UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2020

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 001-38596

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-2082553**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

500 Unicorn Park
Woburn MA 01801
(Address of principal executive offices)
(Zip Code)
(781) 222-9600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 o
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

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

The number of shares of the registrant's Common Stock, par value $0.001 per share, outstanding as of August 4, 2020 was 40,288,329.

REPLIMUNE GROUP, INC.

FORM 10-Q

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements.

REPLIMUNE GROUP, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	June 30, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 104,797	$ 59,500
Short-term investments	156,962	109,055
Research and development incentives receivable	2,951	2,962
Prepaid expenses and other current assets	3,031	2,734
Total current assets	267,741	174,251
Property, plant and equipment, net	7,357	6,860
Research and development incentives receivable - long term	679	
Restricted cash	1,636	1,636
Right-to-use asset - operating leases	5,852	4,425
Right-to-use asset - financing leases	46,318	46,925
Total assets	$ 329,583	$ 234,097
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,480	$ 3,434
Accrued expenses and other current liabilities	5,139	5,156
Operating lease liabilities, current	830	873
Financing lease liabilities, current	2,429	2,411
Total current liabilities	11,878	11,874
Long term debt, net of debt discount	9,764	9,801
Operating lease liabilities, non-current	5,210	3,737
Financing lease liabilities, non-current	24,917	24,967
Total liabilities	51,769	50,379
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, $0.001 par value; 150,000,000 shares authorized as of June 30, 2020 and March 31, 2020; 40,280,420 and 36,668,743 shares issued and outstanding as of June 30, 2020 and March 31, 2020, respectively	40	37
Additional paid-in capital	408,755	296,961
Accumulated deficit	(129,791)	(112,298)
Accumulated other comprehensive loss	(1,190)	(982)
Total stockholders' equity	277,814	183,718
Total liabilities and stockholders' equity	$ 329,583	$ 234,097

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

REPLIMUNE GROUP, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 12,157	$ 7,457
General and administrative	5,676	3,450
Total operating expenses	17,833	10,907
Loss from operations	(17,833)	(10,907)
Other income:		
Research and development incentives	686	621
Investment income	527	687
Interest expense on finance lease liability	(561)	-
Interest expense on debt obligations	(284)	-
Other income	(28)	91
Total other income, net	340	1,399
Net loss attributable to common stockholders	$ (17,493)	$ (9,508)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.44)	$ (0.30)
Weighted average common shares outstanding, basic and diluted	39,862,319	31,661,430

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

REPLIMUNE GROUP, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Amounts in thousands)
(Unaudited)

	Three Months Ended June 30,	
	2020	**2019**
Net loss	$ (17,493)	$ (9,508)
Other comprehensive loss:		
Foreign currency translation loss	(12)	(182)
Net unrealized gain (loss) on short-term investments, net of tax	(196)	65
Comprehensive loss	$ (17,701)	$ (9,625)

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

REPLIMUNE GROUP, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share amounts)
(Unaudited)

	Common stock		Additional paid-in	Accumulated	Accumulated other comprehensive	Total stockholders'
	Shares	Amount	capital	deficit	loss	equity
Balances as of March 31, 2020	36,668,743	$ 37	$ 296,961	$ (112,298)	$ (982)	$ 183,718
Issuance of prefunded warrants to purchase common stock, net of $2,100 issuance costs	-	-	32,900	-	-	32,900
Issuance of common stock, net of issuance costs and underwriter fees of $5,117	3,478,261	3	74,879			74,882
Foreign currency translation adjustment	-	-	-	-	(12)	(12)
Unrealized loss on short-term investments	-	-	-	-	(196)	(196)
Exercise of stock options	133,416		1,547	-	-	1,547
Stock-based compensation expense	-	-	2,468	-	-	2,468
Net loss	-	-	-	(17,493)	-	(17,493)
Balances as of June 30, 2020	40,280,420	$ 40	$ 408,755	$ (129,791)	$ (1,190)	$ 277,814
Balances as of March 31, 2019	31,656,950	32	198,645	(59,766)	(1,055)	137,856
Foreign currency translation adjustment	-	-	-	-	(182)	(182)
Unrealized gain on short-term investments	-	-	-	-	65	65
Exercise of stock options	6,751	-	18	-	-	18
Stock-based compensation expense	-	-	1,810	-	-	1,810
Impact of adoption of ASC 842	-	-	-	93	-	93
Net loss	-	-	-	(9,508)	-	(9,508)
Balances as of June 30, 2019	31,663,701	$ 32	$ 200,473	$ (69,181)	$ (1,172)	$ 130,152

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

REPLIMUNE GROUP, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)
(Unaudited)

	Three Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (17,493)	$ (9,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,468	1,810
Depreciation and amortization	391	42
Noncash interest expense	63	-
Net amortization of premiums and discounts on short-term investments	91	(436)
Changes in operating assets and liabilities:		
Research and development incentives receivable	(684)	(621)
Prepaid expenses and other current assets	(301)	(847)
Operating lease, right-of-use-asset	135	85
Finance lease, right-of-use-asset	607	
Long term prepaid rent	-	(6,895)
Accounts payable	(224)	3,764
Accrued expenses and other current liabilities	(11)	(885)
Operating lease liabilities	(132)	(91)
Net cash used in operating activities	(15,090)	(13,582)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(932)	(362)
Purchase of short-term investments	(125,812)	(18,486)
Proceeds from sales and maturities of short-term investments	77,618	45,659
Net cash provided by (used in) investing activities	(49,126)	26,811
Cash flows from financing activities:		
Payment of issuance costs	(100)	-
Proceeds from issuance of common stock in follow-on public offering, net of underwriting fees and discounts	75,199	-
Proceeds from issuance of prefunded warrants to purchase common stock, net of underwriting fees and discounts	32,900	-
Principal payment of finance lease obligation	(32)	-
Exercise of stock options	1,547	18
Net cash provided by financing activities	109,514	18
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1)	(137)
Net increase in cash, cash equivalents and restricted cash	45,297	13,110
Cash, cash equivalents and restricted cash at beginning of period	61,136	26,890
Cash, cash equivalents and restricted cash at end of period	$ 106,433	$ 40,000
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 221	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Net unrealized gain (loss) on short-term investments	$ (196)	$ 65
Issuance costs included in accounts payable	$ 317	$ -
Purchases of property and equipment included in accounts payable	$ 64	$ -
Lease assets obtained in exchange for new operating lease liabilities	$ 1,580	$ 789

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

1. Nature of the business

Replimune Group, Inc. (the "Company") is a clinical-stage biotechnology company focused on the development of oncolytic immunotherapies to treat cancer. Replimune Group, Inc., whose predecessor was founded in 2015, is the parent company of its wholly owned subsidiaries: Replimune Limited ("Replimune UK"); Replimune, Inc. ("Replimune US"); and Replimune Securities Corporation.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Basis of presentation

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since its inception, including net losses of $17,493 and $9,508 for the three months ended June 30, 2020 and 2019, respectively. In addition, as of June 30, 2020, the Company had an accumulated deficit of $129,791. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of these consolidated financial statements, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements. The Company expects to seek additional funding through public and private equity financings, debt financings, collaborations, licensing arrangements, and/or strategic alliances.

If the Company is unable to obtain funding it could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or it may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of the COVID-19 coronavirus

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society, which has resulted, and will likely continue to result, in significant disruptions to the global economy as well as businesses and capital markets around the world.

In response to public health directives and orders and to help minimize the risk of the virus to employees, the Company has taken precautionary measures, including implementing work-from-home policies for the Company's employees, other than certain essential employees in our laboratory and who perform manufacturing functions, and certain other employees who we deem essential from time to time. For those essential employees, the Company has implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. The Company has taken these and other precautionary steps while maintaining business continuity in order to continue to progress its programs. While there has been no prolonged material disruption to the Company's business to date, the impact of the virus, including work-from-home policies, may negatively impact productivity, disrupt the Company's business, and delay its preclinical research and clinical trial activities and its development program timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course. Other impacts to the Company's business may include temporary closures of its suppliers and disruptions or restrictions on its employees' ability to travel. Any prolonged material disruption to the Company's employees or suppliers could adversely impact the Company's preclinical research and clinical trial activities, financial condition and results of operations, including its ability to obtain financing.

2. Summary of significant accounting policies

Principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and include the accounts of the Company and its wholly owned subsidiaries, Replimune UK, Replimune US and Replimune Securities Corporation, after elimination of all intercompany accounts and transactions. The consolidated financial statements reflect the capital as if Replimune Group, Inc. had been in existence for all periods presented.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of common stock and stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including, expenses, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods.

Estimates are periodically reviewed in light of reasonable changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates or assumptions.

Unaudited interim financial information

The accompanying consolidated balance sheet as of June 30, 2020, the consolidated statements of operations, of comprehensive loss and of cash flows for the three months ended June 30, 2020 and 2019 and the consolidated statement of stockholders' equity as of June 30, 2020 and 2019 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2020 and the results of its operations and its cash flows for the three months ended June 30, 2020 and 2019. The financial data and other information disclosed in these consolidated notes related to the three months ended June 30, 2020 and 2019 are unaudited. The results for the three months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending March 31, 2021, any other interim periods or any future year or period. The financial information included herein should be read in conjunction with the financial statements and notes in the Company's Annual Report on Form 10-K for the year ended March 31, 2020.

During the three months ended June 30, 2020, there have been no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the year ended March 31, 2020, except as described below.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework- Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The amendments in this ASU require certain existing disclosure requirements in Topic 820 to be modified or removed, and certain new disclosure requirements to be added to the Topic. In addition, this ASU allows entities to exercise more discretion when considering fair value measurement disclosures. The Company adopted ASU 2018-13 on April 1, 2020. The adoption of ASU 2018-13 did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU2018-18"), which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, including adoption in any interim period for public business entities for periods in which financial statements have not been issued. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in this Update retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The Company adopted ASU 2018-18 on April 1, 2020. The adoption of ASU 2018-18 did not have a material impact on the Company's consolidated financial statements.

Recently issued accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments- Credit Losses (Topic 326).* The standard changes how entities will measure credit losses for most financial assets and certain other instruments that are not measured at fair value through net income. Financial assets measured at amortized cost will be presented at the net amount expected to be collected by using an allowance for credit losses. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, which clarifies and corrects certain unintended applications of the guidance contained in each of the amended Topics. Additionally, in May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments - Credit Losses (Topic 326)*, which provides an option to irrevocably elect to measure certain individual financial assets at fair value instead of amortized cost. The standard is effective for fiscal years and interim periods beginning after December 15, 2023. Early adoption is permitted for all periods beginning after December 15, 2018. The adoption of ASU 2016-13 is not expected to have a material impact on the Company's consolidated financial statements.

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements as of June 30, 2020 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Money market funds	$ -	$ 43,566	$ -	$ 43,566
US Treasury bonds	-	84,785	-	84,785
US Government Agency bonds	-	105,624	-	105,624
	$ -	$ 233,975	$ -	$ 233,975

	Fair Value Measurements as of March 31, 2020 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Money market funds	$ -	$ 36,712	$ -	$ 36,712
Commercial paper	-	21,884	-	21,884
US Treasury bonds	-	35,810	-	35,810
US Government Agency bonds	-	15,295	-	15,295
Corporate debt securities	-	36,066	-	36,066
	$ -	$ 145,767	$ -	$ 145,767

The underlying securities held in the money market funds held by the Company are all government backed securities.

During the three months ended June 30, 2020 and 2019, there were no transfers between levels.

Valuation of cash equivalents and short-term investments

Money market funds, commercial paper, U.S. Treasury bonds, U.S. Government Agency bonds and corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. Cash equivalents consisted of money market funds at June 30, 2020 and March 31, 2020.

4. Short-term investments

Short-term investments by investment type consisted of the following:

	June 30, 2020			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper				$ -
US Government agency bonds	$ 90,147	$ 37	$ (9)	$ 90,175
US Treasury bonds	66,688	102	(3)	66,787
	$ 156,835	$ 139	$ (12)	$ 156,962

	March 31, 2020			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Commercial paper	$ 21,818	$ 66	$ -	$ 21,884
US Government agency bonds	15,217	78	-	15,295
US Treasury bonds	35,590	220	-	35,810
Corporate debt securities	36,107	24	(65)	36,066
	$ 108,732	$ 388	$ (65)	$ 109,055

5. Property, plant and equipment, net

Property, plant and equipment, net consisted of the following:

	June 30, 2020	March 31, 2020
Construction in progress	$ 1,246	$ 1,217
Plant and laboratory equipment	4,409	3,669
Leasehold improvements	647	532
Computer equipment	1,662	1,658
Office equipment	721	721
	8,685	7,797
Less: Accumulated depreciation and amortization	(1,328)	(937)
	$ 7,357	$ 6,860

Depreciation and amortization expense was $391 and $42 for the three months ended June 30, 2020 and 2019, respectively, and recorded within research and development and general and administrative expenses in the consolidated statement of operations.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2020	March 31, 2020
Accrued research and development costs	$ 2,872	$ 2,009
Accrued compensation and benefits costs	1,189	2,065
Accrued professional fees	503	779
Other	575	303
	$ 5,139	$ 5,156

7. Long-term debt

Long-term debt consisted of the following:

	June 30, 2020	March 31, 2020
Principal amount of long-term debt	$ 10,000	$ 10,000
Unamortized debt discount	(236)	(199)
Long-term debt, net of discount	$ 9,764	$ 9,801

Hercules Loan Agreement

On August 8, 2019, (the “Closing Date”) and as amended on June 1, 2020 (“the First Amendment”), the Company and certain of its affiliates entered into a Loan and Security Agreement (the “Hercules Loan Agreement”) with Hercules Capital, Inc. (“Hercules”) pursuant to which Hercules agreed to make available to the Company a secured term loan facility in the amount of $30,000 (the “Term Loan Facility”), subject to certain terms and conditions. The Company borrowed $10,000 under the Hercules Loan Agreement in one advance as a single tranche Term Loan on the Closing Date upon which the Company paid a $225 facility charge and incurred $130 in additional closing and legal fees. The Company may borrow the unused $20,000 available under the Term Loan Facility in two separate advances. The second advance of up to $10,000 may be borrowed between January 1, 2020 and December 15, 2020 and the third advance of up to $10,000 may be borrowed between July 1, 2020 and June 30, 2021.

In June 2020, the Company entered into the First Amendment to the Hercules Loan Agreement (the “Hercules First Amendment”), which amended the secured term loan facility from $30,000 to $40,000, subject to terms and conditions, by adding a fourth advance of up to $10,000. The Company may borrow the second advance of $10,000 may between October 1, 2020 and December 15, 2020. In the event the Company does not draw on the second advance or if the Term Loan Facility is terminated prior to a draw of the second advance, the Company shall pay Hercules a one-time facility charge fee of $0.1 million on the earliest of (i) December 16, 2020 or (ii) the date the Company prepays the outstanding obligations. The third advance of up to $10,000 may be borrowed between July 1, 2020 and June 30, 2021. The fourth advance of up to $10,000 may be borrowed between July 1, 2021 and December 15, 2021. The Company incurred $103 in additional closing and legal fees in connection with Hercules First Amendment, of which $100 will be capitalized and amortized as part of the effective yield. Additionally, the Amortization Date was changed from March 1, 2022 to September 1, 2022 (the “Amortization Date”) to extend the interest only payment period by six months.

Advances under the Term Loan Facility bear interest at a rate per annum equal to the greater of either (i) the prime rate as reported in The Wall Street Journal plus 2.75%, or (ii) 8.75%. The Hercules Loan Agreement includes covenants, limitations, and events of default customary for similar facilities. The term of the Hercules Loan Agreement is four years, ending August 1, 2023.

Interest is payable on a monthly basis until the Amortization Date. After the Amortization Date, payments shall consist of equal monthly installments of principal and interest payable until the secured obligations are repaid in full.

At any time the Company may prepay the principal of any advance pursuant to the terms of the Term Loan Facility subject to a prepayment charge equal to: 3.0%, if such advance is prepaid within the first twelve months following the Closing Date, 2.0%, if such advance is prepaid after twelve months but prior to twenty four months following the Closing Date, and 1.0%, if such advance is prepaid anytime thereafter. The Company will also pay a charge equal to the product of 4.95% and the aggregate amount of any advance made pursuant to the terms of the Term Loan Facility.

The Term Loan Facility is secured by substantially all of the Company's assets, but excluding its intellectual property, and subject to certain exceptions and exclusions.

The Hercules Loan Agreement contains customary covenants for transactions of this type and other covenants agreed to by the parties, including, among others, (i) the provision of delivery of annual and quarterly financial statements and insurance policies and restrictions on incurring debt, granting liens, making acquisitions, making loans, paying dividends, dissolving, and entering into leases and asset sales. The Hercules Loan Agreement also provides for customary events of default, including, among others, events of default relating to failure to make payment, bankruptcy, breach of covenants, breaches of representations and warranties, change of control, judgment and material adverse effects.

In connection with entering into the Hercules Loan Agreement, the Company paid Hercules $355 of upfront fees, including closing costs and legal fees associated with entering into the agreement, which were recorded as a debt discount. In connection with entering into the Hercules First Amendment, the Company paid $100 of upfront fees, including closing costs and legal fees associated with entering into the amendment, which were recorded as debt discount, totaling the debt discount to $455 as of June 30, 2020. The debt discount is reflected as a reduction of the carrying value of long-term debt on the Company's consolidated balance sheet and is being amortized to interest expense over the term of the loan using the effective interest method.

The Company recognized aggregate interest expense under the Hercules Loan Agreement of $284 during the three months ended June 30, 2020, which included non-cash interest expense of $27 and $36 related to the accretion of the debt discount and the final payment. As of June 30, 2020, the unamortized debt discount was $236. The Company's annual effective interest rate of the Hercules First Amendment was approximately 10.5% as of June 30, 2020.

There were no principal payments due or paid under the Hercules Loan Agreement during the three months ended June 30, 2020.

Future payments of long-term debt as of June 30, 2020 are as follows (fiscal years):

Debt maturity as of June 30, 2020	
Future long-term debt payments:	
2021 (remaining nine months)	$ -
2022	-
2023	5,722
2024	4,278
Total debt payments	$ 10,000

The table of future payments of long-term debt excludes the end of term charge of $495 which is due upon the maturity of the loan.

8. Stockholders' Equity

Common stock

As of June 30, 2020 and March 31, 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 150,000,000 shares of common stock, par value $0.001 per share.

As of June 30, 2020 and March 31, 2020, the Company had reserved 13,670,676 and 10,449,033 shares of common stock for the exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2018 Omnibus Incentive Compensation Plan and the Company's Employee Stock Purchase Plan (see Note 9) and the exercise of the outstanding warrants to purchase shares of common, respectively.

Undesignated preferred stock

As of June 30, 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.001 per share. There were no undesignated preferred shares issued or outstanding as of June 30, 2020.

Convertible preferred stock and preferred stock warrants

The Company has issued series seed convertible preferred stock (the "series seed preferred stock"), series A convertible preferred stock (the "series A preferred stock") and series B convertible preferred stock (the "series B preferred stock"). The series seed preferred stock, series A preferred stock and series B preferred stock are collectively referred to as the "preferred stock." In connection with the closing of the IPO, the preferred stock converted into 19,157,360 shares of common stock on a 1:9.94688 basis. There was no preferred stock outstanding as of June 30, 2020 and March 31, 2020.

In connection with the issuance of the series seed preferred stock, the Company issued to the holders of the series seed preferred stock warrants for the purchase of 50,000 shares of series seed preferred stock, which became fully vested and exercisable in the year of issuance. The warrants to purchase shares of series seed preferred stock were issued at an exercise price of $10.00 per share and expire on the earlier of September 16, 2025 or a qualified change of control event. Upon the closing of the Company's IPO in July 2018, the series seed preferred stock warrants became exercisable for 497,344 shares of common stock and were reclassified to stockholders' equity.

ATM program

In August 2019, the Company entered into a Sales Agreement (as amended, the "Sales Agreement") with SVB Leerink LLC (the "Agent"), pursuant to which the Company could sell, from time to time, at its option, up to an aggregate amount of $75,000 of shares of the Company's common stock, $0.001 par value per share (the "Shares"), through the Agent, as the Company's sales agent. In June 2020, the Sales Agreement was amended to reduce the aggregate offering amount under the Sales Agreement from $75,000 of shares to $30,000 of Shares. Any Shares to be offered and sold under the Sales Agreement will be issued and sold (i) by methods deemed to be an "at the market offering" ("ATM"), as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended or in negotiated transactions, if authorized by the Company, and (ii) pursuant to, and only upon the effectiveness of, a registration statement on Form S-3 filed by the Company with the Securities and Exchange Commission on August 8, 2019 for an offering of up to $250,000 of various securities, including shares of the Company's common stock, preferred stock, debt securities, warrants and/or units for sale to the public in one or more public offerings.

Subject to the terms of the Sales Agreement, the Agent will use commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the Agent a commission of 3.0% of the gross proceeds from the sale of the Shares, if any. During the year ended March 31, 2020, the Company issued and sold 287,559 Shares for gross proceeds of $4,568 less offering fees of $137 for net proceeds of $4,431 under the ATM. As of June 30, 2020, the Company had $25,432 of Shares remaining available for sale under the ATM.

Equity offerings

In November 2019, the Company entered into an Underwriting Agreement (the "November 2019 Underwriting Agreement") with J.P. Morgan Securities LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (the "November 2019 Underwriters"), relating to the issuance and sale of an aggregate of (a) 3,678,031 shares of the Company's common stock (the "November 2019 Shares"), and (b) pre-funded warrants to purchase 2,200,000 shares of the Company's common stock (the "November 2019 Pre-Funded Warrants") to the Underwriters (the "November 2019 Offering"). The November 2019 Shares were sold to the purchasers at the public offering price of $13.61 per share. The November 2019 Pre-Funded Warrants were sold at a public offering price of $13.6099 per November 2019 Pre-Funded Warrant, which represents the per share public offering price for the Company's common stock less a $0.0001 per share exercise price for each such November 2019 Pre-Funded Warrant. In December 2019, the November 2019 Underwriters partially exercised their purchase option pursuant to the Underwriting Agreement, and the Company issued and sold an additional 838,530 shares of its common stock. The Company received aggregate net proceeds of approximately $85,598 in the November 2019 Offering, after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately $5,814.

Funds affiliated with Redmile Group, LLC purchased all of the November 2019 Pre-Funded Warrants. The November 2019 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of November 2019 Pre-Funded Warrants may not exercise the November 2019 Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of November 2019 Pre-Funded Warrants may increase or decrease this percentage up to 19.99% by providing at least 61 days' prior notice to the Company. As of June 30, 2020, none of the November 2019 Pre-Funded Warrants had been exercised.

In June 2020, the Company entered into a separate Underwriting Agreement (the "June 2020 Underwriting Agreement") with J.P. Morgan Securities LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (the "June 2020 Underwriters"), relating to the issuance and sale of an aggregate of (a) 2,826,088 shares of the Company's common stock (the "June 2020 Shares"), and (b) pre-funded warrants to purchase 1,521,738 shares of the Company's common stock (the "June 2020 Pre-Funded Warrants") to the Underwriters (the "June 2020 Offering"). The June 2020 Shares were sold to the purchasers at the public offering price of $23.00 per share. The June 2020 Pre-Funded Warrants were sold at a public offering price of $22.9999 per June 2020 Pre-Funded Warrant, which represents the per share public offering price for the Company's common stock less a $0.0001 per share exercise price for each such June 2020 Pre-Funded Warrant. The June 2020 Underwriters fully exercised their purchase option pursuant to the June 2020 Underwriting Agreement, and the Company issued and sold an additional 652,173 shares of its common stock. The Company received aggregate net proceeds of approximately $107,782 after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately $7,217.

Funds affiliated with Redmile Group, LLC and funds affiliated with a second institutional investor purchased all of the June 2020 Pre-Funded Warrants. The June 2020 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of June 2020 Pre-Funded Warrants may not exercise the June 2020 Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise. A holder of June 2020 Pre-Funded Warrants may increase or decrease this percentage up to 19.99% by providing at least 61 days' prior notice to the Company. As of June 30, 2020, none of the June 2020 Pre-Funded Warrants had been exercised.

All of the Company's pre-funded warrants to purchase the Company's common stock were purchased by funds affiliated with Redmile Group, LLC (in both the November 2019 Offering and the June 2020 Offering) and funds affiliated with a second institutional investor (in the June 2020 Offering). Other than as set forth in Note 10 to these consolidated financial statements, the 3,721,738 shares of the Company's common stock into which the November 2019 Pre-Funded Warrants and the June 2020 Pre-Funded Warrants are exercisable are not included in the number of issued and outstanding shares of the Company's common stock set forth herein. However, the November 2019 Pre-Funded Warrants and the June 2020 Pre-Funded Warrants are included in the calculation of basic and diluted net loss per share attributable to common stockholders (see Note 10).

9. Stock-based compensation

2015 Enterprise Management Incentive Share Option Plan

The 2015 Enterprise Management Incentive Share Option Plan of Replimune UK (the "2015 Plan") provided for Replimune UK to grant incentive stock options, non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options are granted only to the Company's employees, including officers and directors who are also employees. Non-statutory stock options are granted to employees, members of the board of directors, outside advisors and consultants of the Company.

2017 Equity Compensation Plan

In July 2017, in conjunction with the Reorganization, the 2015 Plan was terminated, and all awards were cancelled with replacement awards issued under the 2017 Equity Compensation Plan (the "2017 Plan"). Subsequent to the Reorganization, no additional grants will be made under the 2015 Plan and any outstanding awards under the 2015 Plan will continue with their original terms. The Company concluded that the cancellation of the 2015 Plan and issuance of replacement awards under the 2017 Plan was a modification with no change in the material rights and preferences and therefore no recorded change in the fair value of each respective award.

The Company's 2017 Plan provides for the Company to grant incentive stock options or non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options may be granted only to the Company's employees, including officers and directors who are also employees. Restricted stock awards and non-statutory stock options may be granted to employees, officers, members of the board of directors, advisors and consultants of the Company. The maximum number of common shares that may be issued under the 2017 Plan was 2,659,885 of which 0 remained available for future grants as of June 30, 2020. Shares with respect to which awards have expired, terminated, surrendered or cancelled under the 2017 Plan without having been fully exercised will be available for future awards under the 2017 Plan. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.

2018 Omnibus Incentive Compensation Plan

On July 9, 2018, the Company's board of directors adopted, and the Company's stockholders approved the 2018 Omnibus Incentive Compensation Plan (the "2018 Plan"), which became effective immediately prior to the effectiveness of the registration statement for the Company's initial public offering. The 2018 Plan provides for the issuance of incentive stock options, non-qualified stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. The number of shares initially reserved for issuance under the 2018 Plan is 3,617,968 shares. If any options or stock appreciation rights, including outstanding options and stock appreciation rights granted under the 2017 Plan (up to 2,520,247 shares), terminate, expire, or are canceled, forfeited, exchanged, or surrendered without having been exercised, or if any stock awards, stock units or other stock-based awards, including outstanding awards granted under the 2017 Plan, are forfeited, terminated, or otherwise not paid in full in shares of common stock, the shares of the Company's common stock subject to such grants will be available for purposes of our 2018 Plan. On April 1, 2020, the number of shares reserved for issuance under the 2018 Plan automatically increased by 1,466,749 shares pursuant to the terms of the 2018 Plan. On April 1, 2019, the number of shares reserved for issuance under the 2018 Plan automatically increased by 1,266,278 shares pursuant to the terms of the 2018 Plan. As of June 30, 2020, 1,909,204 shares remained available for future grants under the 2018 Plan.

The 2015 Plan, the 2017 Plan and the 2018 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. However, the board of directors shall administer and approve all grants made to non-employee directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire ten years after the grant date, unless the board of directors sets a shorter term. Vesting periods for both plans are determined at the discretion of the board of directors. Incentive stock options granted to employees and non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years.

Employee Stock Purchase Plan

On July 9, 2018, the Company's board of directors adopted and the Company's stockholders approved the Employee Stock Purchase Plan (the "ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the Company's IPO. The total shares of common stock initially reserved for issuance under the ESPP is limited to 348,612 shares. In addition, as of the first trading day of each fiscal year during the term of the ESPP (excluding any extensions), an additional number of shares of the Company's common stock equal to 1% of the total number of shares outstanding on the last trading day in the immediately preceding fiscal year or 697,224 shares, whichever is less (or such lesser amount as determined by the Company's board of directors) will be added to the number of shares authorized under the ESPP. In accordance, on April 1, 2020, the number of shares reserved for issuance under the ESPP automatically increased by 366,687 shares, for a total of 1,031,868 shares reserved for the ESPP. In accordance, on April 1, 2019, the number of shares reserved for issuance under the ESPP automatically increased by 316,569 shares, for a total of 665,181 shares reserved for the ESPP. If the total number of shares of common stock to be purchased pursuant to outstanding purchase rights on any particular date exceed the number of shares then available for issuance under the ESPP, then the plan administrator will allocate the available shares pro-rata and refund any excess payroll deductions or other contributions to participants.

Stock option valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company lacks company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors:

	Three Months Ended June 30,	
	2020	**2019**
Risk-free interest rate	1.24%	2.34%
Expected term (in years)	6.5	6.0
Expected volatility	75.0%	71.0%
Expected dividend yield	0%	0%

Stock options

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of March 31, 2020	4,964,381	$ 9.78	8.02	$ 15,344
Granted	1,721,504	10.43	9.77	
Exercised	(133,416)	11.60		
Cancelled	(41,947)	12.02		
Outstanding as of June 30, 2020	6,510,522	9.90	8.29	$ 97,322
Options exercisable as of March 31, 2020	2,117,721	$ 5.66	7.20	$ 11,733
Options exercisable as of June 30, 2020	2,545,850	$ 7.01	7.21	$ 45,430

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the three months ended June 30, 2020 and 2019 was $6.94 and $9.96, respectively. The total fair value of options vested during the three months ended June 30, 2020 and 2019 was $4,633 and $211, respectively.

Stock-based compensation expense

Stock-based compensation expense was classified in the consolidated statements of operations as follows:

	Three Months Ended June 30,	
	2020	2019
Research and development	$ 1,000	$ 841
General and administrative	1,468	969
	$ 2,468	$ 1,810

As of June 30, 2020, total unrecognized compensation cost related to the unvested stock-based awards was $27,901, which is expected to be recognized over a weighted average period of 2.96 years.

10. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended June 30,	
	2020	2019
Numerator:		
Net loss attributable to common stockholders	$ (17,493)	$ (9,508)
Denominator:		
Weighted average common shares outstanding, basic and diluted	39,862,319	31,661,430
Net loss per share attributable to common stockholders, basic and diluted	$ (0.44)	$ (0.30)

The November 2019 Pre-Funded Warrants and the June 2020 Pre-Funded Warrants are included in the calculation of basic and diluted net loss per share attributable to common stockholders. The Company's potentially dilutive securities, which include stock options, preferred stock and warrants to purchase shares of series seed preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended June 30,	
	2020	2019
Options to purchase common stock	6,510,522	4,845,068
Warrants to purchase convertible preferred stock (as converted to common stock)	497,344	497,344
	7,007,866	5,342,412

11. Significant agreements

Agreement with Bristol-Myers Squibb Company

In February 2018, the Company entered into an agreement with Bristol-Myers Squibb Company ("BMS"). Pursuant to the agreement, BMS will provide to the Company, at no cost, a compound for use in the Company's ongoing clinical trial. Under the agreement, the Company will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted the Company a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to its compound in the clinical trial and agreed to supply its compound, at no cost to the Company, for use in the clinical trial. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 refractory melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to the Company to use BMS's compound in the clinical trial will terminate.

In April 2019, the Company entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide to the Company, at no cost, nivolumab for use in the Company's Phase 1 clinical trial of RP2 in combination with nivolumab.

As of June 30, 2020, the Company had not incurred any costs and does not expect to incur future costs in connection with this agreement.

Agreement with Regeneron Pharmaceuticals, Inc.

In May 2018, the Company entered into an agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"). The Company and Regeneron are each independently developing compounds for the treatment of certain tumor types. Pursuant to the agreement, the Company and Regeneron will undertake one or more clinical trials using a combination of the compounds being developed by each entity. Under the agreement, each study will be conducted under terms set out in a separately agreed upon study plan that will identify the name of the sponsor and which party will manage the particular clinical trial, and include the protocol, the budget and a schedule of clinical obligations. In June 2018, under the terms of the agreement between the Company and Regeneron, the parties agreed to the first study plan. The Company and Regeneron have agreed to the protocol, budget, sample testing and clinical obligations schedule under the study plan. Development and supply costs associated with the study plan will be split equally between the Company and Regeneron.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license under its respective intellectual property and agreed to contribute the necessary resources needed to fulfill its respective obligations, in each case, under the terms of the agreed-upon or to-be agreed upon study plans. Development costs of a particular clinical trial will be split equally between the Company and Regeneron.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

The Company will account for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company will recognize any amounts received from Regeneron in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.

Under the terms of the agreement, on a quarterly basis the Company and Regeneron true-up costs of the study and make corresponding payments to the party that incurred the majority of the costs. During the three months ended June 30, 2020 or 2019, the Company did not make any payments under the terms of the agreement to Regeneron. During the three months ended June 30, 2020 and 2019, the Company received payments under the terms of the agreement to Regeneron of $971 and $337, respectively. As of June 30, 2020 and March 31, 2020, the Company recorded $1,432 and $971 of receivables from Regeneron in connection with this agreement in prepaid expenses and other current assets in the consolidated balance sheet, respectively.

12. Commitments and contingencies

Leases

In April 2016, the Company entered into a lease agreement for office and laboratory space in Abingdon, England. On June 29, 2020 the Company modified the lease terms to extend the expiration date to April 3, 2031 and the lease modification was not accounted for as a separate contract. As part of the lease modification, the lease liability was remeasured in accordance with the updated terms of the contract and the associated lease liability and right-of-use asset was increased by $1,580. The Company has the right to terminate the lease as of April 4, 2026 upon at least twelve months' prior written notice. Monthly lease payments are inclusive of base rent, ancillary charges, non-rent shared tenant occupancy costs and the respective value added tax to be paid. Monthly lease payments include base rent of approximately $29 through June 23, 2020, $14 from June 24, 2020 through December 24, 2020, and $29 thereafter. Monthly base rent is subject to increase after April 2021 in proportion to the Retail Price Index or market rates. The lease is classified as an operating lease.

In June 2018, the Company entered into an agreement to lease approximately 63,000 square feet of office, manufacturing and laboratory space in Framingham, Massachusetts. Pursuant to the lease agreement, the lease term commenced in December 2018, subject to the landlord completing certain agreed upon landlord improvements. The rent commencement date started in August 2019. The initial lease term is ten years from the rent commencement date and includes two optional five-year extensions. Annual lease payments during the first year were $2,373 with increases of 3.0% each year thereafter until the expiration of the lease.

Construction was completed associated with approximately 10,500 square feet of the leased space in Framingham, Massachusetts and the Company occupied the building as office space beginning August 1, 2019. The Company recorded a right-of-use asset and lease liability associated with the occupied space as of August 1, 2019. The Company recorded $2,368 in related construction costs to the right-of-use asset upon the lease commencement date which were reclassified from prepaid rent. The Company occupied the remainder of the facility, approximately 53,000 square feet used as laboratory space, on October 22, 2019. The Company recorded a right-of-use asset and lease liability associated with the remaining space as of October 22, 2019. The Company recorded $18,164 in related construction costs and $261 in rent payments made prior to the lease commencement date to the right-of-use asset upon the lease commencement date which were reclassified from prepaid rent. The lease is classified as a financing lease.

In June 2019, the Company entered into an agreement to lease approximately 18,700 square feet of office space in Woburn, Massachusetts. Pursuant to the lease agreement, the lease term commenced in August 2019. The rent commenced in September 2019. The initial lease term is ten years from the rent commencement date and includes an optional five-year extension. Annual lease payments during the first year are $488 with increases of approximately 1.6% each year. The Company recorded a right-of-use asset and a lease liability of $4,363 upon the commencement date of the lease and the lease is classified as an operating lease.

The Company determines if an arrangement is a lease at inception. Operating leases are included in our balance sheet as right-to-use—operating leases, operating lease liabilities, current and operating lease liabilities, non-current. Finance leases are included in the balance sheet as right-to-use asset—finance lease finance lease liabilities, current, and finance lease liabilities, non-current. Certain of the Company's lease agreements contain renewal options; however, the Company does not recognize right-of-use assets or lease liabilities for renewal periods unless it is determined that the Company is reasonably certain of renewing the lease at inception or when a triggering event occurs. As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component. Some of the Company's lease agreements contain rent escalation clauses (including index-based escalations). The Company recognizes the minimum rental expense on a straight-line basis based on the fixed components of a lease arrangement. The Company amortizes this expense over the term of the lease beginning with the date of initial possession, which is the date the Company can enter the leased space and begin to make improvements in preparation for its intended use. Variable lease components represent amounts that are not fixed in nature and are not tied to an index or rate, and are recognized as incurred.

	Three Months Ended June 30,	
Lease cost	**2020**	**2019**
Finance lease costs:		
Amortization of right-to-use asset	$ 607	$ -
Interest on lease liabilities	561	-
Operating lease costs	230	114
Total lease cost	$ 1,398	$ 114

Finance lease costs of $90 and $0 are recognized in general and administrative expenses for the three months ended June 30, 2020 and 2019, respectively, and $517 and $0 in research and development expenses for the three months ended June 30 and 2019, respectively. Operating leases costs are recognized in general and administrative expenses for the three months ended June 30, 2020 and 2019. The following table summarizes the maturity of the Company's lease liabilities on an undiscounted cash flow basis and a reconciliation to the operating and financing lease liabilities recognized on our balance sheet as of June 30, 2020:

	June 30, 2020		
	Operating leases	Financing lease	Total
2022 (remaining nine months)	$ 599	$ 1,817	$ 2,416
2023	930	2,483	3,413
2024	939	2,558	3,497
2025	949	2,634	3,583
2026	958	2,713	3,671
Thereafter	4,832	43,686	48,518
Total lease payments	9,207	55,891	65,098
Less: interest	3,167	28,545	31,712
Total lease liabilities	$ 6,040	$ 27,346	$ 33,386

The following table provides lease disclosure as of June 30, 2020 and March 31, 2020:

	June 30, 2020	March 31, 2020
Leases		
Right-to-use operating lease asset	$ 5,852	$ 4,425
Right-to-use finance lease asset	46,318	46,925
Total lease assets	$ 52,170	$ 51,350
Operating lease liabilities, current	$ 830	$ 873
Finance lease liabilities, current	2,429	2,411
Operating lease liabilities, non-current	5,210	3,737
Finance lease liabilities, non-current	24,917	24,967
Total lease liabilities	$ 33,386	$ 31,988

The following table provides lease disclosure for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,	
	2020	2019
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 209	$ 114
Operating cash flows from finance leases	$ 561	$ -
Financing cash flows from finance leases	$ 32	$ -
Right-to-use asset obtained in exchange for new operating lease liabilities	$ 1,580	$ 789
Weighted-average remaining lease term - operating leases	9.8 years	1.8 years
Weighted-average remaining lease term - financing leases	19.3 years	-
Weighted-average discount rate - operating leases	10%	15%
Weighted-average discount rate - financing leases	8%	0%

The variable lease costs and short-term lease costs were insignificant for three months ended June 30, 2020 and 2019.

Manufacturing commitments

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of June 30, 2020 and March 31, 2020, the Company had committed to minimum payments under these arrangements totaling $3,109 and $3,569, respectively, through March 31, 2021.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and therefore it has not accrued any liabilities related to such obligations in its consolidated financial statements as of June 30, 2020 or March 31, 2020.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

13. Geographic information

The Company operates in two geographic regions: the United States (Massachusetts) and the United Kingdom (Oxfordshire). Information about the Company's long-lived assets held in different geographic regions is presented in the tables below:

	June 30, 2020	March 31, 2020
United States	$ 6,806	$ 6,357
United Kingdom	551	503
	$ 7,357	$ 6,860

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and related notes appearing in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto for the year ended March 31, 2020, included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020.

Some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10- Q, including information with respect to our plans and strategy for our business, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, particularly including those risks identified in Part II, Item 1A "Risk factors" and our other filings with the SEC.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

General

We are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients. We use our proprietary Immulytic platform to design and develop product candidates that are intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy, which we intend to establish as the second cornerstone of immune-based cancer treatment, is an emerging class of immuno-oncology therapy, alongside checkpoint blockade, that exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Such oncolytic, or "cancer killing," viruses have the potential to generate an immune response targeted to an individual patient's particular set of tumor antigens, including neo-antigens that are uniquely present in tumors. Our product candidates incorporate multiple mechanisms of action into a practical "off-the-shelf" approach that is intended to maximize the immune response against a patient's cancer and to offer significant advantages over personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will simplify the development path of our product candidates, while also improving patient outcomes at a lower cost to the healthcare system than the use of multiple different drugs.

The foundation of our Immulytic platform consists of a proprietary, engineered strain of herpes simplex virus 1, or HSV-1, that has been "armed" with a fusogenic glycoprotein intended to substantially increase anti-tumor activity. Our Immulytic platform enables us to incorporate various genes into HSV-1 that are intended to further augment the inherent properties of HSV-1 in order to both directly destroy tumor cells and induce an anti-tumor immune response. We currently have three product candidates in our development pipeline, RP1, our lead product candidate, and additionally RP2 and RP3.

We are currently conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with a focus on immune-responsive tumors. We are conducting a randomized, controlled Phase 2 clinical trial of RP1 in approximately 240 patients with cutaneous squamous cell carcinoma, or CSCC, RP1's lead indication. This registration-directed clinical trial is evaluating RP1 in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron Pharmaceuticals, Inc., or Regeneron, versus cemiplimab alone. Regeneron has granted to us a non-exclusive royalty-free license to cemiplimab for use in this trial, is funding one-half of the clinical trial costs, and is supplying cemiplimab at no cost to us. If compelling clinical data are generated demonstrating the benefits of the combined treatment in this clinical trial, we believe the data from this Phase 2 clinical trial could support a filing with regulatory authorities for marketing approval. Recruitment into this Phase 2 clinical trial is expected to take approximately eighteen to twenty-four months and we expect the primary data readout from the clinical trial in 2022. We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients with CSCC, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients). We intend to enroll approximately 30 patients in this clinical trial to assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC.

We have entered into a collaboration with Bristol-Myers Squibb Company, or BMS, under which it has granted us a non-exclusive, royalty-free license to, and is supplying at no cost, its anti-PD-1 therapy, nivolumab, for use in combination with RP1 in a multi-cohort clinical trial. We are currently enrolling a 125-patient extension cohort of RP1 combined with nivolumab in anti-PD-1 refractory cutaneous melanoma. We initiated this cohort after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The data generated in the melanoma cohort demonstrated that RP1 combined with nivolumab has the potential to treat anti-PD-1 refractory melanoma. We also believe this cohort to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients).

We continue to enroll patients in other Phase 2 cohorts of approximately 30 patients each, testing RP1 in combination with nivolumab in non-melanoma skin cancers and microsatellite instability high, or MSI-H/dMMR, tumors under our collaboration with BMS. Due in part to COVID-19 related disruptions, we expect that the non-melanoma skin cancer cohort to be fully accrued by the end of 2020. Similarly, it is likely that accumulating sufficient data to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development will be delayed into 2021. In addition, as a result of changes in the competitive landscape, we recently announced our intention to replace a 30 patient bladder cancer cohort with a cohort of patients with anti-PD-1 refractory non-small cell lung cancer, or NSCLC. We intend to initiate enrollment into this cohort later this year.

We are also developing additional product candidates, RP2 and RP3, that have been further engineered to enhance anti-tumor immune responses and are intended to address additional tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF, RP2 has been engineered to express an antibody-like molecule intended to block the activity of CTLA-4, a protein that inhibits the immune response to tumors. RP3 has been engineered with the intent to further stimulate an anti-tumor response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40 and 4-1BB.

We initiated a Phase 1 clinical trial of RP2 in October 2019. The Phase 1 clinical trial of RP2 is also being conducted as a collaboration with BMS, under which BMS has granted us a non-exclusive, royalty-free license to, and will supply at no cost, nivolumab, for use in combination with RP2. We expect to release initial safety and efficacy data from this Phase 1 clinical trial in the second half of 2020. Based on the data generated to date, we have decided to amend the protocol to allow for an expansion of the second part of this clinical trial (of RP2 combined with nivolumab) from 12 to 30 patients.

We intend to file an Investigational New Drug application, or IND, and/or foreign equivalents for RP3 and, assuming regulatory clearance, enter clinical development during 2020. IND and/or foreign equivalent enabling studies of RP3 are currently underway.

Recent Developments

During the quarter ended June 30, 2020, we announced interim data from the Phase 2 part of our Phase 1/2 clinical trial of RP1 in which we are assessing the safety and efficacy of RP1 in combination with nivolumab in cohorts of approximately 30 patients. We announced that four of seven evaluable CSCC patients in the 30-patient non-melanoma skin cancer cohort have ongoing complete responses and six of the seven evaluable patients have either an ongoing complete response or an ongoing partial response. We continue to believe this interim data demonstrates that RP1 in combination with nivolumab is well-tolerated, demonstrates immune activation and continues to drive deep and durable responses in patients with CSCC. Of particular note, we observed clear differentiation in the number of complete responses in patients with advanced CSCC who were treated with RP1 in combination with nivolumab as compared to the number of complete responses which we believe would be expected in patients if they were treated with nivolumab alone.

We have enrolled and treated 36 melanoma patients, including the six melanoma patients enrolled into the Phase 1 expansion cohort of RP1 combined with nivolumab. 16 patients with anti-PD-1 refractory cutaneous melanoma have been treated as have an additional 20 patients with anti-PD-1 naïve cutaneous melanoma, uveal melanoma (all anti-PD-1 refractory), and mucosal melanoma (anti-PD-1 naïve or refractory). Five of the 16 anti-PD-1 refractory cutaneous melanoma patients at the data cut-off date met the formal definition of response, with an additional two patients remaining on treatment with the opportunity for response. Accordingly, we will observe a final response rate from this cohort of at least 31%. Four of eight anti-PD-1 naïve cutaneous melanoma patients met the formal definition of response at the data cut-off date, with an additional two patients continuing on treatment with the opportunity for response. Additionally, two of the six mucosal melanoma patients met the formal definition of response at the data cut-off date, and two of the six uveal melanoma patients are on study with the opportunity of response, with one such uveal melanoma patient demonstrating a 27.3% reduction in target disease burden as of the last CT scan in April 2020.

Financial overview

Since our inception, we have devoted substantially all of our resources to developing our Immulytic platform and our lead product candidate, RP1, building our intellectual property portfolio, conducting research and development of our product candidates, business planning, raising capital and providing general and administrative support for our operations. To date, we have financed our operations primarily with proceeds from the sale of equity securities and to a lesser extent the proceeds from the issuance of debt securities. We do not have any products approved for sale and have not generated any revenue from product sales. On July 24, 2018, we completed our initial public offering ("IPO") of our common stock and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of approximately $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock, resulting in additional net proceeds of approximately $9.9 million after deducting discounts and commissions but before deducting other offering expenses.

On August 8, 2019, we entered into a Loan and Security Agreement with Hercules Capital, Inc. ("Hercules Loan Agreement"), pursuant to which we borrowed $10.0 million under a secured term loan facility in the amount of $30.0 million ("Term Loan Facility"). The Hercules Loan Agreement was subsequently amended on June 1, 2020, in order to, among other things, increase the secured term loan facility from $30.0 million to $40.0 million.

Also on August 8, 2019, we entered into a Sales Agreement with SVB Leerink LLC ("Sales Agreement"), pursuant to which we could sell, from time to time, at our option, up to an aggregate amount of $75.0 million of shares of our common stock, of which we have sold $4.5 million as of June 30, 2020. In June 2020 the Sales Agreement was amended to reduce the aggregate offering amount under the Sales Agreement from $75,000 of shares to $30,000 of Shares.

On November 18, 2019, we completed a follow-on public offering, or the November Offering, of (i) 3,678,031 shares of our common stock at a public offering price of $13.61 per share and (ii) pre-funded warrants to purchase 2,200,000 shares of our common stock at a purchase price of $13.6099 per pre-funded warrant, the public offering price per share of common stock less the $0.0001 per share exercise price of each pre-funded warrant. On December 13, 2019 we sold 838,530 shares of our common stock to the underwriters at the public offering price in connection with the underwriters' partial exercise of their option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $85.6 million after deducting underwriting discounts, commissions and other offering expenses of approximately $5.8 million.

On June 11, 2020, we completed an additional follow-on public offering, or the "June Offering", of (i) 2,826,088 shares of our common stock at a public offering price of $23.00 per share and (ii) pre-funded warrants to purchase 1,521,738 shares of our common stock at a purchase price of $22.9999 per pre-funded warrant, the public offering price per share of common stock less the $0.0001 per share exercise price of each pre-funded warrant. On June 29, 2020 we sold 652,173 shares of our common stock to the underwriters at the public offering price in connection with the underwriters' full exercise of their option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $107.8 million after deducting underwriting discounts, commissions and other offering expenses of approximately $7.2 million.

Funds affiliated with two separate institutional investors hold all of our outstanding pre-funded warrants. Other than as set forth in Note 10 of our condensed consolidated financial statements appearing elsewhere in this Quarterly Report, the 3,721,738 shares of our common stock into which our outstanding pre-funded warrants are exercisable are not included in the number of issued and outstanding shares of our common stock set forth in this Quarterly Report. However, the November 2019 Pre-Funded Warrants and the June 2020 Pre-Funded Warrants are included in the calculation of basic and diluted net loss per share attributable to common stockholders (see Note 10).

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. Our net losses were $17.5 million and $9.5 million for the three months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $129.8 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates, and if and as we:

- conduct our current and future clinical trials with RP1;
- progress the clinical development of RP2 and preclinical development of RP3;
- operate our own in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and general and administration personnel;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs and any future commercialization efforts.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for RP1 or our other product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership in any jurisdiction, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates.

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

As of June 30, 2020, we had cash and cash equivalents and short-term investments of $261.8 million. We believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12 months from the issuance of the consolidated financial statements included in this Quarterly Report on Form 10-Q.

See "—Liquidity and capital resources" and "Risk factors—Risks related to our financial position and need for additional capital."

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales as we do not have any approved products and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for RP1 or any other product candidates that we may develop in the future are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from those collaborations or license agreements.

Operating expenses

Our expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- expenses incurred under agreements with third parties, including clinical research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements in connection with the development of our product candidates; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

These costs will be partially offset by our agreement with Regeneron related to our Phase 2 clinical trial of RP1 in approximately 240 patients with CSCC clinical trial.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Our direct external research and development expenses are tracked on a program-by-program basis and consist of costs, such as fees paid to consultants, contractors, CMOs, and CROs in connection with our preclinical and clinical development activities. To date, we have not allocated expenses to our earlier-stage programs for RP2 and RP3. In addition, we do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified.

The table below summarizes our research and development expenses by product candidate or development program for each of the periods presented:

	Three Months Ended June 30,	
	2020	2019
	(Amounts in thousands)	
Direct research and development expenses by program:		
RP1	5,997	$ 3,701
Unallocated research and development expenses:		
Personnel related (including stock-based compensation)	5,060	3,086
Other	1,100	670
Total research and development expenses	$ 12,157	$ 7,457

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue enrollment and initiate additional clinical trials of RP1, pursue initial stages of clinical development of RP2, complete preclinical development of RP3 and continue to discover and develop additional product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the scope, rate of progress, expense and results of our ongoing clinical trials, as well future clinical trials or other product candidates and other research and development activities that we may conduct;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- uncertainties in clinical trial design and patient enrollment rates;
- the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;

- our success in operating a manufacturing facility, or securing manufacturing supply through relationships with third parties;
- our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidates, if and when approved;
- the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;
- our ability to successfully develop our product candidates for use in combination with third-party products or product candidates;
- negative developments in the field of immuno-oncology;
- competition with other products; and
- significant and changing government regulation and regulatory guidance.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and the development and potential commercialization of our product candidates. We also expect to continue to incur increased expenses, including accounting, audit, legal, regulatory and tax-related services costs associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Other income (expense), net

Research and development incentives

Research and development incentives consists of reimbursements of research and development expenditures. We participate, through our subsidiary in the United Kingdom, in the research and development program provided by the United Kingdom tax relief program, such that a percentage of up to 14.5% of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as other income.

Investment income

Investment income consists of income earned on our cash and cash equivalents and short-term investments.

Interest expense on finance lease liability

Interest expense on finance lease liability consists of amortization of finance charges under our financing lease.

Interest expense on debt obligations

Interest expense on debt obligations consists of the amortization of debt discount and cash paid for interest under the Term Loan Facility.

Other income (expense), net

Other income (expense), net consists primarily of realized and unrealized foreign currency transaction gains and losses.

Income taxes

Since our inception and through June 30, 2020, we have not recorded any income tax benefits for the net losses we incurred in each jurisdiction in which we operate, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards will not be realized.

Results of operations

Comparison of the three months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(Amounts in thousands)		
Operating expenses:			
Research and development	$ 12,157	$ 7,457	$ 4,700
General and administrative	5,676	3,450	2,226
Total operating expenses	17,833	10,907	6,926
Loss from operations	(17,833)	(10,907)	(6,926)
Other income (expense):			
Research and development incentives	686	621	65
Investment income	527	687	(160)
Interest expense on finance lease liability	(561)	-	(561)
Interest expense on debt obligations	(284)	-	(284)
Other income	(28)	91	(119)
Total other income (expense), net	340	1,399	(940)
Net loss	$ (17,493)	$ (9,508)	$ (7,866)

Research and development expenses

	Three Months Ended June 30,		
	2020	2019	Change
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	5,997	$ 3,701	$ 2,296
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	5,060	3,086	1,974
Other	1,100	670	430
Total research and development expenses	$ 12,157	$ 7,457	$ 4,700

Research and development expenses for the three months ended June 30, 2020 were $12.2 million, compared to $7.5 million for the year ended June 30, 2019. The increase of $4.7 million was due primarily to an increase of approximately $2.3 million in direct research costs associated with RP1 and an approximately $2.4 million increase in our unallocated research and development costs. The increase in RP1 costs was due primarily to an increase in clinical trial costs in the three months ended June 30, 2020 associated with our ongoing clinical trials as well as costs associated with operations of our new manufacturing facility for RP1 clinical trial supplies

The increase in unallocated research and development expenses reflected an increase of $2.0 million in personnel-related costs, including stock-based compensation and an increase of $0.2 million in other costs. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions as we expanded the development plan for RP1 in multiple indications. Personnel related costs for the three months ended June 30, 2020 and 2019 included stock-based compensation expense of $1.0 million and $0.8 million, respectively. Other costs increased primarily due to our potential registrational studies associated with our RP1 development plan with multiple cohorts as well as costs associated with operations of our new manufacturing facility.

General and administrative expenses

General and administrative expenses were $5.7 million for the three months ended June 30, 2020, compared to $3.5 million for the three months ended June 30, 2019. The increase of $2.2 million primarily reflected increases of $1.0 million in personnel related costs, increases of $0.6 million in facility and other variable costs and increases of $0.6 million in professional fees. The increase in personnel related costs was due to the hiring of additional personnel in our general and administrative functions as we expanded our operations in the United States. The increase in professional fees was due to costs associated with increased spending to build out our information technology capabilities as well legal and accounting fees related to ongoing business operations and enhancements to the internal control environment. The increase in facility and other variable costs was due primarily to an increase in costs associated with our directors and officers insurance.

Total other income, net

Other income (expense) was $0.3 million for the three months ended June 30, 2020, compared to $1.4 million for the three months ended June 30, 2019. The decrease of $1.1 million was primarily attributable to a $0.6 million increase in interest related to our finance lease liability, a $0.3 million increase in interest expense on debt obligations related to our Term Loan Facility, a $0.1 decrease in other income due primarily to the changes in foreign exchange rates of the Great British Pounds to United States Dollar and a $0.2 million decrease in investment income due to fluctuations in the rate of return on investments, partially offset by a $0.1 million increase in research and development incentives.

The COVID-19 Pandemic

In December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, which continues to spread throughout the U.S. and worldwide. We could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19. We are continuing to monitor the global outbreak and spread of COVID-19 and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address the COVID-19 pandemic. The spread of COVID-19 has caused us to modify our business practices, including implementing a global work from home policy for certain employees who are able to perform their duties remotely and restricting all nonessential travel. For those employees working from our facilities, including certain essential employees in our laboratory and who perform manufacturing functions, and certain other employees who we deem essential from time to time, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees, the patients we serve and other business partners in light of COVID-19. The COVID-19 pandemic has delayed, and we expect it may continue to delay, the timing of patient enrollment and treatment in certain of our ongoing clinical studies. For example, the enrollment of our clinical trial of RP1 in solid organ transplant patients with CSCC, representing a highly immunocompromised patient populations, has been slower than expected for reasons we attribute to the COVID-19 pandemic. However, the extent of such delay is currently unknown and has and will likely continue to vary by clinical study site. In addition, we may incur unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. The impact of COVID-19 on our business future results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. See “Risk Factors—Our financial condition and results of operations could be adversely affected by the recent novel coronavirus disease-2019, or COVID-19, outbreak.” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Liquidity and capital resources

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, if at all.

Sources of liquidity

To date, we have financed our operations primarily with proceeds from the sale of equity securities and, to a lesser extent, proceeds from the issuance of debt securities. Through June 30, 2020, we had received gross proceeds of approximately $419.0 million from our sales of equity instruments and $10.0 million from the issuance of debt. As of June 30, 2020, we had cash and cash equivalents and short-term investments of $261.8 million.

On July 24, 2018, we completed our IPO and issued and sold 6,700,000 shares of our common stock at a public offering price of $15.00 per share, resulting in net proceeds of $93.5 million after deducting underwriting discounts and commissions but before deducting offering costs. On July 30, 2018, we issued and sold an additional 707,936 shares of our common stock at the IPO price of $15.00 per share pursuant to the underwriters’ partial exercise of their option to purchase additional shares of our common stock, resulting in additional net proceeds of $9.9 million after deducting discounts and commissions but before deducting other offering expenses. On August 8, 2019, we entered into the Hercules Loan Agreement, pursuant to which we borrowed $10.0 million under the secured Term Loan Facility in the amount of $30.0 million. On June 1, 2020, the Company amended the Hercules Loan Agreement to, among other things, increase the secured term loan facility from $30.0 million to $40.0 million by adding a fourth advance of up to $10.0 million which may be borrowed between July 1, 2021 and December 15, 2021. On August 8, 2019, we entered into the Sales Agreement with SVB Leerink LLC, pursuant to which we may sell, from time to time, at our option, up to an aggregate amount of $75.0 million of shares of our common stock, of which we sold $4.5 million as of June 30, 2020. On June 8, 2020 the Sales Agreement was amended to reduce the aggregate offering amount under the Sales Agreement from $75.0 million of shares to $30.0 million of Shares. On November 18, 2019, we closed the November Offering of (i) 3,678,031 shares of its common stock at a public offering price of $13.61 per share and (ii) pre-funded warrants to purchase 2,200,000 shares of our common stock at a purchase price of $13.6099 per pre-funded warrant, the public offering price per share of the common stock less the $0.0001 per share exercise price of each pre-funded warrant. On December 13, 2019, we sold 838,530 shares of our common stock at the public offering price in connection with the underwriters’ partial exercise of an option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $85.6 million after deducting underwriting discounts, commissions and other offering expenses of approximately $5.8 million. On June 12, 2020, we closed the June Offering of (i) 2,826,088 shares of our common stock at a public offering price of $23.00 per share and (ii) pre-funded warrants to purchase 1,521,738 shares of our common stock at a purchase price of $22.9999 per pre-funded warrant, the public offering price per share of common stock less the $0.0001 per share exercise price of each pre-funded warrant. On June 29, 2020 we sold 652,173 shares of our common stock to the underwriters at the public offering price in connection with the underwriters’ full exercise of their option to purchase additional shares of our common stock. We received aggregate net proceeds of approximately $107.8 million after deducting underwriting discounts, commissions and other offering expenses of approximately $7.2 million.

Cash flows

The following table summarizes our cash flows for each of the periods presented:

	Three Months Ended June 30,	
	2020	2019
	(Amounts in thousands)	
Net cash used in operating activities	$ (15,090)	$ (13,582)
Net cash provided by (used in) investing activities	(49,126)	26,811
Net cash provided by financing activities	109,514	18
Effect of exchange rate changes on cash and cash equivalents	(1)	(137)
Net increase (decrease) in cash and cash equivalents	$ 45,297	$ 13,110

Operating activities

During the three months ended June 30, 2020, net cash used in operating activities was $15.1 million, primarily resulting from our net loss of $17.5 million and net cash used by changes in our operating assets and liabilities of $0.6 million, partially offset by non-cash charges of $3.0 million. Net cash used by our changes in our operating assets and liabilities for the three months ended June 30, 2020 consisted primarily of a $0.7 million increase in research and development incentive receivables, partially from the United Kingdom government due to the timing and amount of our qualifying expenditures, $0.3 million increase in prepaid expenses and other current assets and $0.2 million decrease in accounts payable, partially offset by $0.6 million net decrease related to ASC 842 (including changes in operating lease liabilities, operating lease, right-of-use asset and financing lease, right-of-use asset). The changes in accounts payable were primarily due to the timing of vendor invoicing and payments.

During the three months ended June 30, 2019, net cash used in operating activities was $13.6 million, primarily resulting from our net loss of $9.5 million and net cash used by changes in our operating assets and liabilities of $5.5 million, partially offset by net non-cash charges of $1.4 million. Net cash used by changes in our operating assets and liabilities for the three months ended June 30, 2019 consisted primarily of a $6.9 million increase in long term prepaid rent, a $0.9 million decrease in accrued expenses and other current liabilities, a $0.8 million increase in prepaid expenses and other current assets, a $0.6 million increase in the research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures and $0.1 million decrease in lease liabilities, partially offset by a $3.8 million increase in accounts payable and $0.1 million decrease in right-to-use asset.

Investing activities

During the three months ended June 30, 2020, net cash used in investing activities was $49.1 million, consisting of $125.8 million in purchases of available for sale securities and $0.9 million in purchases of property, plant and equipment, partially offset by $77.6 million in proceeds from sales and maturities of short-term investments.

During the three months ended June 30, 2019, net cash provided by investing activities was $26.8 million, consisting of $45.7 million in proceeds from sales and maturities of short-term investments, partially offset by $18.5 million in purchases of available for sale securities and $0.4 million in purchases of property, plant and equipment.

Financing Activities

During the three months ended June 30, 2020, net cash provided by financing activities was $109.5 million, consisting of $75.2 million from the issuance of common stock, $32.9 million in net proceeds from the issuance of pre-funded warrants to purchase common stock in connection with our follow-on public offering in June 2020, $1.5 million in proceeds from the exercise of stock options, partially offset by $0.1 million of issuance costs.

During the three months ended June 30, 2019, net cash provided by financing activities consists of an immaterial amount of proceeds from the exercise of stock options.

Hercules Loan Agreement

On August 8, 2019 and as amended on June 1, 2020, we and certain of our affiliates entered into the Hercules Loan Agreement with Hercules Capital, Inc., which, provided for aggregate borrowings of up to $40.0 million in the form of term loans. We borrowed $10.0 million at closing under the Hercules Loan Agreement. We may borrow the unused $30.0 million available under the Term Loan Facility in three separate advances. The second advance of up to $10.0 million may be borrowed between October 1, 2020 and December 15, 2020, the third advance of up to $10.0 million may be borrowed between July 1, 2020 and June 30, 2021 and the fourth advance of up to $10.0 million may be borrowed between July 1, 2021 and December 15, 2021 which contains certain borrowing milestones as defined in the agreement. In the event the Company does not draw on the second advance or if the Term Loan Facility is terminated prior to a draw of the second advance, the Company shall pay Hercules a one-time facility charge fee of $0.1 million on the earliest of (i) December 16, 2020 or (ii) the date the Company prepays the outstanding obligations.

Borrowings under the Hercules Loan Agreement bear interest at a rate per annum equal to the greater of either (i) the prime rate as reported in The Wall Street Journal plus 2.75%, or (ii) 8.75%. Under the Hercules Loan Agreement, we were required to make monthly interest-only payments through September 1, 2022, and are required to make equal monthly payments of principal, plus accrued interest, from October 1, 2022 through August 1, 2023. As of June 30, 2020, the outstanding principal amount under the Hercules Loan Agreement was $10.0 million. The term of the Hercules Loan Agreement is four years, ending August 1, 2023.

We may voluntarily prepay all, but not less than all, of the outstanding principal at any time prior to the maturity date, subject to a prepayment fee, which ranges from 1% to 3% of the outstanding principal. A final payment of 4.95% of the aggregate amount of any advances made under the Hercules Loan Agreement.

The Term Loan Facility is secured by substantially all of our assets, excluding our intellectual property, and subject to certain exceptions and exclusions. The Hercules Loan Agreement contains customary affirmative and negative covenants, including restrictions on our ability to pay dividends, incur debt, grant liens, make acquisitions, make loans, dissolving, and entering into leases and asset sales, but does not contain any financial covenants.

Funding requirements

Our plan of operation is to continue implementing our business strategy, continue research and development of RP1 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates, and if and as we:

- conduct our current and future clinical trials of RP1;
- progress the preclinical and clinical development of RP2 and RP3;
- operate our own in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- until our planned manufacturing facility is fully validated, continued manufacturing by third parties of larger quantities of our product candidates for clinical development.
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs and any future commercialization efforts.

As of June 30, 2020, we had cash and cash equivalents and short-term investments of $261.8 million. We believe that our existing cash and cash equivalents and short-term investments along with our debt commitments will enable us to fund our operating expenses and capital expenditure requirements to mid-2023.

Because of the numerous risks and uncertainties associated with the development of RP1 and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including those described in this section and above under "—Operating expenses —Research and development expenses."

Developing novel biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of therapies that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of our equity or convertible debt securities, our shareholders' interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

During the three months ended June 30, 2020, there were no material changes to our contractual obligations and commitments from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" in our Annual Report on Form 10-K for the year ended March 31, 2020, which was filed with the Securities and Exchange Commission on June 3, 2020.

Collaborations

BMS

On February 26, 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with Bristol-Myers Squibb Company, or BMS. Pursuant to the agreement, BMS is providing to us, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in our ongoing Phase 1/2 clinical trial. Under the agreement, we will sponsor, fund and conduct the clinical trial in accordance with an agreed-upon protocol. BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use nivolumab in the clinical trial and has agreed to supply nivolumab, at no cost to us, for use in the clinical trial. Both parties will own the study data produced in the clinical trial, other than study data related solely to nivolumab, which will belong solely to BMS, or study data related solely to RP1, which will belong solely to us. In January 2020, this agreement was expanded to cover an additional cohort of 125 patients with anti-PD-1 refractory melanoma.

Unless earlier terminated, the agreement will remain in effect until (i) the completion of the clinical trial, (ii) all related clinical trial data have been delivered to both parties and (iii) the completion of any statistical analyses and bioanalyses contemplated by the clinical trial protocol or any analysis otherwise agreed upon by the parties. The agreement may be terminated by either party (i) in the event of an uncured material breach by the other party, (ii) in the event the other party is insolvent or in bankruptcy proceedings or (iii) for safety reasons. Upon termination, the licenses granted to us to use nivolumab in the clinical trial will terminate. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature.

On April 12, 2019, we entered into a separate agreement with BMS on terms similar to the terms set forth in the agreement described above, pursuant to which BMS will provide, at no cost to us, nivolumab for use in our Phase 1 clinical trial of RP2 in combination with nivolumab.

Regeneron

On May 29, 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron Pharmaceuticals, Inc., or Regeneron. Pursuant to the agreement we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which is our ongoing Phase 2 clinical trial testing RP1 in combination with cemiplimab versus cemiplimab alone in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the Phase 2 clinical trial in CSCC has been agreed.

Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources needed to fulfill their respective obligations, in each case, under the terms of agreed study plans. Development costs of a particular clinical trial will be split equally. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 virus, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our ongoing Phase 2 clinical trial in CSCC, and expire upon the one-year anniversary of the commencement of the applicable study plan.

The agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed, (ii) the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (iii) in the event of a material breach.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report Form on 10-Q, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued research and development expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities and conducting preclinical studies and clinical trials on our behalf;
- CMOs in connection with the production of preclinical and clinical trial materials;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with preclinical and clinical development activities; and
- vendors related to product manufacturing and development and distribution of preclinical and clinical supplies.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-based compensation

We measure stock-based awards granted to employees and directors based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. See Note 9 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information. Forfeitures are accounted for as they occur. The fair value of each stock-based award is estimated on the date of grant based on the fair value of our common stock on that same date.

Prior to the adoption of ASC 2018-07 on April 1, 2019, for stock-based awards granted to consultants and non-employees, we recognize compensation expense over the period during which services are rendered by such non-employees and consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option pricing model.

After the adoption of ASC 2018-07, for stock-based awards granted to consultants and non-employees, we measure stock-based these awards based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We have to date only issued stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield.

We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging growth company status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Item 4. Controls and Procedures Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures 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 such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our Chief Executive Officer and Chief Financial Officer have concluded that, as of June 30, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed below. Notwithstanding these material weaknesses, our Chief Executive Officer and Chief Financial Officer concluded that the financial statements included elsewhere in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles, or GAAP.

Material Weakness

During the audit of our consolidated financial statements as of and for the years ended March 31, 2020 and 2019, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified were as follows:

We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

These material weaknesses also resulted in adjustments to preferred stock, stock compensation expense, warrant liability and deferred rent in our consolidated financial statements as of and for the year ended March 31, 2017, which were recorded prior to their issuance.

Remediation activities

We have identified and implemented, and continue to implement, certain remediation efforts to improve the effectiveness of our internal control over financial reporting and disclosure controls and procedures. These remediation efforts are ongoing. The following remedial actions have been completed as of the quarter ended June 30, 2020:

- We hired a Chief Financial Officer and other additional full-time accounting resources with appropriate levels of experience and reallocated responsibilities across the accounting organization to provide for segregation of duties and that the appropriate level of knowledge and experience is applied based on risk and complexity of transactions and tasks under review.

- We have increased the level of involvement and oversight from our new Chief Financial Officer and will maintain this level of oversight until the control environment and risk assessment processes have matured.

- We engaged a professional accounting services firm to assist us in testing the operating effectiveness of our formal policies, processes and internal controls for complying with the Sarbanes-Oxley Act, including formal policies, processes and internal controls to analyze, account for and disclose complex accounting transactions.

- We have performed a detailed financial reporting risk assessment to identify areas that require improvement and developed and implemented plans to address these areas; as a result, we have improved documentation of account reconciliations, and management review procedures and enhanced our GAAP training initiatives in key areas

The process of implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may take additional actions to address control deficiencies or modify certain of the remediation measures described above.

While progress has been made to enhance our internal control over financial reporting, we are still in the process of implementing, documenting and testing these processes, procedures and controls. Additional time is required to complete implementation and to assess and ensure the sustainability of these procedures. We will continue to devote significant time and attention to these remedial efforts. However, the material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in internal control over financial reporting

Other than the applicable remediation efforts described above that were implemented or commenced during the three months ended June 30, 2020, there have been no other changes in our internal control over financial reporting during the three months ended June 30, 2020 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.

We are not currently a party to any material legal proceedings.

Item 1A. Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including our consolidated financial statements and related notes and "Management's discussion and analysis of results of operations and financial condition." If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks related to product development

Our product candidates are in the early stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We have never generated any revenue from product sales and may never be profitable.

All of our product candidates are in research or early development. We have not generated any revenues from the sale of products and do not expect to do so for at least the next several years. Our lead product candidate, RP1, and any other product candidates will require extensive preclinical and/or clinical testing and regulatory approval prior to commercial use. Our research and development efforts may not be successful. Even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably.

We currently have only two product candidates in clinical development. A failure of these product candidates in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same or similar therapeutic approaches.

RP1 and RP2 are our only clinical development-stage product candidates. Although we have another product candidate, RP3, in preclinical development and we may develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as those that are in clinical development, and there can be no assurance that they will ever do so. Since all of the product candidates in our current pipeline are based on our Immulytic platform, if RP1 fails in development as a result of any underlying problem with our Immulytic platform, then we may be required to discontinue development of all product candidates that are based on our therapeutic approach. If we were required to discontinue development of RP1, RP2 or our other product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.

Our lead product candidate, RP1, is in an ongoing Phase 1/2 clinical trial alone and in combination with nivolumab and we have initiated a Phase 2 clinical trial of RP1 in combination with cemiplimab in CSCC. We have also opened for enrollment a Phase 1b clinical trial of single agent RP1 in solid organ transplant recipients in approximately 30 patients with CSCC. Additionally, RP2, the next product candidate from our Immulytic platform, is in an ongoing Phase 1/2 clinical trial alone and in combination with nivolumab. Our third product candidate, RP3, is in preclinical development, and we expect to enter clinical development in 2020. Our product candidates will require preclinical and/or clinical trials before we can submit a marketing application to the applicable regulatory authorities.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations, or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;

- statutes or regulations could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a Biologics License Application, or BLA, or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development; and
- we, the third parties on which we rely, and the FDA may have delays in the conduct of our respective operations as a result of the effects of the COVID-19 pandemic, which could result in delays or prevent our ability to receive marketing approval or commercialize our product candidates.

Our development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We anticipate that our product candidates will be used in combination with third-party drugs, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Our product candidates may be administered in combination with checkpoint blockade drugs, a class of drugs that are intended to stop tumor cells from "switching off" an immune system attack against themselves. We have entered into agreements with BMS for the supply of nivolumab, its anti-PD-1 therapy, for use in connection with our current Phase 1/2 clinical trials with RP1 and RP2. We have also entered into a clinical collaboration agreement with Regeneron, which includes the supply of cemiplimab, its anti-PD-1 therapy, for clinical trials conducted thereunder. We are enrolling patients in our first planned clinical trial under the Regeneron agreement, a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, versus cemiplimab alone, in approximately 240 patients with CSCC. We may enter into additional agreements for the supply of anti-PD-1 products for use in connection with the development of one or more of our product candidates. Our ability to develop and ultimately commercialize our product candidates used in combination with nivolumab, cemiplimab or any other checkpoint blockade therapy will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint blockade therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. While we are planning a new clinical trial for use of RP1 as a monotherapy, we are developing RP1 and our other product candidates for use in combination with anti-PD-1 or anti-PDL1 therapies and may develop RP1 or our other product candidates for use with other therapies. The FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross-labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that BMS, Regeneron or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing an anti-PD-1 therapy. Additionally, should the supply of products from BMS, Regeneron or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of an alternative anti-PD-1 therapy, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

Our lead product candidate is RP1. A key part of our strategy is to pursue clinical development of RP1 and additional product candidates, including RP2 and RP3. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure our shareholders that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of solid tumors, we cannot assure our shareholders that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Risks related to regulatory approval

Even if our development efforts are successful, we may not obtain regulatory approval for any of our product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize our product candidates.

We are not permitted to market or promote or sell any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a BLA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB approval, or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

The FDA or a comparable foreign regulatory authority may determine that our product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

To date, the most commonly reported adverse events observed for RP1 are local injection site reactions and systemic constitutional symptoms, such as fatigue, fevers and chills. However, there can be no assurance that additional undesirable side effects or serious adverse events will not be caused by or associated with RP1 or our other product candidates as they continue through or enter clinical development. Serious adverse events or undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our product candidates.

Undesirable side effects caused by any of our product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post approval study requirements, or other testing and surveillance.

If any of our product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off label" uses, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off label uses, and our business, financial condition, results of operations, stock price and prospects may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off label use.

If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of our products, following approval, for off label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines and agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, shortage reporting, risk management plans, supply chain security, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post approval.

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

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA preapproval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;

- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, 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 be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from and, in some cases, greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Additionally, the outcome of the United Kingdom's impending withdrawal from the European Union, commonly referred to as Brexit, remains uncertain. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal of the United Kingdom from the European Union could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing 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. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

Risks related to commercialization

If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for RP1 or any of our other product candidates, our ability to generate revenues from our product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market the product candidates;
- creating market demand for our product candidates through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize product candidates in the United States;
- manufacturing product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;

- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- achieving market acceptance of our product candidates by patients, the medical community, and third- party payors;
- achieving appropriate reimbursement for our product candidates;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While our product candidates are intended to be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our product candidates. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;

- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated all of our research and development efforts on product candidates based on our Immulytic platform, and our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies. Only one oncolytic immunotherapy, T-Vec, has received FDA approval to date. Any product candidates that are approved may be subject to extensive post approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements.

If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- the efficacy of our product candidates in combination with marketed checkpoint blockade drugs;
- the commercial success of the checkpoint blockade drugs with which our products are co-administered;
- the prevalence and severity of adverse events associated with our product candidates or those products with which they are co-administered;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product candidates by direct injection into tumors, a less common method for the administration of oncology therapies than systemic administration, which may result in slower adoption of our therapies;
- the relative convenience and ease of administration of any products with which our product candidates are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the price concessions required by third-party payors to obtain coverage;
- the extent and strength of our marketing and distribution of our product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product candidates, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;

- the actions of companies that market any products with which our product candidates are co-administered;
- the approval of other new products;
- adverse publicity about our product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for oncolytic immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

Negative developments in the field of immuno-oncology could damage public perception of RP1 or any of our other product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of RP1 or our other product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for RP1 or our other product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of a modified virus, adverse developments in antiviral vaccines or clinical trials of other oncolytic immunotherapy products based on viruses may result in a disproportionately negative effect for RP1 or our other product candidates as compared to other products in the field of immuno-oncology that are not based on viruses. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for RP1 or our other product candidates.

Risks related to our financial position and need for additional capital

We are a clinical stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history, and we are early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities, including the sale of our common stock in our public offerings. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our Immulytic platform, RP1 and our other product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable and have incurred losses in each period since our inception. For the three months ended June 30, 2020 we reported a net loss of $17.5 million. At June 30, 2020, we had an accumulated deficit of $129.8 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 marketing approvals for, RP1, our other product candidates and any additional product candidates we may develop.

Even if we succeed in receiving marketing approval for and commercialize RP1, we will continue to incur substantial research and development and other expenditures to develop and market additional potential products. 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 have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of, RP1 and our other product candidates;
- obtaining marketing approvals for RP1 and our other product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for RP1 and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing RP1 and our other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of RP1 and our other product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if our product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market RP1 or our other product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. At June 30, 2020, our cash and cash equivalents and short-term investments were $261.8 million We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing RP1 and our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for RP1 and our other product candidates if clinical trials are successful;
- the success of any collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of operating our manufacturing facility;
- the cost of manufacturing RP1 and our other product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Our ability to obtain debt financing may be limited by covenants we have made under our Loan and Security Agreement with Hercules Capital, Inc. (“Hercules”) and our pledge to Hercules of our assets as collateral. Based on our research and development plans, we expect that our existing cash and cash equivalents and short-term investments will enable us to fund our planned operating expenses and capital expenditure requirements to mid-2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RP1 or our other product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our existing stockholders' interest will be diluted. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to grant rights to develop and market one or more of our product candidates or technologies that we would otherwise prefer to develop and market ourselves.

Risks related to intellectual property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, Immulytic platform, RP1 and our other product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology or for RP1 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize RP1 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our Immulytic platform and each of our product candidates, we have filed six patent applications under the PCT. Five of these PCT applications have entered the national phase and are pending in a range of countries, and one is still in the international phase. Three US patents have been granted. Other than the foregoing, none of our PCT-derived patent applications or U.S. provisional applications have been granted by a patent office and examination has started only in connection with the European and US national phase applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or RP1 or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and other third parties who have access to our trade secrets. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, in the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

Third parties may in the future initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell RP1 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third-party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third-party to continue developing, manufacturing and commercializing RP1 and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing RP1 or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business.

In addition, we are developing certain of our product candidates in combination with nivolumab and cemiplimab, which are covered by patents or licenses held by BMS and Regeneron, respectively, to which we do not have a license other than for use in connection with the applicable clinical trial. We also plan to develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with RP1 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost 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. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own in the future. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time 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, nonpayment of fees and failure to properly legalize and submit formal documents. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to RP1 or our other product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect RP1 and our other product candidates.

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 involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings, even in applications filed before the Leahy-Smith Act came into effect. Because these third-party challenges before the USPTO have a lower evidentiary bar for patent invalidation as compared with the evidentiary standard in a U.S. Federal Court, it is possible for a third party to invalidate a patent claim before the USPTO that would not have been invalidated before a District Court. Additionally, rights of review and appeal for these USPTO third-party challenges is still a developing area of law.

On March 16 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Since patent applications in the United States and many other countries are confidential for a period of time after a filing, we cannot be certain that we were the first to file any patent application or first to invent any of the inventions claimed in our patents or patent applications. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant lawmaking bodies in other countries, 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.

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

Competitors may infringe any future licensed patents or any patent we own in the future or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to assert that we are infringing their intellectual property rights or to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

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

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Our collaborators' employees may currently be or previously have been employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these persons, including each member of our senior management team, executed proprietary rights, nondisclosure and noncompetition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we take steps to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of noncompetition or nonsolicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we take steps to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their noncompetition or nonsolicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to RP1 and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing RP1 and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize RP1 and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment of our patents in such a way that they no longer cover and protect RP1 and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our or our licensing partners' patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on RP1 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as RP1 and our other product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Patient Protection and Affordable Care Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

RP1 and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and if all of the patents that cover our particular biological product expire before the 12 year market exclusivity expires, the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Risks related to manufacturing and our reliance on third parties

We have agreements with BMS and Regeneron, and in the future may have agreements with other companies, to obtain the supply of anti-PD-1 therapies for the development of our product candidates. If our relationships with BMS, Regeneron, or any future collaborator or supplier are not successful, we may be delayed in completing the development of our product candidates.

We have entered into arrangements with BMS and Regeneron as part of our clinical development for RP1 and RP2. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our ongoing Phase 1/2 clinical trials with RP1 and RP2 and Regeneron is providing cemiplimab, its anti-PD-1 therapy, for use in our randomized, controlled Phase 2 clinical trial with RP1 in approximately 240 patients with CSCC and may potentially do so for other clinical trials in the future. We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies for use in the development of RP1 and our other product candidates. The outcome of these clinical trials is dependent both on the performance of our partners' products and product candidates and also on our partners' ability to deliver sufficient quantities of adequately produced product. Should any of our partners' products or product candidates fail to produce the results that we anticipate, we may have to re-run clinical trials for RP1 or our other product candidates or may otherwise be delayed in the commercialization of RP1 or our other product candidates. Similarly, should any partner fail to provide us with a product or product candidate that suits our requirements, we may have to re-run clinical trials for RP1 or our other product candidates or may be otherwise delayed in the commercialization of RP1 or our other product candidates.

Our collaboration agreements with any future partners may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate it licenses to us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

If the manufacturers upon which we rely fail to produce our product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.

Until our manufacturing facility is fully operational and for a period of time thereafter, we will rely on third-party contract manufacturers to manufacture our clinical trial product supplies. There can be no assurance that our clinical development will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the therapeutic substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

We currently have only one contract manufacturer for our product candidates for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or their components. The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our contract manufacturers may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

Contract manufacturers of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

The transition of our manufacturing operations to our new facility may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.

We have completed the build-out of, obtained an occupancy certificate with respect to, and successfully completed our first two tech transfers at, our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts at which we intend to operate our own manufacturing facility in order to secure supplies for pivotal studies and commercial launch. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. We may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient backup supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable foreign regulatory authorities' cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspection. These requirements include the qualification and validation of our manufacturing equipment and processes. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.

In operating our own manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline.

Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

Risks related to legal and compliance matters

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is 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. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and

- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anticorruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anticorruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anticorruption laws that apply in countries where we do business. The FCPA, the Bribery Act, and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if noncompliant, could potentially subject us to liability under the FCPA, Bribery Act or local anticorruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and the United Kingdom and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anticorruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anticorruption laws or trade control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or VHCA, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act, or HITECH), or HIPAA, the FCPA, the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those that apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal, state and foreign privacy, data protection, security, reimbursement, and fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third- party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Regulatory authorities and third-party payors, such as private health insurers, and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of therapeutics in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. A few states have also passed or are considering legislation intended to prevent significant price increases. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

For example, legislative changes have been proposed and adopted since the ACA was enacted in 2010. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went effective on April 1, 2013. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Centers for Medicare and Medicaid Services, or CMS, promulgated regulations governing manufacturers' obligations and reimbursement under the Medicaid Drug Rebate Program, and promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the product to individuals and entities to which product ownership is transferred, are required to label products with a product identifier, and are required to keep certain records regarding the product. The transfer of information to subsequent product owners by manufacturers is also required to be done electronically. Manufacturers are also being required to verify that purchasers of the manufacturers' products are appropriately licensed. Further, manufactures have product investigation, quarantine, disposition, and FDA, other comparable foreign regulatory authorities, and trading partner notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. 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, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our development programs.

Our internal computer systems, and those of our CROs, CMOs, information technology suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyber-attacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from completed, ongoing or planned 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 personal, confidential or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed.

Risks related to our operations

Our financial condition and results of operations could be adversely affected by the recent novel coronavirus disease-2019, or COVID-19, outbreak.

In December 2019, a novel strain of coronavirus, now referred to as COVID-19, surfaced in Wuhan, China. The virus continues to spread globally, including the United States, the United Kingdom and other countries in which we conduct clinical trials, and has been declared a pandemic by the World Health Organization. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. In an effort to halt the outbreak of COVID-19, many countries, including the United States, the United Kingdom and certain other countries in which we conduct clinical trials, placed significant restrictions on travel and business operations or issued shelter-in-place orders. These restrictions and orders continue to remain in effect to varying degrees, the effect of which required, and in some instances, continue to require, certain of our employees and clinical trial staff to work remotely and avoid unnecessary travel. While these restrictions and orders have eased in certain geographies in which we operate, the effect of these restrictions and orders has impacted the pace of enrollment in our clinical trials, and if they continue, may affect our results and operations.

The COVID-19 pandemic is affecting the United States and global economies and has affected and may continue to affect our operations and those of third parties on which we rely, including by causing disruptions in our raw material and anti-PD-1 supply, the manufacturing of our product candidates, the commercialization of our product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic has affected and may continue to affect the operations of the FDA and comparable foreign regulatory authorities, which could result in delays of reviews and approvals, including with respect to RP1 and our other product candidates. The evolving COVID-19 pandemic has also directly or indirectly impacted and is likely to continue to impact the pace of enrollment in our clinical trials as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff may no longer be able to get to the clinic. Such facilities and offices have and may continue to be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services. For example, our clinical trial of RP1 in solid organ transplant patients with CSCC, representing a highly immunocompromised patient populations, has been slower than expected. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic and the federal, state and local responses to such virus, could materially impact the efficiency and pace with which we work and develop our product candidates.

The COVID-19 pandemic and the government and public health response continues to rapidly evolve. In light of the COVID-19 pandemic, the FDA has issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 pandemic on many clinical trial programs in the United States and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. Additionally, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, which includes a number of provisions that are applicable to the pharmaceutical industry, and further acts, laws or regulations may be enacted or implemented in the future.

While the potential economic impact brought by, and the duration and severity of, the COVID-19 pandemic are difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. Additionally, the stock market has been unusually volatile during the COVID-19 outbreak and such volatility may continue. To date, during certain periods of the COVID-19 pandemic, our stock price fluctuated significantly, and such fluctuation may continue to occur. The ultimate impact of the COVID-19 pandemic on our business will largely depend on future developments, which are highly uncertain, cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We do not yet know the full extent of the delays or impacts on our business, financing or clinical trial activities, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely. To the extent to COVID-19 pandemic materially impacts our business and financial results, it may also have the effect of significantly heightening many of the other risk described in this "Risk Factors" section.

We will need to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose 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, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and

- strengthening our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize RP1 and our other 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 in order 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. The services include substantially all aspects of clinical trial management and manufacturing, as well as support for our financial reporting and accounting functions. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can 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, we may not comply with our financial reporting and accounting obligations on a timely basis and we may not be able to obtain marketing approval of RP1 and our other product candidates or otherwise advance our business. We cannot assure you that we will 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 qualified 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 RP1 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We are highly dependent on our key personnel, including Philip Astley-Sparke, our Chief Executive Officer; Robert Coffin, Ph.D., our President and Chief Research & Development Officer; and Colin Love, Ph.D., our Chief Operating Officer. If we are not successful in attracting, motivating 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, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our founders, as well as our other scientific, manufacturing, quality and medical personnel. Philip Astley-Sparke, our Chief Executive Officer, Robert Coffin, Ph.D., our President and Chief Research & Development Officer, and Colin Love, Ph.D., our Chief Operating Officer, were the founder and senior management team of BioVex Group, Inc., or BioVex, where they invented and developed T-Vec, the only oncolytic immunotherapy to receive FDA approval. BioVex was acquired by Amgen Inc., or Amgen, in 2011. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. Furthermore, the historical results, past performance and/or acquisitions of companies with which our founders were affiliated, including BioVex, do not necessarily predict or guarantee similar results for our company.

We conduct our operations at our facilities near Boston, Massachusetts and near Oxford, England, each of which are in regions that are home to many other biopharmaceutical companies and many academic and research institutions.

Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of these regions, and doing so may be costly and difficult.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants 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. Although we have employment agreements with our key employees, these employment agreements generally 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 any of these individuals or the lives of any of our other employees.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the audits of our consolidated financial statements as of and for the years ended March 31, 2020, 2019 or 2018, we identified material weaknesses in our internal control over financial reporting. However, these material weaknesses did not result in a restatement for the years ended March 31, 2020, 2019 or 2018. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price and ability to access the capital markets in the future.

The material weaknesses we identified were as follows:

- We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, our insufficient segregation of duties in our accounting function. This material weakness further contributed to the material weakness below.

- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions, including accounting for preferred stock, stock-based compensation, warrant liabilities and leases.

Each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

These material weaknesses also resulted in adjustments to preferred stock, stock compensation expense, warrant liability and deferred rent in our consolidated financial statements as of and for the year ended March 31, 2017, which were recorded prior to their issuance.

Prior to the completion of our IPO, we were a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We have implemented, and continue to implement, measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses. In December 2019 we hired Jean Franchi, our first Chief Financial Officer, and we continue to hire additional finance and accounting personnel. We have also engaged a third-party consulting firm to assist us in the design and documentation of appropriate controls. We are continuing these efforts in order to design and implement our financial control environment, including the establishment of controls to account for and disclose complex transactions.

We cannot assure you that the measures we have taken to date, and actions we intend to take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, our independent registered public accounting firm has not performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, potentially resulting in restatements of our financial statements, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result.

If we fail to establish and maintain proper and effective internal control over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal control over financial reporting. We must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to incur substantial professional fees and internal costs for our accounting and finance functions, expend significant management efforts, continue to implement plans developed to address areas that we have identified as requiring improvement, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our disclosure controls and procedures were not effective as of June 30, 2020, and in any event may not prevent or detect all errors or acts of fraud.

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, we concluded that, as of June 30, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed above. Notwithstanding these material weaknesses, our management has concluded that the financial statements included elsewhere in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large onetime expenses and acquire intangible assets that could result in significant future amortization expense or intangible asset impairment charges. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business.

Global financial markets have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices. We are unable to predict the likely duration and severity of the current disruptions in financial markets and adverse economic conditions throughout the world. These economic developments affect businesses such as ours and those of third parties on which we rely in a number of ways that could result in unfavorable consequences to us. Current economic conditions or a deepening economic downturn in the United States and elsewhere may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

At June 30, 2020, we had $261.8 million of cash and cash equivalents and short-term investments. Although we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments since that date, we cannot assure you that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments, or our ability to meet our financing objectives. Furthermore, our stock price may decline due, in part, to the volatility of the stock market and general economic downturns.

Exchange rate fluctuations may materially affect our results of operations and financial conditions.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source third-party manufacturing, consulting and other services in the United Kingdom and the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Risks related to our common stock

An active trading market for our common stock may not be sustained.

Our common stock began trading on the Nasdaq Global Select Market on July 20, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for shares of our common stock may not be sustained. In the absence of an active trading market for shares of our common stock, our stockholders may not be able to sell their common stock at or above the price at which such stockholder acquired our common stock or at the time that they would like to sell.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which it was acquired. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of RP1 and our other product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of RP1 and our other product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- political and economic instability, including the impact of COVID-19, the possibility of an economic recession, international hostilities, acts of terrorism and governmental restrictions, inflation, trade relationships and military and political alliances; and
- the other factors described in this “Risk factors” section.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- the total expenses we incur in connection with equipping and operating our manufacturing facility;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on the FDA's and comparable foreign regulatory authorities' guidelines and requirements, the quantity of production and the terms of any agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the timing and outcomes of clinical and preclinical studies for RP1 and our other product candidates or competing product candidates;
- competition from existing and potential future products that compete with RP1 and our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of RP1 or our other product candidates;
- the level of demand for RP1 and our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with RP1 and our other product candidates;
- our ability to commercialize RP1 and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- the success of and our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- political and economic instability, including the impact of the COVID-19 coronavirus, the possibility of an economic recession, international hostilities, acts of terrorism and governmental restrictions, inflation, trade relationships and military and political alliances;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

These factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We have broad discretion in how we use our cash, cash equivalents and investments, and may not use these resources effectively, which could affect our results of operations and cause our stock price to decline.

Our management has considerable discretion in the application of our cash, cash equivalents and investments. We intend to use our resources to fund our preclinical and clinical development programs as well as for general corporate purposes, including working capital requirements and other operating expenses. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of our resources. We may use our resources for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.

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. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

Our executive officers, directors, and stockholders and their affiliates who beneficially own more than 5% of our common stock exercise significant influence over our company, which limits your ability to influence corporate matters and could delay or prevent a change in corporate control.

Based on the number of shares outstanding as of June 30, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant portion of our voting stock and, accordingly, these stockholders will continue to have significant influence over matters requiring stockholder approval. For example, these stockholders will continue 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.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested. Neither the principal stockholders nor the representatives of the principal stockholders on our board of directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware and could take any such opportunity for themselves or offer it to their other affiliates, unless such opportunity is expressly offered to them solely in their capacity as members of our board of directors.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration of contractual or legal restrictions on resale lapse, the market price of our common stock could decline. These sales may make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisition.

In addition, approximately 13.7 million shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans or subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of shares of our common stock pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

We may sell up to $30.0 million of shares of our common stock in “at-the-market” offerings pursuant to the sales agreement entered into with SVB Leerink LLC on August 8, 2019 and as amended on June 8, 2020. The sale of a substantial number of shares of our common stock pursuant to the sales agreement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. In addition, issuances of any shares of our common stock sold pursuant to the sales agreement will have a dilutive effect on our existing stockholders.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act and related SEC and Nasdaq rules impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and have made some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

Antitakeover provisions in our charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may delay or prevent an acquisition of our company or a change in our management. These provisions include a classified board of directors and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with our company. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board of directors were considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for our stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements 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 and critical audit matters reporting, reduced disclosure obligations regarding executive compensation in 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 for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) March 31, 2024, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion, or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior September 30th, and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period.

Additionally, we are also a "smaller reporting company," as defined in Regulation S-K. We will remain a smaller reporting company if we have (1) less than $250 million in market value of our shares held by non-affiliates as of the last business day of our second fiscal quarter or (2) less than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and less than $700 million in market value of our shares held by non-affiliates as of the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely on 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.

Under the Jumpstart Our Business Startups Act of 2012, 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 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.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal affairs doctrine.

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

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Date	Number
4.1	Form of Pre-Funded Warrant.	8-K	June 8, 2020	4.1
10.1*#	Employment Agreement, dated May 25, 2020, by and between Replimune Inc. and Andrea Pirzkall.			
10.2	First Amendment to Loan and Security Agreement by and among Replimune Group, Inc., Replimune, Inc., Replimune Limited and Hercules Capital, Inc., dated June 1, 2020.	10-K	June 3, 2020	10.21
10.3*	Deed of Variation, dated June 29, 2020, by and among MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited, and Replimune Limited.			
31.1*	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
31.2*	Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.1*	Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
32.2*	Certification of the Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).			
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.			

* Filed or furnished herewith. The certifications furnished in Exhibit 32.1 and Exhibit 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

# Indicates management contract or compensatory plan.

SIGNATURES

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

REPLIMUNE GROUP, INC.

Dated: August 7, 2020

By: /s/ Philip Astley-Sparke
Name: Philip Astley-Sparke
Title: Chief Executive Officer and Director
(Principal Executive Officer)

Dated: August 7 , 2020

By: /s/ Jean Franchi
Name: Jean Franchi
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into by and between Replimune, Inc. (the "Company") and Andrea Pirzkall (the "Executive") as of May 22, 2020.

WHEREAS, the Company desires to employ the Executive as its Chief Medical Officer, and the Executive desires to serve in such capacity on behalf of the Company.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants and agreements hereinafter set forth, the Company and the Executive hereby agree as follows:

1. Employment.

(a) Term. The initial term of this Agreement shall begin on the first day of the Executive's employment with the Company on or around July 7, 2020, which actual date shall be mutually agreed to by the parties (such first day of the Executive's employment shall be referred to herein as the "Effective Date"), and shall continue for two years, unless the Executive's employment is sooner terminated in accordance with Sections 6, 7, 8, 9, 10 or 11. Unless earlier terminated, the term of this Agreement shall automatically renew for periods of one year unless either party gives the other party written notice at least 90 days prior to the end of the then existing term that the term of this Agreement shall not be further extended. The period commencing on the Effective Date and ending on the date on which the term of this Agreement terminates is referred to herein as the "Term."

(b) Duties.

(i) During the Term, the Executive shall serve as the Chief Medical Officer of the Company, with duties, responsibilities, and authority commensurate therewith, and shall report to the President and Chief Research & Development Officer of the Company. The Executive shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to the Executive by the President and Chief Research & Development Officer.

(ii) The Executive represents to the Company that the Executive is not subject to or a party to any employment agreement, noncompetition covenant, or other agreement that would be breached by, or prohibit the Executive from, executing this Agreement and performing fully the Executive's duties and responsibilities hereunder. The Executive acknowledges that during her prior employment, she may have had access to trade secrets or proprietary information of her prior employer that may continue to be of value to her prior employer. The Executive represents that she will not disclose her prior employer's trade secrets or proprietary information to anyone within the Company, use those trade secrets and proprietary information in the course of her duties with the Company or bring those trade secrets and proprietary information onto the Company's premises.

(iii) From the Effective Date and until August 31, 2020 ("Part-Time Period"), the Executive will be employed on a part-time basis and the Executive will be expected to devote approximately two to three hours per week on average (not to exceed eight hours per week) to the performance of her duties hereunder.

(c) Best Efforts. During the Term, the Executive shall devote her best efforts and sufficient time and attention to promote the business and affairs of the Company and its affiliated entities, and may be engaged in other business activities only to the extent the Executive has received the prior written consent of the Board of Directors of the Company (the "Board") and such activities do not materially interfere or conflict with the Executive's obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 15 below. The foregoing shall not be construed as preventing the Executive from (i) serving on civic, educational, philanthropic or charitable boards or committees and (ii) managing personal investments, so long as such activities are permitted under the Company's code of conduct and employment policies and do not violate the provisions of Section 15 below.

(d) Principal Place of Employment. During the Term and following the Executive's relocation to the Boston, MA metropolitan area, the Executive understands and agrees that her principal place of employment will be in the Company's offices located in the Boston, MA metropolitan area. Following the Part-Time Period, the Executive will be required to travel for business in the course of performing her duties for the Company. It is recognized that for at least the first year of the Executive's employment hereunder, the Executive will continue to be based in North Carolina, and therefore frequent travel from North Carolina to the Boston, MA metropolitan area following the Part-Time Period may be required.

2. Compensation.

(a) Hourly Rate. During the Part-Time Period, the Executive will be paid at an hourly rate of $204.00, which shall be paid in accordance with the Company normal payroll practices. The Executive is required to track her hours on a weekly basis and notify the Company the number of hours worked during such week no later than Monday of the week following the week in which the hours were worked.

(b) Base Salary. During the Term and following the Part-Time Period, the Company shall pay the Executive a base salary ("Base Salary"), at the annual rate of $425,000, which shall be paid in installments in accordance with the Company's normal payroll practices. The Executive's Base Salary shall be reviewed annually by the President and Chief Research & Development Officer, pursuant to the normal performance review policies for senior-level executives and may be adjusted from time to time as the Compensation Committee of the Board (the "Compensation Committee") deems appropriate. The Compensation Committee may take any actions of the Board pursuant to this Agreement.

(c) Annual Bonus. The Executive shall be eligible to be awarded an annual discretionary bonus for each fiscal year during the Term, based on the establishment and attainment of individual and corporate performance goals and targets established by the Compensation Committee ("Annual Bonus") in its sole discretion. The target amount of the Executive's Annual Bonus for any fiscal year during the Term is 40% of the Executive's annual Base Salary, and the actual Annual Bonus awarded, if any, may be more or less than the target amount, as determined by the Compensation Committee in its sole discretion. Any Annual Bonus awarded shall be paid after the end of the fiscal year to which it relates, at the same time and under the same terms and conditions as the bonuses for other executives of the Company; provided that the Executive must be employed in good standing on the date that the Executive's Annual Bonus is paid. The Annual Bonus shall be subject to the terms of the annual bonus plan that is applicable to other executives of the Company, including the requirement as to continued employment in good standing, subject to the provisions of Section 7 below. Any Annual Bonus for fiscal year 2020 will be prorated for the period following Part-Time Period during which the Executive works for the Company in fiscal year 2020. For the avoidance of doubt, the Executive shall not be entitled to an Annual Bonus for hours worked during the Part-Time Period.

(d) Stock Option. Subject to the approval of the Compensation Committee, which has already been obtained contingent on the Executive's commencement of employment, the Executive will be granted a Nonqualified Stock Option (as defined in the Replimune Group, Inc. 2018 Omnibus Incentive Compensation Plan (the "Plan")) to purchase 300,000 shares (the "Option"), pursuant to the terms of the Company's Plan and subject to the standard form of Nonqualified Stock Option Award Agreement under the Plan. Vesting and exercisability of the Option will be over four years from the date of grant with 25% vesting and becoming exercisable on the first anniversary of the date of grant, and the remainder vesting and becoming exercisable monthly for three years thereafter.

3. Retirement and Welfare Benefits. During the Term and following the Part-Time Period, the Executive shall be eligible to participate in the Company's health, life insurance, long-term disability, retirement and welfare benefit plans, and programs available to similarly-situated employees of the Company, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the Company or any Affiliate (as defined below) of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date.

4. Paid Time Off. During the Term and following the Part-Time Period, the Executive shall be entitled to five weeks of paid time off, in accordance with the Company's paid time off policy, as may in effect from time to time. The Executive may use paid time off for vacation, personal time, or sick time (in accordance with applicable law).

5. Expenses.

(a) Business Expenses. The Company shall reimburse the Executive for all necessary and reasonable travel (which does not include commuting) and other business expenses incurred by the Executive in the performance of her duties hereunder in accordance with such policies and procedures as the Company may adopt generally from time to time for executives.

(b) Relocation and Pre-Relocation Travel Expenses. Following the Part-Time Period, the parties expect that Executive will (but Executive is not required to) travel to the Company's offices in the Boston, MA metropolitan area for approximately three to five days per week, two to four weeks per month. For up to two years after the end of the Part-Time Period and during the Term, the Company shall reimburse the Executive for reasonable travel expenses, including economy airfare for flights between North Carolina and Boston, MA, local transportation costs and lodging expenses. Following the first full year after the end of the Part-Time Period, the parties agree to review the travel arrangement and certain adjustments may be made, including extending the reimbursement period beyond two years after the end of the Part-Time Period. Upon the Executive's relocation to the Boston, MA metropolitan area during the Term, the Executive shall be eligible to receive reimbursement of reasonable relocation expenses for the move to the Boston, MA metropolitan area from North Carolina. Such reasonable relocation expenses shall be limited to moving company services, packing and unpacking services, one-way economy airfare for members of the Executive's immediate family, and vehicle transportation services.

6. Termination Without Cause; Resignation for Good Reason. The Company may terminate the Executive's employment at any time without Cause (as defined below) upon 30 days' advance written notice. If the Company terminates the Executive's employment without Cause during the Part-Time Period, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any Accrued Obligations (as defined below). The Executive may initiate a termination of employment by resigning for Good Reason following the Part-Time Period, as described below. Upon termination by the Company without Cause or resignation by the Executive for Good Reason, in each case, following the Part-Time Period, whether before or after the Change of Control Protection Period (as defined below), if the Executive executes and does not revoke a written Release (as defined below), the Executive shall be entitled to receive, in lieu of any payments under any severance plan or program for employees or executives, the following:

(a) The Company will pay the Executive an amount equal to 0.75 times the Executive's annual Base Salary. Payment shall be made over the nine-month period following the termination date in installments in accordance with the Company's normal payroll practices. Payment will begin within 60 days following the termination date, and any installments not paid between the termination date and the date of the first payment will be paid with the first payment.

(b) Provided that the Executive is eligible for and timely elects continuation coverage under COBRA, the Company will reimburse the Executive on a monthly basis for the COBRA premiums the Executive pays for continued health care coverage under the Company's group health plans for the Executive and the Executive's eligible dependents ("COBRA Reimbursement"). The Company will pay the Executive the COBRA Reimbursements for the period from the Executive's termination date until the earliest to occur of (i) the end of the nine-month period following the Executive's termination date; (ii) the date the Executive becomes eligible for group health insurance coverage through a subsequent employer; or (iii) the date the Executive ceases to be eligible for COBRA coverage for any reason, including the Executive ceasing to pay the applicable COBRA premiums (each of the events described in (ii) or (iii) in this Section 6(b) shall be referred to herein as a "Disqualifying Event"). The Executive is required to notify the Company within five days of becoming aware that a Disqualifying Event has occurred or will occur. The COBRA health care continuation coverage period under section 4980B of the Internal Revenue Code of 1986, as amended (the "Code"), shall run concurrently with the period during which the Company pays the COBRA Reimbursements.

(c) The Company shall pay any other amounts earned, accrued, and owing but not yet paid under Section 2 above and any benefits accrued and due under any applicable benefit plans and programs of the Company ("Accrued Obligations"), regardless of whether the Executive executes or revokes the Release.

7. Change of Control Termination. Notwithstanding the foregoing, upon termination by the Company without Cause or resignation by the Executive for Good Reason, in each case on or within 12 months following a Change of Control (as defined in the Plan, or a successor to the Plan) (the "Change of Control Protection Period") and following the Part-Time Period, and provided that the Executive executes and does not revoke a written Release, then the Executive shall be entitled to receive, in lieu of any payments under Section 6 of this Agreement or any severance plan or program for employees or executives, the following:

(a) The Company will pay the Executive an amount equal to the sum of (x) the Executive's annual Base Salary, plus (y) the Executive's target Annual Bonus for the year of termination. Payment shall be made over the 12-month period following the termination date in installments in accordance with the Company's normal payroll practices. Payment will begin within 60 days following the termination date, and any installments not paid between the termination date and the date of the first payment will be paid with the first payment.

(b) Provided that the Executive is eligible for and timely elects continuation coverage under COBRA, the Company will pay the Executive the COBRA Reimbursements for the period from the Executive's termination date until the earliest to occur of (i) the end of the 12-month period following the Executive's termination date or (ii) a Disqualifying Event. The Executive is required to notify the Company within five days of becoming aware that a Disqualifying Event has occurred or will occur. The COBRA health care continuation coverage period under section 4980B of the Code shall run concurrently with the period during which the Company pays the COBRA Reimbursements.

(c) The Company shall pay any Accrued Obligations, regardless of whether the Executive executes or revokes the Release.

8. Cause. The Company may immediately terminate the Executive's employment at any time for Cause upon written notice to the Executive, in which event all payments under this Agreement shall cease, except for any Accrued Obligations.

9. Voluntary Resignation Without Good Reason. The Executive may voluntarily terminate employment without Good Reason upon 30 days' prior written notice to the Company. In such event, after the effective date of such termination, no payments shall be due under this Agreement, except that the Executive shall be entitled to any Accrued Obligations.

10. Disability. If the Executive incurs a Disability during the Term, in accordance with applicable law, the Company may terminate the Executive's employment on or after the date of Disability. If the Executive's employment terminates on account of Disability, the Executive shall be entitled to receive any Accrued Obligations. For purposes of this Agreement, the term "Disability" shall mean the Executive is eligible to receive long-term disability benefits under the Company's long-term disability plan; provided that if the Executive is not covered under the Company's long-term disability plan, "Disability" shall mean the Executive is unable to perform the essential functions of the job, with or without reasonable accommodation, by reason of any medically determinable physical or mental impairment that can be expected to last for a continuous period of not less than six months, subject to applicable law.

11. Death. If the Executive dies during the Term, the Executive's employment shall terminate on the date of death and the Company shall pay any Accrued Obligations to the Executive's executor, legal representative, administrator or designated beneficiary, as applicable. Otherwise, the Company shall have no further liability or obligation under this Agreement to the Executive's executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through the Executive.

12. Resignation of Positions. Effective as of the date of any termination of employment for any reason, the Executive will be automatically deemed to resign from all Company-related positions, including as an officer and director of the Company and its parents, subsidiaries and Affiliates, as applicable, and shall execute all documentation necessary to effectuate such resignation(s).

13. Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

(a) "Cause" shall mean a determination by the Board that the Executive (i) has breached this Agreement or any confidentiality, nonsolicitation, noncompetition or inventions assignment agreement or obligations with the Company; (ii) committed an act of dishonesty, fraud, embezzlement or theft; (iii) engaged in conduct that causes, or is likely to cause, material damage to the property or reputation of the Company; (iv) failed to perform satisfactorily the material duties of the Executive's position (other than by reason of Disability) after receipt of a written warning from the Board; (v) committed a felony or any crime of moral turpitude; or (vi) materially failed to comply with the Company's code of conduct or employment policies.

(b) "Good Reason" shall mean, following the Part-Time Period, the occurrence of one or more of the following without the Executive's consent, other than on account of the Executive's Disability:

(i) A material diminution by the Company of the Executive's authority, duties or responsibilities;

(ii) Following Executive's relocation to the Boston, MA metropolitan area, a material and permanent change in the geographic location at which the Executive must perform services under this Agreement (which, for purposes of this Agreement, means relocation of the offices of the Company at which the Executive is principally employed to a location that increases the Executive's commute to work by more than 50 miles);

(iii) A material diminution in the Executive's Base Salary, other than a general reduction in Base Salary that affects all similarly-situated executives in substantially the same proportions;

(iv) Any action or inaction that constitutes a material breach by the Company of this Agreement; or

(v) The Company elects not to renew the Term of this Agreement pursuant to Section 1(a) above for any reason other than Cause or Disability and does not offer the Executive continued employment on substantially similar terms as set forth in this Agreement.

The Executive must provide written notice of termination for Good Reason to the Company within 30 days after the event constituting Good Reason. The Company shall have a period of 30 days in which it may correct the act or failure to act that constitutes the grounds for Good Reason as set forth in the Executive's notice of termination. If the Company does not correct the act or failure to act, the Executive's employment will terminate for Good Reason on the first business day following the Company's 30-day cure period. If the Executive does not provide written notice of termination for Good Reason to the Company within 30 days after an event constituting Good Reason, then the Executive will be deemed to have waived the Executive's right to terminate for Good Reason with respect to such event.

(c) "Release" shall mean a separation agreement and general release of any and all claims against the Company and all related parties with respect to all matters arising out of the Executive's employment by the Company, and the termination thereof (other than claims for any entitlements under the terms of this Agreement or under any plans or programs of the Company under which the Executive has accrued and is due a benefit). The Release will be in a standard form determined by and acceptable to the Company and shall include the Restrictive Covenants set forth in Section 15.

14. Section 409A.

(a) This Agreement is intended to comply with section 409A of the Code, and its corresponding regulations, or an exemption thereto, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. Severance benefits under this Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. Notwithstanding anything in this Agreement to the contrary, if required by section 409A of the Code, if the Executive is considered a "specified employee" for purposes of section 409A of the Code and if payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to section 409A of the Code, payment of such amounts shall be delayed as required by section 409A of the Code, and the accumulated amounts shall be paid in a lump-sum payment within 10 days after the end of the six-month period. If the Executive dies during the postponement period prior to the payment of benefits, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executive's estate within 60 days after the date of the Executive's death.

(b) All payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service," if required under section 409A of the Code. For purposes of section 409A of the Code, each payment hereunder shall be treated as a separate payment, and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the calendar year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of the Executive's execution of the Release, directly or indirectly, result in the Executive's designating the calendar year of payment of any amounts of deferred compensation subject to section 409A of the Code, and if a payment that is subject to execution of the Release could be made in more than one taxable year, payment shall be made in the later taxable year.

(c) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of section 409A of the Code, including, where applicable, the requirement that (i) any reimbursement be for expenses incurred during the period specified in this Agreement, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during a fiscal year not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other fiscal year, (iii) the reimbursement of an eligible expense be made no later than the last day of the fiscal year following the year in which the expense is incurred, and (iv) the right to reimbursement or in-kind benefits not be subject to liquidation or exchange for another benefit.

15. Restrictive Covenants.

(a) Noncompetition. The Executive agrees that during the Executive's employment with the Company and its Affiliates and the one-year period following the date on which the Executive's employment terminates for any reason (the "Restriction Period"), the Executive will not, without the Board's express written consent, engage (directly or indirectly) in any Competitive Business in the Restricted Area. The term "Competitive Business" means any activities or services conducted by any third party with respect to the research, development, marketing, manufacturing or sale of oncolytic immunotherapies that are similar to the activities or services the Executive has performed (or gained Proprietary Information about (as defined below)) at any time during the last two years of the Executive's employment with the Company. The term "Restricted Area" means the United States of America, Canada and countries within Europe, in respect of which the Company or any of its Affiliates has material business operations as of the date on which the Executive's employment terminates and in which the Executive has provided services or had a material presence or influence at any time during the last two years of the Executive's employment with the Company or its Affiliates. The Executive agrees that this offer of employment, and the hourly wage provided for in Section 2(a), the Base Salary provided for in Section 2(b), the Annual Bonus percentage opportunity provided for in Section 2(c), the Option grant provided for in 2(d), the separation benefits provided for in Section 6 and the Change of Control Termination benefits provided for in Section 7, are fair and reasonable consideration for the Executive's compliance with this Section 15(a). The Executive understands and agrees that, given the nature of the business of the Company and its Affiliates and the Executive's position with the Company, the foregoing geographic scope is reasonable and appropriate and that more limited geographical limitations on this non-competition covenant are therefore not appropriate. For purposes of this Agreement, the term "Affiliate" means the Company's sole shareholder, any subsidiary of the Company or other entity under common control with the Company. The Company shall not enforce this Section 15(a) if it terminates the Executive's employment without Cause as defined in Section 13(a).

(b) Nonsolicitation of Company Personnel. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, hire or attempt to hire any employee, consultant or independent contractor of the Company or its Affiliates, or solicit or attempt to solicit any such person to change or terminate his or her relationship with the Company or an Affiliate or otherwise to become an employee, consultant or independent contractor to, for or of any other person or business entity, unless more than 12 months shall have elapsed between the last day of such person's employment or service with the Company or Affiliate and the first day of such solicitation or hiring or attempt to solicit or hire. If any employee, consultant or independent contractor is hired or solicited by any entity that has hired or agreed to hire the Executive, such hiring or solicitation shall be conclusively presumed to be a violation of this subsection (b).

(c) Nonsolicitation of Business Partners. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, solicit, divert or appropriate, or attempt to solicit, divert or appropriate for the benefit of a Competitive Business, any (i) business partner or (ii) prospective business partner of the Company or an Affiliate who is or was identified through leads developed during the course of the Executive's employment or service with the Company, in each case, with whom the Executive was involved as part of the Executive's job responsibilities during the Executive's employment or service with the Company, or regarding whom the Executive learned Proprietary Information (as defined below) during the Executive's employment or service with the Company.

(d) Proprietary Information. At all times, the Executive will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Proprietary Information (defined below) of the Company or an Affiliate, except as such disclosure, use or publication may be required in connection with the Executive's work for the Company or as described in Section 15(e) below, or unless the Company expressly authorizes such disclosure in writing. "Proprietary Information" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company and its Affiliates and shareholders, including but not limited to information relating to financial matters, investments, budgets, business plans, marketing plans, personnel matters, business contacts, products, processes, know-how, designs, methods, improvements, discoveries, inventions, ideas, data, programs, and other works of authorship. Proprietary Information does not include information which (i) was disclosed in response to a valid order by a court or other governmental body, where the Executive provided the Company with prior written notice of such disclosure, (ii) was or becomes generally available to the public other than as a result of disclosure by the Executive or any of the Executive's agents, advisors or representatives, (iii) was within the Executive's possession prior to its being furnished to the Executive by or on behalf of the Company, provided that the source of the information was not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to the Executive by a contractual, legal or fiduciary obligation, or (iv) was or becomes available to the Executive on a non-confidential basis from a source other than the Company or its representatives, provided that such source is not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to the Executive by a contractual, legal or fiduciary obligation.

(e) Reports to Government Entities. Nothing in this Agreement shall prohibit or restrict the Executive from initiating communications directly with, responding to any inquiry from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, Congress, any agency Inspector General or any other federal, state or local regulatory authority, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation. The Executive does not need the prior authorization of the Company to engage in conduct protected by this subsection, and the Executive does not need to notify the Company that the Executive has engaged in such conduct. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose trade secrets to their attorneys, courts, or government officials in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

(f) Work Made for Hire; Inventions Assignment. The Executive agrees that all inventions, innovations, improvements, developments, methods, designs, analyses, reports, and all similar or related information which relates to the Company's or its Affiliates' actual or anticipated business, research and development or existing or future products or services and which are conceived, developed or made by the Executive while employed by the Company ("Work Product") belong to the Company. The Executive acknowledges that, by reason of being employed by the Company at the relevant times, to the extent permitted by law, all of the Work Product consisting of copyrightable subject matter is "work made for hire" as defined in 17 U.S.C. § 101 and such copyrights are therefore owned by the Company. To the extent that the foregoing does not apply, the Executive hereby irrevocably assigns to the Company, for no additional consideration, the Executive's entire right, title, and interest in and to all Work Product and intellectual property rights therein, including, without limitation, the right to sue, counterclaim, and recover for all past, present, and future infringement, misappropriation, or dilution thereof, and all rights corresponding thereto throughout the world. The Executive will promptly disclose such Work Product to the Board and perform all actions reasonably requested by the Board (whether during or after the Term) to establish and confirm such ownership (including, without limitation, executing assignments, consents, powers of attorney and other instruments). If requested by the Company, the Executive agrees to execute any inventions assignment and confidentiality agreement that is required to be signed by Company employees generally. Nothing contained in this Agreement shall be construed to reduce or limit the Company's rights, title, or interest in any Work Product or intellectual property rights so as to be less in any respect than that the Company would have had in the absence of this Agreement. The Executive understands that this Agreement does not, and shall not be construed to, grant the Executive any license or right of any nature with respect to any Work Product or intellectual property rights or any Proprietary Information, materials, software, or other tools made available to the Executive by the Company.

(g) Return of Company Property. Upon termination of the Executive's employment with the Company for any reason, and at any earlier time the Company requests, the Executive will (i) deliver to the person designated by the Company all originals and copies of all documents and property of the Company or an Affiliate that is in the Executive's possession or under the Executive's control or to which the Executive may have access, (ii) deliver to the person designated by the Company all Company property, including keys, key cards, access cards, identification cards, security devices, employer credit cards, network access devices, computers, cell phones, smartphones, PDAs, pagers, fax machines, equipment, manuals, reports, files, books, compilations, work product, e-mail messages, recordings, disks, thumb drives or other removable information storage devices, hard drives, and data, and (iii) to the extent that the Executive made use of the Executive's personal electronics (e.g., laptop, iPad, telephone, thumb drives, etc.) during employment with the Company, permit the Company to delete all Company property and information from such personal devices. The Executive will not reproduce or appropriate for the Executive's own use, or for the use of others, any property, Proprietary Information or Work Product.

16. Legal and Equitable Remedies.

(a) Because the Executive's services are personal and unique **and** the Executive has had and will continue to have access to and has become and will continue to become acquainted with the Proprietary Information of the Company and its Affiliates**,** and because any breach by the Executive of any of the restrictive covenants contained in Section 15 would result in irreparable injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to enforce Section 15 and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the restrictive covenants set forth in Section 15. The Executive agrees that in any action in which the Company seeks injunction, specific performance or other equitable relief, the Executive will not assert or contend that any of the provisions of Section 15 are unreasonable or otherwise unenforceable.

(b) The Executive irrevocably and unconditionally (i) agrees that any legal proceeding arising out of this Agreement shall be brought solely in the United States District Court for the District of Massachusetts, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the State of Massachusetts, (ii) consents to the exclusive jurisdiction of such court in any such proceeding, and (iii) waives any objection to the laying of venue of any such proceeding in any such court. The Executive also irrevocably and unconditionally consents to the service of any process, pleadings, notices or other papers.

(c) Notwithstanding anything in this Agreement to the contrary, if the Executive breaches any of the Executive's obligations under Section 15, the Company shall be obligated to provide only the Accrued Obligations, and all payments under Section 2, Section 6, or Section 7 hereof, as applicable, shall cease. In such event, and in addition to any legal and equitable remedies permitted by law, the Company may require that the Executive repay all amounts theretofore paid to her pursuant to Sections 6 and 7 hereof (other than Sections 6(c) and 7(c)), and in such case, the Executive shall promptly repay such amounts on the terms determined by the Company.

17. Survival. The respective rights and obligations of the parties under this Agreement (including, but not limited to, under Sections 15 and 16) shall survive any termination of the Executive's employment or termination or expiration of this Agreement to the extent necessary to the intended preservation of such rights and obligations.

18. No Mitigation or Set-Off. In no event shall the Executive be obligated to seek other employment or take any other action by way of mitigation of the amounts payable to the Executive under any of the provisions of this Agreement, and such amounts shall not be reduced regardless of whether the Executive obtains other employment. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including, without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against the Executive or others.

19. Section 280G. In the event of a change in ownership or control under section 280G of the Code, if it shall be determined that any payment or distribution in the nature of compensation (within the meaning of section 280G(b)(2) of the Code) to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would constitute an "excess parachute payment" within the meaning of section 280G of the Code, the aggregate present value of the Payments under the Agreement shall be reduced (but not below zero) to the Reduced Amount (defined below) if and only if the Accounting Firm (described below) determines that the reduction will provide the Executive with a greater net after-tax benefit than would no reduction. No reduction shall be made unless the reduction would provide the Executive with a greater net after-tax benefit. The determinations under this Section shall be made as follows:

(a) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with section 280G(d)(4) of the Code. The term "Excise Tax" means the excise tax imposed under section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(b) Payments under this Agreement shall be reduced on a nondiscretionary basis in such a way as to minimize the reduction in the economic value deliverable to the Executive. Where more than one payment has the same value for this purpose and they are payable at different times, they will be reduced on a pro rata basis. Only amounts payable under this Agreement shall be reduced pursuant to this Section.

(c) All determinations to be made under this Section shall be made by an independent certified public accounting firm selected by the Company and agreed to by the Executive immediately prior to the change-in-ownership or -control transaction (the "Accounting Firm"). The Accounting Firm shall provide its determinations and any supporting calculations both to the Company and the Executive within 10 days of the transaction. Any such determination by the Accounting Firm shall be binding upon the Company and the Executive. All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section shall be borne solely by the Company.

20. Notices. All notices and other communications required or permitted under this Agreement or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand-delivered or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received):

If to the Company, to:

Replimune Inc.
500 Unicorn Park
Woburn, MA 01801
Attn: Chief Executive Officer

with a copy to:

Morgan, Lewis & Bockius LLP
One Federal Street
Boston, MA 02110
Attn: Gitte Blanchet

If to the Executive, to the most recent address on file with the Company or to such other names or addresses as the Company or the Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section.

21. Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state, and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. The Executive shall bear all expense of, and be solely responsible for, all federal, state, and local taxes due with respect to any payment received under this Agreement.

22. Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

23. Assignment. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors, and assigns of the parties hereto, except that the duties and responsibilities of the Executive under this Agreement are of a personal nature and shall not be assignable or delegable in whole or in part by the Executive. The Company may assign its rights, together with its obligations hereunder, in connection with any sale, transfer or other disposition of all or substantially all of its business and assets, and such rights and obligations shall inure to, and be binding upon, any successor to the business or any successor to substantially all of the assets of the Company, whether by merger, purchase of stock or assets or otherwise, which successor shall expressly assume such obligations, and the Executive acknowledges that in such event the obligations of the Executive hereunder, including but not limited to those under Section 15, will continue to apply in favor of the successor.

24. Company Policies. This Agreement and the compensation payable hereunder shall be subject to any applicable clawback or recoupment policies, share trading policies, and other policies that may be implemented by the Board from time to time with respect to officers of the Company.

25. Indemnification. In the event the Executive is made, or threatened to be made, a party to any legal action or proceeding, whether civil or criminal, including any governmental or regulatory proceedings or investigations, by reason of the fact that the Executive is or was a director or officer of the Company or any of its Affiliates, the Executive shall be indemnified by the Company, and the Company shall pay the Executive's related expenses when and as incurred, to the fullest extent permitted by applicable law and the Company's articles of incorporation and bylaws. During the Executive's employment with the Company or any of its Affiliates and after termination of employment for any reason, the Company shall cover the Executive under the Company's directors' and officers' insurance policy applicable to other officers and directors according to the terms of such policy.

26. Entire Agreement; Amendment. This Agreement sets forth the entire agreement of the parties hereto and supersedes any and all prior agreements and understandings concerning the Executive's employment by the Company. This Agreement may be changed only by a written document signed by the Executive and the Company.

27. Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement, which can be given effect without the invalid or unenforceable provision or application, and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances.

28. Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the substantive and procedural laws of Massachusetts without regard to rules governing conflicts of law.

29. Acknowledgements. The Executive acknowledges (a) that the Company hereby advises her to consult with legal counsel prior to signing this Agreement, (b) that she has had a full and adequate opportunity to read and understand the terms and conditions contained in this Agreement, (c) that she has been provided with this Agreement a minimum of 10 business days prior to the date this Agreement becomes effective, and (d) that the post-employment noncompetition and nonsolicitation provisions are supported by fair and reasonable consideration.

30. Counterparts. This Agreement may be executed in any number of counterparts (including facsimile counterparts), each of which shall be an original, but all of which together shall constitute one instrument.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

REPLIMUNE, INC.

/s/ Philip Astley-Sparke
Name: Philip Astley-Sparke
Title: Chief Executive Officer

Date: May 25, 2020

EXECUTIVE

/s/ Andrea Pirzkall
Name: Andrea Pirzkall

Date: May 24, 2020

Exhibit 10.3

DATED **29 June** **2020**

(1) MEPC MILTON PARK NO.1 LIMITED AND MEPC MILTON PARK NO.2 LIMITED

and

(2) REPLIMUNE LIMITED

DEED OF VARIATION

relating to a lease of

69 and 70 Innovation Drive
Milton Park

Knights plc
Midland House
West Way
Botley
Oxford
OX2 0PH

PARTICULARS

DATE	:	29 June 2020
LANDLORD	:	**MEPC MILTON PARK NO. 1 LIMITED** (Company number 5491670) and **MEPC MILTON PARK NO. 2 LIMITED** (Company number 5491806), on behalf of MEPC Milton LP (LP No. 014504), both of whose registered offices are at Sixth Floor, 150 Cheapside, London EC2V 6ET;
TENANT	:	**REPLIMUNE LIMITED** (Company number 09496393) whose registered office is at 69 Innovation Drive, Milton Park, Abingdon, Oxfordshire, United Kingdom, OX14 4RQ

BACKGROUND

(A) This Deed is supplemental to the Lease;

(B) The Landlord and the Tenant have agreed that the Lease shall be varied as set out in this Deed.

The parties agree as follows:

1 DEFINITIONS

1.1 In this Deed, unless the context requires otherwise, the following definitions shall apply:

Landlord	includes successors in title to the freehold estate in the Property;
Lease	a lease of the Property dated 4 April 2016 made between (1) MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited and (2) Replimune Limited, a copy of which is appended to this Deed, and all documents supplemental thereto;
Licence to Alter	a licence to carry out works outside the Property dated 7 February 2019 made between (1) MEPC Milton Park No. 1 Limited and MEPC Milton Park No. 2 Limited and (2) Replimune Limited;
Property	69 and 70 Innovation Drive, Milton Park, Abingdon, Oxfordshire OX14 4RQ as more particularly defined in the Lease; and
Tenant	includes successors in title to the term created by the Lease.

1.2 The Particulars are incorporated in and form part of this Deed so that in this Deed the words and expressions set out in the Particulars shall have the meanings ascribed to them in the Particulars.

1.3 Expressions defined in the Lease shall (save where the context requires otherwise) have the same meanings as in this Deed.

1.4 The provisions of the Lease relating to its interpretation apply to this Deed except to the extent that they are expressly varied by this Deed.

2 VARIATION

In consideration of the sum of one pound (£1) paid by the Tenant to the Landlord (receipt of which the Landlord acknowledges) it is mutually agreed and declared that with effect from the date of this Deed the Lease shall be varied in accordance with the provisions set out in the Schedule.

3 CONTINUING EFFECT

3.1 The Landlord and Tenant acknowledge that by entering into this deed that there has been a deemed surrender and re-grant of the Lease. The Landlord and Tenant confirm that the new lease created by this Deed is granted in consideration of the surrender of the Lease.

3.2 Notwithstanding the effect of clause 3.1, the Parties intend that all of the terms, requirements, covenants, conditions, stipulations and provisions of the Lease shall apply to the lease created by this Deed, save to the extent any such terms requirements, covenants, conditions, stipulations and provisions are modified by this Deed through the provisions contained in the Schedule.

4 LICENCE TO ALTER

The parties hereby agree and acknowledge that the provisions of the Licence to Alter shall continue in full force and effect notwithstanding the effect of clause 3.1 and that references to the "Lease" in the Licence to Alter shall be deemed to refer to the lease created by this Deed.

5 EXCLUSION OF CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

A person who is not a party to this Deed shall not have any right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Deed.

6 SUCCESSORS

This deed binds the respective successors in title of the Landlord and the Tenant.

7 EXCLUSION OF SECURITY OF TENURE

7.1 The Landlord and the Tenant agree that sections 24 to 28 of the 1954 Act shall be excluded from the tenancy created by this Deed;

7.2 The Landlord has served on the Tenant a notice as referred to in section 38A(3)(a) of the 1954 Act and the Tenant has made a statutory declaration pursuant to the requirements of Schedule 2 of the 2003 Order the original or a true copy of which declaration is annexed to this Deed.

8 REGISTRATION

Promptly following the completion of this deed, the Tenant shall apply to register this deed at HM Land Registry in order to close the Tenant's registered title number ON325431 for the Lease and to register the new lease granted by this Deed against the Landlord's registered title number ON130606.

9 GOVERNING LAW

This deed and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England.

10 JURISDICTION

Each party irrevocably agrees that the courts of England shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this deed or its subject matter or formation (including non-contractual disputes or claims).

Executed by the parties as a **Deed** on the date stated at the beginning of this document

SCHEDULE

Agreed Variations to the Lease

1. In the Prescribed Clauses, LR6. amended as follows:

LR6. Term for which the Property is leased	From and including 4 April 2016 To and including 3 April 2031

2. In the **Lease Particulars** the definition of "Contractual Term" shall be deleted and substituted by the following**:**

"Contractual term : fifteen (15) years from the 4 April 2016 to and including 3 April 2031"

3. **Clause 1.1** [Definitions] and in the **Lease Particulars** the definition of "**Break Date**" shall be deleted and substituted by the following:

"**Break Date** means 4 April 2026;"

4. In **Clause 1.1** [Definitions] the definition of "**Principal Rent**" and "**Initial Principal Rent**" in the **Lease Particulars** shall both be deleted and substituted by the following:

"Principal Rent means:

From and including the Rent Commencement Date to and including 3 December 2016: ONE HUNDRED AND THIRTY NINE THOUSAND FIVE HUNDRED AND SEVEN POUNDS AND SEVENTY FIVE PENCE (£139,507.75) per annum;

From and including 4 December 2016 to and including 23 June 2020: TWO HUNDRED AND SEVENTY NINE THOUSAND AND FIFTEEN POUNDS AND FIFTY PENCE (£279,015.50) per annum;

From and including 24 June 2020 to and including 24 December 2020: ONE HUNDRED AND THIRTY NINE THOUSAND FIVE HUNDRED AND SEVEN POUNDS AND SEVENTY FIVE PENCE (£139,507.75) per annum;

From and including 25 December 2020 to and including the day before the Review Date: TWO HUNDRED AND SEVENTY NINE THOUSAND AND FIFTEEN POUNDS AND FIFTY PENCE (£279,015.50) per annum;

Subject to increase in accordance with the Second Schedule;"

5. In **Clause 1.1** [Definitions] and in the **Lease Particulars** the definition of "**Review Date**" shall be deleted and substituted by the following:

"Review Date means each of the First Review Date and the Second Review Date, whichever is relevant, and **Relevant Review Date** shall be interpreted accordingly;"

6. In **Clause 1.1** [Definitions] the following shall be added as new definitions:

"**First Review Date** means 4 April 2021;"

"**Second Review Date** means 4 April 2026;"

7. **Clause 8.1** [Break Clause] shall be deleted and substituted by the following:

"The Tenant may terminate the Contractual Term on the Break Date by giving to the Landlord not less than twelve (12) months' previous notice in writing;"

8. **Clause 8.2** [Break Clause] shall be deleted and substituted by the following:

"Any notice given by the Tenant shall operate to terminate the Contractual Term only if:

(i) the Principal Rent reserved by this lease has been paid by the time of such termination; and

(ii) the Tenant gives the Landlord possession of the Property on termination free from any sublease and any third party occupational interests; and

(iv) the Tenant has previously paid to the Landlord in cleared funds a sum equivalent to three months' Principal Rent then payable;"

9. A new **Clause 8.6** shall be added as follows:

"If the Tenant does not terminate this Lease on the Break Date in accordance with this clause 8 then the Principal Rent shall be reduced by half for the period of six (6) months immediately following the Break Date and for the avoidance of doubt the Principal Rent shall resume to its full amount immediately following this six (6) month period."

10. The **Second Schedule** [Rent Review] shall be deleted and substituted by the following:

"1. In this Schedule:

1.1 **First Review Date** means the First Review Date;

1.2 **Second Review Date** means the Second Review Date;

1.3 **Review Date** means each of the First Review Date and the Second Review Date, whichever is relevant, and **Relevant Review Date** shall be interpreted accordingly;

1.4 **Current Rent** means the Principal Rent payable under this lease immediately before the Relevant Review Date;

1.5 **Index** means the Retail Prices Index (All Items: including housing and mortgage costs) published by the Office for National Statistics or (if not available) such index of comparative prices as the Landlord shall reasonably require;

1.6 **Indexed Rent** means Current Rent multiplied by (A/B) per annum where:

A = The figure shown in the Index for February 2021 (for the First Review Date) or February 2026 (for the Second Review Date); and

B = the figure shown in the Index for February 2016 (for the First Review Date) or February 2021 (for the Second Review Date)

1.7 **Revised Rent** means the new Principal Rent following the Relevant Review Date pursuant to paragraph 2 (for the First Review Date) or paragraph 3 (for the Second Review Date) of this Second Schedule.

1.8 **Rack Rental Value** means the annual rent (exclusive of VAT) at which the Property might reasonably be expected to be let in the open market at the Second Review Date;

ASSUMING

(a) the letting is on the same terms as those contained in this lease but subject to the following qualifications:

(i) the term shall commence on the Second Review Date and be five (5) years;

(ii) the amount of the Principal Rent shall be disregarded, but it shall be assumed that the Principal Rent is subject to review on the terms of and at the same intervals as the Principal Rent under this lease;

(b) the Property is available to let as a whole, with vacant possession, by a willing landlord to a willing tenant, without premium;

(c) the Property is ready, fit and available for immediate occupation and use for the Permitted Use;

(d) all the obligations on the part of the Tenant contained in this lease have been fully performed and observed;

(e) no work has been carried out to the Property which has reduced the rental value of the Property;

(f) if the whole or any part of the Property has been destroyed or damaged it has been fully reinstated;

(g) that there is no alternative basis in the hypothetical lease for the assessment of rent on review other than for assessment of the Rack Rental Value;

BUT DISREGARDING:

(g) any goodwill attached to the Property by reason of any business carried on there;

(h) any effect on rent of the fact that any Tenant and any undertenant is or has been in occupation of the Property;

(i) any effect on rent of any improvements at the Property made with the Landlord's consent by the Tenant or any undertenant, except improvements carried out pursuant to an obligation to the Landlord or at the expense of the Landlord;

PROVIDED THAT the Rack Rental Value shall be that which would be payable after the expiry of any rent free period or concessionary rent period for fitting out (or the receipt of any contribution to fitting out works or other inducement in lieu thereof) which might be given on a letting of the Property, so that no discount reduction or allowance is made to reflect (or compensate the tenant for the absence of) any such rent free or concessionary rent period or contribution or other inducement.

1.9 **Expert** means a surveyor (who shall be a Fellow of the Royal Institution of Chartered Surveyors with at least ten (10) years' experience in the letting and valuation of premises of a similar nature to and situate in the same region as the Property) agreed between the Landlord and the Tenant, or in the absence of agreement nominated on the application of either party by the President for the time being of the Royal Institution of Chartered Surveyors.

2. The Principal Rent shall be reviewed on the First Review Date to the higher of:

    2.1 the Current Rent (disregarding any suspension or abatement of the Principal Rent); and

    2.2 the Indexed Rent ascertained in accordance with this lease.

3. The Principal Rent shall be reviewed on the Second Review Date to the higher of:

    3.1 the Current Rent (disregarding any suspension or abatement of the Principal Rent); and

    3.2 the Indexed Rent ascertained in accordance with this lease; and

    3.3 the Rack Rental Value on the Second Review Date agreed or determined in accordance with this lease.

4 The Rack Rental Value at the Second Review Date shall be:

    4.1 agreed in writing between the Landlord and the Tenant; or

    4.2 determined by an Expert (acting as an expert) on the application of either Landlord or Tenant at any time after the Second Review Date;

5 In the case of determination by an Expert:

    5.1 the Expert will be instructed to afford the Landlord and the Tenant the opportunity to make written representations to him and comment upon written representations received by him;

    5.2 if an Expert dies, refuses to act or becomes incapable of acting, or if he fails to notify the parties of his determination within 2 months after receiving the last submission delivered to him, either the Landlord or the Tenant may apply to the President for the time being of the Royal Institution of Chartered Surveyors to discharge him and appoint another in his place;

    5.3 the fees and expenses of the Expert and any VAT thereon shall be paid by the Landlord and the Tenant in such shares as the Expert shall decide (or in equal shares if the Expert does not decide this point); if one party pays all the Expert’s fees and expenses, the paying party may recover the other’s share from the other party, in the case of the Landlord as arrears of rent.

6. If a Revised Rent has not been ascertained by the Relevant Review Date:

6.1 the Current Rent shall continue to be payable until the Revised Rent is ascertained;

6.2 when the Revised Rent is ascertained:

6.2.1 the Tenant shall pay within 14 days of ascertainment of the Revised Rent:

(i) any difference between the Principal Rent payable immediately before the Relevant Review Date and the Principal Rent which would have been payable had the Revised Rent been ascertained on the Relevant Review Date (the **Balancing Payment**); and

(ii) interest on the Balancing Payment at Base Rate from the date of dates when the Balancing Payment or the relevant part or parts would have been payable had the Revised Rent been ascertained on the Relevant Review Date;

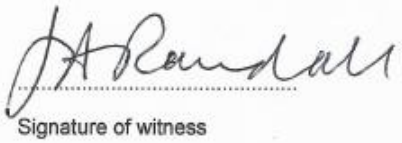
6.2.2 the Landlord and Tenant shall sign and exchange a memorandum recording the amount of the Revised Rent.

7. Time shall not be of the essence for the purposes of this Schedule.

11. In the **Lease Particulars** the definition of "**Review Type**" shall be deleted.

EXECUTED as a DEED by
_____as attorney for
MEPC MILTON PARK NO. 1 LIMITED
in the presence of:

NJ RANDALL as attorney for **MEPC MILTON PARK NO. 1 LIMITED**



Signature of witness

Witness name: JA RANDALL

Address: GRANTHAM HOUSE
HIGHCLERE
RG20 9PF

EXECUTED as a DEED by
_____ as attorney for **MEPC MILTON PARK NO. 2 LIMITED** in the presence of:

NJ RANDALL as attorney for **MEPC MILTON PARK NO. 2 LIMITED**

Signature of witness

Witness name: JA RANDALL

Address: GRANTHAM HOUSE
HIGHCLERE
RG20 9PF

EXECUTED as a DEED by
REPLIMUNE LIMITED acting by

A director in the presence of:

/s/ Colin Love

Director

/s/ Sam Goddard

Witness Name: Sam Goddard

Address:

Occupation:

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Philip Astley-Sparke, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Replimune Group, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 7, 2020

By: /s/ Philip Astley-Sparke
Philip Astley-Sparke
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jean Franchi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Replimune Group, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer 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 7, 2020

BY: /s/ JEAN FRANCHI

Jean Franchi
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION 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 of Replimune Group, Inc. (the "Company") for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Philip Astley-Sparke, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 7, 2020

BY: /s/ PHILIP ASTLEY-SPARKE
Philip Astley-Sparke
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION 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 of Replimune Group, Inc. (the "Company") for the quarter ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jean Franchi, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: August 7, 2020

BY: /S/ JEAN FRANCHI
Jean Franchi
Chief Financial Officer
(Principal Financial Officer)