In addition, on October 5, 2018, we entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent, pursuant to which we may offer and sell, from time to time, shares of common stock with an aggregate offering price of up to $60.0 million. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Any such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the existing holders of our common stock.

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

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

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

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

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

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

A severe or prolonged economic downturn could result in a variety of risks to our business, including reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our relationships with our contractors and potential collaboration partners. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, Brexit has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision remains uncertain. A process of negotiation will determine the future terms of the United Kingdom’s relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our financial condition.

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

None.

Purchase of Equity Securities

We did not purchase any of our registered securities during the period covered by this Quarterly Report.

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 INDEX

Exhibit number	Description of exhibit
3.1[(1)]	Amended and Restated Certificate of Incorporation of the Registrant.

3.2[2]	Amended and Restated Bylaws of the Registrant.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2[3]	Form of Common Stock Certificate of the Registrant.

4.3[4]	Second Amended and Restated Investor Rights Agreement by and among the Registrant and certain of its stockholders, dated August 22, 2014.
4.4[5]	Registration Rights Agreement by and among the Registrant and Baker Brothers Life Sciences, LP, and two of its affiliated funds, dated January 15, 2016.
10.1[6]	Bellicum Pharmaceuticals, Inc. 2019 Equity Incentive Plan and forms of stock option grant notice, stock option agreement and notice of exercise, and forms of restricted stock award notice and restricted stock award agreement thereunder.
10.2+	Bellicum Pharmaceuticals, Inc. 2014 Equity Incentive Plan, as amended.
31.1	Certification of Chief Executive 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.
31.2	Certification of Chief 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	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
+	Indicates management contract or compensatory plan.
*	Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant as determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.
(1)	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 23, 2014 (File No. 001-36783).
(2)	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 (File No. 001-36783).
	Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-200328), as amended, originally filed with the SEC on November 18, 2014.
(3)	
(4)	Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-200328), as amended, originally filed with the SEC on November 18, 2014.
(5)	Incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2016 (File No. 001-36783).

	Incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8, filed with the SEC on July 23, 2019 (File No. 333-232774).
(6)	

Signatures

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

Bellicum Pharmaceuticals, Inc.

Date: August 5, 2019

By: /s/ Richard A. Fair

Richard A. Fair

President and Chief Executive Officer

Date: August 5, 2019

By: /s/ Atabak Mokari

Atabak Mokari

Chief Financial Officer

Date: August 5, 2019

By: /s/ Rosemary Y. Williams

Rosemary Y. Williams

Principal Accounting Officer

Exhibit 31.1

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

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

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

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

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

Date: August 5, 2019

By: /s/ Richard A. Fair

Richard A. Fair
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF 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, Atabak Mokari, certify that:

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

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

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

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

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

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

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

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

Date: August 5, 2019

By: /s/ Atabak Mokari
Atabak Mokari
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 (the "Report") of Bellicum Pharmaceuticals, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, the undersigned, in their capacities as officers of the Registrant, do each hereby certify, that, to the best of such officer's knowledge:

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

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

/s/ Richard A. Fair

Richard A. Fair
President and Chief Executive Officer
(Principal Executive Officer)
August 5, 2019

/s/ Atabak Mokari

Atabak Mokari
Chief Financial Officer
(Principal Financial Officer)

August 5, 2019

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.