

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended December 31, 2020

OR

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

For the transition period from to

Commission file number 001-38596

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

82-2082553
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

The number of shares of the registrant's Common Stock, par value \$0.001 per share, outstanding as of February 1, 2021 was 46,493,467.

REPLIMUNE GROUP, INC.

FORM 10-Q

Table of Contents

	<u>Page No.</u>
<u>PART I FINANCIAL INFORMATION</u>	<u>3</u>
<u>Item 1. Condensed Consolidated Financial Statements (Unaudited)</u>	<u>3</u>
<u>Condensed Consolidated Balance Sheets</u>	<u>3</u>
<u>Condensed Consolidated Statements of Operations</u>	<u>4</u>
<u>Condensed Consolidated Statements of Comprehensive Loss</u>	<u>5</u>
<u>Condensed Consolidated Statements of Stockholders' Equity</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows</u>	<u>7</u>
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	<u>8</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>24</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>43</u>
<u>Item 4. Controls and Procedures</u>	<u>43</u>
<u>PART II OTHER INFORMATION</u>	<u>45</u>
<u>Item 1. Legal Proceedings</u>	<u>45</u>
<u>Item 1A. Risk Factors</u>	<u>46</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>83</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>83</u>
<u>Item 4. Mine Safety Disclosure</u>	<u>83</u>
<u>Item 5. Other Information</u>	<u>83</u>
<u>Item 6. Exhibits</u>	<u>84</u>
<u>SIGNATURES</u>	<u>85</u>

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)

	December 31, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 324,475	\$ 59,500
Short-term investments	168,797	109,055
Research and development incentives receivable	2,121	2,962
Prepaid expenses and other current assets	4,035	2,734
Total current assets	499,428	174,251
Property, plant and equipment, net	7,166	6,860
Restricted cash	1,636	1,636
Right-to-use asset - operating leases	5,839	4,425
Right-to-use asset - financing leases	45,129	46,925
Total assets	<u>\$ 559,198</u>	<u>\$ 234,097</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,350	\$ 3,434
Accrued expenses and other current liabilities	7,234	5,156
Operating lease liabilities, current	965	873
Financing lease liabilities, current	2,469	2,411
Total current liabilities	13,018	11,874
Long term debt, net of debt discount	-	9,801
Operating lease liabilities, non-current	5,170	3,737
Financing lease liabilities, non-current	24,815	24,967
Total liabilities	43,003	50,379
Commitments and contingencies (Note 12)		
Stockholders' equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized as of December 31, 2020 and March 31, 2020; 46,384,675 and 36,668,743 shares issued and outstanding as of December 31, 2020 and March 31, 2020, respectively	46	37
Additional paid-in capital	687,934	296,961
Accumulated deficit	(171,669)	(112,298)
Accumulated other comprehensive loss	(116)	(982)
Total stockholders' equity	516,195	183,718
Total liabilities and stockholders' equity	<u>\$ 559,198</u>	<u>\$ 234,097</u>

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 December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 14,322	\$ 11,948	\$ 40,529	\$ 27,573
General and administrative	5,953	4,716	17,242	12,240
Total operating expenses	<u>20,275</u>	<u>16,664</u>	<u>57,771</u>	<u>39,813</u>
Loss from operations	<u>(20,275)</u>	<u>(16,664)</u>	<u>(57,771)</u>	<u>(39,813)</u>
Other income (expense):				
Research and development incentives	550	951	1,991	2,192
Investment income	116	550	821	1,804
Interest expense on finance lease liability	(560)	(834)	(1,683)	(1,029)
Interest expense on debt obligations	(247)	-	(817)	-
Loss on extinguishment of debt	(913)	-	(913)	-
Other income (expense)	(454)	(192)	(999)	10
Total other income (expense), net	<u>(1,508)</u>	<u>475</u>	<u>(1,600)</u>	<u>2,977</u>
Net loss attributable to common stockholders	<u>\$ (21,783)</u>	<u>\$ (16,189)</u>	<u>\$ (59,371)</u>	<u>\$ (36,836)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.46)</u>	<u>\$ (1.34)</u>	<u>\$ (1.13)</u>
Weighted average common shares outstanding, basic and diluted	<u>49,382,213</u>	<u>34,877,944</u>	<u>44,436,680</u>	<u>32,742,148</u>

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 December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Net loss	\$ (21,783)	\$ (16,189)	\$ (59,371)	\$ (36,836)
Other comprehensive loss:				
Foreign currency translation gain (loss)	548	408	1,162	8
Net unrealized gain (loss) on short-term investments, net of tax	(53)	(25)	(296)	-
Comprehensive loss	<u>\$ (21,288)</u>	<u>\$ (15,806)</u>	<u>\$ (58,505)</u>	<u>\$ (36,828)</u>

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 capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
	Shares	Amount				
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
Foreign currency translation adjustment	-	-	-	-	626	626
Unrealized loss on short-term investments	-	-	-	-	(47)	(47)
Exercise of stock options	31,852	-	291	-	-	291
Stock-based compensation expense	-	-	2,801	-	-	2,801
Net loss	-	-	-	(20,095)	-	(20,095)
Balances as of September 30, 2020	40,312,272	40	411,847	(149,886)	(611)	261,390
Foreign currency translation adjustment	-	-	-	-	548	548
Unrealized loss on short-term investments	-	-	-	-	(53)	(53)
Exercise of stock options	447,403	1	3,068	-	-	3,069
Issuance of prefunded warrants to purchase common stock, net of \$3,750 issuance costs	-	-	58,750	-	-	58,750
Issuance of common stock, net of issuance costs and underwriter fees of \$13,775	5,625,000	5	211,220	-	-	211,225
Stock-based compensation expense	-	-	3,049	-	-	3,049
Net loss	-	-	-	(21,783)	-	(21,783)
Balances as of December 31, 2020	46,384,675	\$ 46	\$ 687,934	\$ (171,669)	\$ (116)	\$ 516,195
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
Foreign currency translation adjustment	-	-	-	-	(218)	(218)
Unrealized loss on short-term investments	-	-	-	-	(40)	(40)
Exercise of stock options	55,645	-	105	-	-	105
Stock-based compensation expense	-	-	1,781	-	-	1,781
Net loss	-	-	-	(11,139)	-	(11,139)
Balances as of September 30, 2019	31,719,346	32	202,359	(80,320)	(1,430)	120,641
Issuance of common stock through ATM sales, net of offering costs	287,559	-	4,431	-	-	4,431
Issuance of common shares upon closing of follow-on public offering, net of issuance costs and underwriter fees of \$4,017	4,516,561	5	57,448	-	-	57,453
Issuance of prefunded warrants to purchase common stock, net of issuance costs and underwriter fees of \$1,797	-	-	28,145	-	-	28,145
Foreign currency translation adjustment	-	-	-	-	408	408
Unrealized loss on short-term investments	-	-	-	-	(25)	(25)
Exercise of stock options	122,184	-	357	-	-	357
Stock-based compensation expense	-	-	2,344	-	-	2,344
Net loss	-	-	-	(16,189)	-	(16,189)
Balances as of December 31, 2019	36,645,650	\$ 37	\$ 295,084	\$ (96,509)	\$ (1,047)	\$ 197,565

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)

	Nine Months Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (59,371)	\$ (36,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,318	5,935
Depreciation and amortization	1,217	191
Noncash interest expense	181	94
Loss on extinguishment of debt	913	-
Net amortization of premiums and discounts on short-term investments	841	(899)
Changes in operating assets and liabilities:		
Research and development incentives receivable	1,078	(2,184)
Prepaid expenses and other current assets	(1,238)	(1,520)
Operating lease, right-of-use-asset	341	421
Finance lease, right-of-use-asset	1,795	666
Long term prepaid rent	-	(14,051)
Accounts payable	(1,018)	(2,585)
Accrued expenses and other current liabilities	1,919	1,781
Operating lease liabilities	(237)	(303)
Net cash used in operating activities	<u>(45,261)</u>	<u>(49,290)</u>
Cash flows from investing activities:		
Purchases of property, plant and equipment	(1,622)	(5,202)
Purchase of short-term investments	(225,029)	(119,611)
Proceeds from sales and maturities of short-term investments	164,148	111,739
Net cash provided by (used in) investing activities	<u>(62,503)</u>	<u>(13,074)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock in follow-on public offering, net of underwriting fees and discounts	286,107	57,453
Proceeds from issuance of prefunded warrants to purchase common stock, net of underwriting fees and discounts	91,650	28,145
Proceeds from issuance of common stock through ATM sales	-	4,431
Proceeds from long-term debt	-	10,000
Principal payment of long-term debt	(10,000)	-
Payment of long-term debt extinguishment costs	(795)	-
Payment of issuance costs	(100)	(355)
Principal payment of finance lease obligation	(92)	(22)
Exercise of stock options	4,907	480
Net cash provided by financing activities	<u>371,677</u>	<u>100,132</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	1,062	(20)
Net increase (decrease) in cash, cash equivalents and restricted cash	264,975	37,748
Cash, cash equivalents and restricted cash at beginning of period	61,136	26,890
Cash, cash equivalents and restricted cash at end of period	<u>\$ 326,111</u>	<u>\$ 64,638</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 636	\$ 282
Supplemental disclosure of non-cash investing and financing activities:		
Net unrealized gain (loss) on short-term investments	\$ (296)	\$ -
Purchases of property and equipment included in accounts payable	\$ 99	\$ -
Lease assets obtained in exchange for new financing lease liabilities	\$ -	\$ 48,224
Lease assets obtained in exchange for new operating lease liabilities	\$ 1,580	\$ 5,152

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

REPLIMUNE GROUP, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Dollars in thousands, except share and per share amounts)
(Unaudited)

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, direct and indirect subsidiaries: Replimune Limited (“Replimune UK”); Replimune, Inc. (“Replimune US”); Replimune Securities Corporation; and Replimune (Ireland) Limited.

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 \$21,783 and \$16,189 for the three months ended December 31, 2020 and 2019, respectively and net losses of \$59,371 and \$36,836 for the nine months ended December 31, 2020 and 2019, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of \$171,669. 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.

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 those in its laboratory, those performing manufacturing functions and certain other employees as deemed appropriate from time to time. For those 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 direct and indirect wholly owned subsidiaries, Replimune UK, Replimune US, Replimune Securities Corporation and Replimune (Ireland) Limited after elimination of all intercompany accounts and transactions.

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 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 December 31, 2020, the consolidated statements of operations, of comprehensive loss and of stockholders' equity for the three and nine months ended December 31, 2020 and 2019 and the consolidated statements of cash flows for the nine months ended December 31, 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 December 31, 2020 and the results of its operations for the three and nine months ended December 31, 2020 and 2019 and its cash flows for the nine months ended December 31, 2020 and 2019. The financial data and other information disclosed in these consolidated notes related to the three and nine months ended December 31, 2020 and 2019 are unaudited. The results for the three and nine months ended December 31, 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 and nine months ended December 31, 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 which was filed with the Securities and Exchange Commission on June 3, 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* (“ASU 2018-18”), 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, 2022. 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.

In December 2019, the FASB issued ASU No. 2019-12 *Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes (ASU 2019-12)*, as part of its initiative to reduce complexity in the accounting standards. The amendments in ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The standard is effective for fiscal years and interim periods beginning after December 15, 2020. The Company is currently evaluating the impact of this new guidance on its financial statements and related disclosures but does not expect the adoption of ASU 2019-12 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 December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	\$ -	\$ 276,076	\$ -	\$ 276,076
US Government Agency bonds	-	63,295	-	63,295
US Treasury bonds	-	105,502	-	105,502
	<u>\$ -</u>	<u>\$ 444,873</u>	<u>\$ -</u>	<u>\$ 444,873</u>

	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
	<u>\$ -</u>	<u>\$ 145,767</u>	<u>\$ -</u>	<u>\$ 145,767</u>

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

During the three and nine months ended December 31, 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 December 31, 2020 and March 31, 2020.

4. Short-term investments

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

	December 31, 2020			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
US Government agency bonds	\$ 63,284	\$ 11	\$ -	\$ 63,295
US Treasury bonds	105,487	17	(2)	105,502
	<u>\$ 168,771</u>	<u>\$ 28</u>	<u>\$ (2)</u>	<u>\$ 168,797</u>

	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
	<u>\$ 108,732</u>	<u>\$ 388</u>	<u>\$ (65)</u>	<u>\$ 109,055</u>

5. Property, plant and equipment, net

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

	December 31, 2020	March 31, 2020
Construction in progress	\$ 1,363	\$ 1,217
Plant and laboratory equipment	4,784	3,669
Leasehold improvements	785	532
Computer equipment	1,667	1,658
Office equipment	721	721
	<u>9,320</u>	<u>7,797</u>
Less: Accumulated depreciation and amortization	(2,154)	(937)
	<u>\$ 7,166</u>	<u>\$ 6,860</u>

Depreciation and amortization expense was \$402 and \$1,217 for the three and nine months ended December 31, 2020, respectively, and \$107 and \$191 for the three and nine months ended December 31, 2019, respectively. Depreciation and amortization expense are 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:

	December 31, 2020	March 31, 2020
Accrued research and development costs	\$ 3,714	\$ 2,009
Accrued compensation and benefits costs	2,638	2,065
Accrued professional fees	363	779
Other	519	303
	<u>\$ 7,234</u>	<u>\$ 5,156</u>

7. Long-term debt

Long-term debt consisted of the following:

	December 31, 2020	March 31, 2020
Principal amount of long-term debt	\$ -	\$ 10,000
Unamortized debt discount	-	(199)
Long-term debt, net of discount	<u>\$ -</u>	<u>\$ 9,801</u>

Hercules Loan Agreement

On August 8, 2019, (the “Closing Date”) the Company and certain of its affiliates entered into a Loan and Security Agreement (as amended, 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.

On June 1, 2020, the Company entered into the First Amendment to the Hercules Loan Agreement (the “Hercules First Amendment”), to, among other things, increase the aggregate principal amount of the secured term loan facility from \$30,000 to \$40,000. Pursuant to the Hercules First Amendment, subject to the achievement of certain milestones, the Company could have borrowed three tranches of up to \$10,000 between October 1, 2020 and December 15, 2020, July 1, 2020 and June 30, 2021, and July 1, 2021 and December 15, 2021, respectively. The Company incurred \$100 in additional closing and legal fees in connection with Hercules First Amendment which were capitalized and will be amortized as part of the effective yield.

On December 15, 2020, the Company entered into a Payoff Letter with respect to the Hercules Loan Agreement, which resulted in a loss on extinguishment of debt of \$913 including both cash and non-cash expense. Pursuant to the Payoff Letter, the Company paid a total of \$10,839 to Hercules, representing \$10,000 in outstanding principal, \$495 end of term charge, \$300 early termination fee due and \$44 in accrued interest owed to Hercules under the Hercules Loan Agreement. In connection with the execution of the Payoff Letter and the repayment of the Company’s outstanding obligations under the Hercules Loan Agreement, the Hercules Loan Agreement and the related loan documents were terminated.

The Term Loan Facility was secured by substantially all of the Company’s assets, but excluding its intellectual property, and subject to certain exceptions and exclusions. All liens on the Company’s assets held by Hercules were released in connection with the execution of the Payoff Letter.

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. 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 \$247 and \$817 during the three and nine months ended December 31, 2020, respectively, which included non-cash interest expense of \$55 and \$181 for the three and nine months ended December 31, 2020, respectively. Non-cash interest expense related to the amortization of the debt discount of \$26 and \$82 and the accretion of the final payment of \$29 and \$99 for the three and nine months ended December 31, 2020, respectively.

8. Stockholders’ equity

Common stock

As of December 31, 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 December 31, 2020 and March 31, 2020, the Company had reserved 14,753,921 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 stock, respectively.

Undesignated preferred stock

As of December 31, 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 December 31, 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 Company's initial public offering (the "IPO") in 2018, 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 December 31, 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. In connection with the closing of the IPO, the series seed preferred stock warrants became exercisable for 497,344 shares of common stock and the exercise price was adjusted to \$1.01 per share. Upon the closing of the IPO, the series seed preferred stock warrants were reclassified to stockholders' equity. The warrants to purchase 497,344 shares of common stock remain outstanding as of December 31, 2020.

ATM program

In August 2019, the Company entered into a Sales Agreement (as amended, the "2019 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, through the Agent, as the Company's sales agent. In June 2020, the 2019 Sales Agreement was amended to reduce the aggregate offering amount under the 2019 Sales Agreement from \$75,000 of shares to \$30,000 of shares.

On August 11, 2020, the 2019 Sales Agreement was terminated by the execution by the Company and the Agent of a new sales agreement, which was subsequently amended on October 21, 2020 (as amended, the "2020 Sales Agreement"). Under the 2020 Sales Agreement the Company may sell, from time to time, at its option, up to an aggregate of \$62,500 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.

Any Shares to be offered and sold under the 2020 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 11, 2020 for an offering of up to \$350,000 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 2020 Sales Agreement, the Agent will use 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 cannot provide any assurances that it will issue any Shares pursuant to the 2020 Sales Agreement. The Company will pay the Agent a commission of up to 3.0% of the gross proceeds from the sale of the Shares, if any. The Company has also agreed to provide the Agent with customary indemnification rights.

During the year ended March 31, 2020, the Company issued and sold 287,559 shares of common stock under the 2019 Sales Agreement, for gross proceeds of \$4,568 less offering fees of \$137 for net proceeds of \$4,431 under the ATM. The Company has not issued and sold any shares under the 2020 Sales Agreement as of December 31, 2020.

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 November 2019 Underwriters (the “November 2019 Offering”). The November 2019 Shares were sold 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 represented the per share public offering price for the November 2019 Shares 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 November 2019 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 Warrants 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.

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 June 2020 Underwriters. The June 2020 Shares were sold 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 represented the per share public offering price for the June 2020 Shares 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 Warrants 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.

In October 2020, pursuant to an underwriting agreement with J.P. Morgan Securities LLC and SVB Leerink LLC, as representatives of the several underwriters named therein, the Company issued and sold to the underwriters (a) 5,625,000 shares of the Company’s common stock, inclusive of the underwriters 30-day option to purchase up to an additional 937,500 shares of the Company’s common stock, and (b) pre-funded warrants to purchase 1,562,500 shares of the Company’s common stock (the “October 2020 Pre-Funded Warrants”). The shares of the Company’s common stock were sold to the underwriters at the public offering price of \$40.00 per share and the pre-funded warrants were sold at a public offering price of \$39.99 per October 2020 Pre-Funded Warrant, which represented the per share public offering price for the Company’s common stock less a \$0.0001 per share exercise price for each such pre-funded warrant. The Company received aggregate net proceeds of approximately \$269,975 after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$17,525.

Funds affiliated with Redmile Group, LLC and funds affiliated with a second institutional investor purchased all of the October 2020 Pre-Funded Warrants. The October 2020 Pre-Funded Warrants are exercisable at any time after the date of issuance. A holder of October 2020 Pre-Funded Warrants may not exercise the October 2020 Pre-Funded Warrants 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 October 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.

Other than as set forth in Note 10 to these consolidated financial statements, including in the calculation of basic and diluted net loss per share attributable to common stockholders, the 5,284,238 shares of the Company's common stock into which the November 2019 Pre-Funded Warrants, the June 2020 Pre-Funded Warrants and October 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. As of December 31, 2020, none of the November 2019 Pre-Funded Warrants, the June 2020 Pre-Funded Warrants, or the October 2020 Pre-Funded Warrants had been exercised.

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 none remained available for future grants as of December 31, 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 December 31, 2020, 1,613,894 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 and 2019, the number of shares reserved for issuance under the ESPP automatically increased by 366,687 and 316,569 shares respectively, for a total of 1,031,868 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. The Company's ESPP is not currently active.

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 December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Risk-free interest rate	0.31%	1.68%	1.01%	2.17%
Expected term (in years)	6.1	6.1	6.4	6.0
Expected volatility	76.3%	69.7%	74.8%	71.0%
Expected dividend yield	0%	0%	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	\$ 15,345
Granted	2,284,004	15.24	9.37	
Exercised	(612,671)	8.01	6.79	
Cancelled	(309,137)	12.59		
Outstanding as of December 31, 2020	6,326,577	11.79	8.04	\$ 167,873
Options exercisable as of March 31, 2020	2,117,721	\$ 5.66	7.20	\$ 11,733
Options exercisable as of December 31, 2020	2,617,429	\$ 7.82	6.91	\$ 79,395

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 nine months ended December 31, 2020 and 2019 was \$10.06 and \$9.63, respectively. The total fair value of options vested during the three months and nine months ended December 31, 2020 was \$2,069 and \$8,330, respectively. The total fair value of options vested during the three months and nine months ended December 31, 2019 was \$1,063 and \$4,480, respectively.

Stock-based compensation expense

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Research and development	\$ 1,454	\$ 1,318	\$ 3,750	\$ 2,974
General and administrative	1,595	1,026	4,568	2,961
	\$ 3,049	\$ 2,344	\$ 8,318	\$ 5,935

As of December 31, 2020, total unrecognized compensation cost related to the unvested stock-based awards was \$31,002, which is expected to be recognized over a weighted average period of 2.95 years.

10. Net loss per share

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

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Numerator:				
Net loss attributable to common stockholders	\$ (21,783)	\$ (16,189)	\$ (59,371)	\$ (36,836)
Denominator:				
Weighted average common shares outstanding, basic and diluted	49,382,213	34,877,944	44,436,680	32,742,148
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (0.46)	\$ (1.34)	\$ (1.13)

The November 2019 Pre-Funded Warrants, the June 2020 Pre-Funded Warrants and October 2020 Pre-Funded Warrants are included as outstanding common stock 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 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 and Nine Months Ended December 31,	
	2020	2019
Options to purchase common stock	6,326,577	4,916,402
Warrants to purchase convertible preferred stock (as converted to common stock)	497,344	497,344
	6,823,921	5,413,746

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 of RP1. 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 failed 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 December 31, 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 in accordance with the agreed upon 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.

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 and nine months ended December 31, 2020 or 2019, the Company did not make any payments under the terms of the agreement from Regeneron. During the three and nine months ended December 31, 2020, the Company received payments under the terms of the agreement from Regeneron of \$1,453 and \$3,857, respectively. During the three and nine months ended December 31, 2019, the Company received payments under the terms of the agreement from Regeneron of \$760 and \$2008, respectively. As of December 31, 2020 and March 31, 2020, the Company recorded \$1,195 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 52,500 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 December 31,		Nine Months Ended December 31,	
	2020	2019	2020	2019
Lease cost				
Finance lease costs:				
Amortization of right-to-use asset	\$ 607	\$ 607	\$ 1,821	\$ 666
Interest on lease liabilities	560	591	1,683	652
Operating lease costs	239	262	705	633
Total lease cost	\$ 1,406	\$ 1,460	\$ 4,209	\$ 1,951

Finance lease costs of \$90 and \$90 are recognized in general and administrative expenses for the three months ended December 31, 2020 and 2019, respectively, and \$268 and \$149 for the nine months ended September 30, 2020 and 2019, respectively. Finance lease costs of \$518 and \$517 are recognized in research and development expenses for the three months ended December 31, 2020 and 2019, respectively, and \$1,553 and \$517 for the nine months ended December 31, 2020 and 2019, respectively. Operating leases costs are recognized in general and administrative expenses for the three and nine months ended December 31, 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 September 30, 2020:

	December 31, 2020		
	Operating leases	Financing lease	Total
2021 (remaining three months)	\$ 240	\$ 611	\$ 851
2022	967	2,487	3,454
2023	976	2,562	3,538
2024	986	2,639	3,625
2025	995	2,718	3,713
Thereafter	5,054	43,704	48,758
Total lease payments	9,218	54,721	63,939
Less: interest	3,083	27,437	30,520
Total lease liabilities	\$ 6,135	\$ 27,284	\$ 33,419

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

	December 31, 2020	March 31, 2020
Leases		
Right-to-use operating lease asset	\$ 5,839	\$ 4,425
Right-to-use finance lease asset	45,129	46,925
Total lease assets	\$ 50,968	\$ 51,350
Operating lease liabilities, current	\$ 965	\$ 873
Finance lease liabilities, current	2,469	2,411
Operating lease liabilities, non-current	5,170	3,737
Finance lease liabilities, non-current	24,815	24,967
Total lease liabilities	\$ 33,419	\$ 31,988

The following table provides lease disclosure for the nine months ended December 31, 2020 and 2019:

	Nine Months Ended	
	December 31,	
	2020	2019
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 582	\$ 516
Operating cash flows from finance leases	\$ 1,682	\$ 623
Financing cash flows from finance leases	\$ 92	\$ 22
Right-to-use asset obtained in exchange for new operating lease liabilities	\$ 1,580	\$ 5,152
Weighted-average remaining lease term - operating leases	9.1	8.6
	years	years
Weighted-average remaining lease term - financing leases	18.6	19.6
	years	years
Weighted-average discount rate - operating leases	9.8%	7%
Weighted-average discount rate - financing leases	8.3%	8%

The variable lease costs and short-term lease costs were insignificant for three and nine months ended December 31, 2020 and 2019.

Manufacturing commitments

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of December 31, 2020 and March 31, 2020, the Company had committed to minimum payments under these arrangements totaling \$1,622 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 executive management team and 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 December 31, 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:

	December 31, 2020	March 31, 2020
United States	\$ 6,564	\$ 6,357
United Kingdom	602	503
	<u>\$ 7,166</u>	<u>\$ 6,860</u>

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, or this Quarterly Report, 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.

In addition to historical information, some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, 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, particularly including those risks identified in Part II, Item 1A “Risk Factors” and our other filings with the SEC.

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. Statements made herein are as of the date of the filing of this Quarterly Report with the Securities Exchange Commission, or 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, 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 is an emerging drug class, which we intend to establish as the second cornerstone of immune-based cancer treatments, alongside checkpoint blockade. Oncolytic immunotherapy 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. 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, RP2 and RP3.

We are 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 actively enrolling patients in a randomized, controlled Phase 2 clinical trial of RP1 in up to 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 this clinical trial generates compelling clinical data demonstrating the benefits of the combined treatment, we believe the data could support a filing with regulatory authorities seeking marketing approval. We expect the primary data read-out from this Phase 2 clinical trial will be 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, including as a potential label expansion after an initial approval of RP1 in a different indication). We are currently enrolling approximately 30 patients in this clinical trial to assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC. Progress in this clinical trial has been particularly impacted by COVID-19, as the patient population is severely immune-compromised and considered very high risk if they were to contract COVID-19. Nevertheless, we expect to dose the first patient in this clinical trial in early 2021 and present initial data from this clinical trial in the second half of the year.

We have also 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 Phase 1/2 clinical trial. We are currently enrolling a 125-patient extension cohort of RP1 combined with nivolumab in anti-PD-1 failed 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 prior melanoma cohort demonstrated that RP1 combined with nivolumab has the potential to treat anti-PD-1 failed 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 expect that the primary data read-out from this Phase 2 melanoma cohort will be in 2022. In October 2020 we announced updated clinical data from our multi-cohort Phase 1/2 clinical trial evaluating RP1 in combination with nivolumab in patients with melanoma and non-melanoma skin cancers. As reported, RP1 in combination with nivolumab has continued to be well tolerated, and we believe demonstrates continued promising efficacy signals of anti-tumor activity in patients with skin cancers, including in patients with anti-PD-1 failed and other difficult-to-treat melanomas, and in patients with CSCC.

We continue to enroll patients in other Phase 2 cohorts under our collaboration with BMS in which we are testing RP1 in combination with nivolumab, including a non-melanoma skin cancers cohort, a microsatellite instability high, or MSI-H/dMMR tumor cohort, and we have recently opened for enrollment a cohort of 30 patients with anti-PD-1 failed non-small cell lung cancer, or NSCLC. We and BMS recently agreed to increase the number of patients in our non-melanoma skin cancer cohort from 30 to 45 patients to include anti-PD-1 failed patients. Due in part to COVID-19 related disruptions, we expect the original 30 patient non-melanoma skin cancer cohort to be fully accrued in early 2021. Before we determine the next stages of development in this indication, we intend to enroll a total of 15 patients into our MSI-H/dMMR cohort. We continue to accumulate data in the MSI-H/dMMR cohort and expect to decide whether to pursue MSI-H/dMMR tumors into registration-directed development later in 2021.

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 full activation of an immune response, including to tumors. RP3, which does not include the expression of GM-CSF, has been engineered with the intent to further stimulate an anti-tumor immune response through activation of the immune co-stimulatory pathways through expression of the ligands for CD40L and 4-1BBL, in addition to anti-CTLA-4 and GALV-GP R(-).

We initiated a Phase 1 clinical trial of RP2 alone and in combination with nivolumab in October 2019. This clinical trial is also being conducted as part of our 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 and BMS recently agreed to increase the number of patients in the combination part of the clinical trial from 12 to 30 patients. In October 2020, we presented positive data from the single agent RP2 portion of the clinical trial that showed deep and durable responses, including demonstration of uninjected tumor response in patients with difficult to treat advanced cancers. This data supports the hypothesis that anti-CTLA-4 delivered intra-tumorally through oncolytic virus replication, with accompanying antigen release and presentation, can provide potent anti-tumor effects. Following the monotherapy phase of this clinical trial with RP2, enrollment of patients treated with RP2 used in combination with nivolumab is currently underway and we expect to present initial combination data in mid-2021.

We have obtained clearance from the Medicines and Healthcare Products Regulatory Agency in the United Kingdom to begin clinical development with RP3 and in December 2020 we initiated dosing in this clinical trial. This Phase 1 clinical trial is designed to evaluate RP3 alone and combined with anti-PD-1 therapy in advanced solid tumor patients. Initial data from this clinical trial is expected to be presented in the second half of 2021.

RP1, RP2 and RP3 are administered by direct injection into solid tumors, guided either visually or by ultrasound, computerized tomography, or CT, or other imaging methods. We believe that direct injection maximizes virus-mediated tumor cell death, provides the most efficient delivery of virus-encoded immune activating proteins into the tumor with the goal of activating systemic immunity, and limits the systemic toxicities that could be associated with intravenous administration. Activation of systemic immunity through local administration is intended to lead to the induction of anti-tumor immune responses leading to clinical response of tumors that have not themselves been injected.

Financial

Since our inception, we have devoted substantially all of our resources to developing our Immulytic platform, 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.

Since our initial public offering, or IPO, on July 24 2018, we have raised an aggregate of approximately \$569.2 million in net proceeds to fund our operations, of which \$101.2 million was from our IPO, \$463.6 million was from three separate follow-on offerings, or the Public Offerings, that we closed in November 2019, June 2020 and October 2020, respectively, and \$4.4 million was from at-the-market offerings. We sold 7,407,936 shares of common stock in our IPO, an aggregate of 13,619,822 shares of our common stock and pre-funded warrants to purchase 5,284,238 shares of our common stock in the Public Offerings, and 287,559 shares of common stock through our at-the-market facility.

Funds affiliated with two separate institutional investors hold all of our outstanding pre-funded warrants. Other than as set forth in Note 8 of our condensed consolidated financial statements appearing elsewhere in this Quarterly Report, the 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.

In addition, on August 8, 2019, we entered into a Loan and Security Agreement with Hercules Capital, Inc., or Hercules, which we refer to as the Hercules Loan Agreement, pursuant to which we borrowed \$10.0 million under a secured term loan facility in the amount of \$30.0 million. 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. On December 15, 2020, we paid a total of \$10.8 million, representing the outstanding principal, accrued and unpaid interest, fees, costs and expenses due and owing under the Hercules Loan Agreement and related loan documents, in repayment of all of our outstanding obligations thereunder, and thereby terminated the Hercules Loan Agreement and the related loan documents.

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 \$21.8 million and \$16.2 million for the three months ended December 31, 2020 and 2019, respectively and net losses of \$59.4 million and \$36.8 million for the nine months ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of \$171.7 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, RP2 and RP3;
- further preclinical development of our platform;
- 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 manufacturing facility is fully validated, continued limited manufacturing by third parties for clinical development;
- 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, any future commercialization efforts and operating as a public company.

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 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 December 31, 2020, we had cash and cash equivalents and short-term investments of \$493.3 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.

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

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 reducing travel. For those employees working from our facilities, including certain essential employees in our laboratory and who perform manufacturing functions, and certain other employees as deemed 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. Fluctuation in infection rates in the regions in which we operate has resulted in periodic changes in restrictions that vary from region to region and require vigilant attention and rapid response to new or reinstated orders. 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 liver and kidney transplant patients with CSCC, representing highly immunocompromised patient populations, has been slower than expected for reasons we attribute to the COVID-19 pandemic. However, the extent of these delays is currently unknown and has and will likely continue to vary by clinical study site and may be amplified as a result of the impacts of a “second wave” of the virus outbreak. In addition, we may incur unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. While vaccines for COVID-19 are being, and have been developed, there is no guarantee that any such vaccine will be effective, work as expected or be made available or will be accepted on a significant scale and in a timely manner. 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.

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;
- 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 clinical trial CSCC.

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. We do not allocate personnel 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. All non-employee costs associated with our manufacturing facility have been fully burdened to our RP1 program.

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

	Three Months Ended		Nine Months Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
(Amounts in thousands)				
Direct research and development expenses by program:				
RP1	\$ 6,737	\$ 4,276	\$ 20,185	\$ 10,660
RP2 & RP3	1,263	197	2,143	627
Unallocated research and development expenses:				
Personnel related (including stock-based compensation)	5,664	4,395	15,889	10,776
Other	658	3,080	2,312	5,510
Total research and development expenses	<u>\$ 14,322</u>	<u>\$ 11,948</u>	<u>\$ 40,529</u>	<u>\$ 27,573</u>

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 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;
- the rate of enrollment in clinical trials;
- 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 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 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 with Hercules.

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 December 31, 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 December 31, 2020 and 2019

The following table summarizes our results of operations for the three months ended December 31, 2020 and 2019:

	Three Months Ended December 31,		Change
	2020	2019	
	(Amounts in thousands)		
Operating expenses:			
Research and development	\$ 14,322	\$ 11,948	\$ 2,374
General and administrative	5,953	4,716	1,237
Total operating expenses	<u>20,275</u>	<u>16,664</u>	<u>3,611</u>
Loss from operations	(20,275)	(16,664)	(3,611)
Other income (expense):			
Research and development incentives	550	951	(401)
Investment income	116	550	(434)
Interest expense on finance lease liability	(560)	(834)	274
Loss on extinguishment of debt	(913)	-	(913)
Interest expense on debt obligations	(247)	-	(247)
Other income (expense)	(454)	(192)	(262)
Total other income (expense), net	<u>(1,508)</u>	<u>475</u>	<u>(1,983)</u>
Net loss	<u>\$ (21,783)</u>	<u>\$ (16,189)</u>	<u>\$ (5,594)</u>

Research and development expenses

	Three Months Ended December 31,		Change
	2020	2019	
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	\$ 6,737	\$ 4,276	\$ 2,461
RP2 & RP3	1,263	197	1,066
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	5,664	4,395	1,269
Other	658	3,080	(2,422)
Total research and development expenses	<u>\$ 14,322</u>	<u>\$ 11,948</u>	<u>\$ 2,374</u>

Research and development expenses for the three months ended December 31, 2020 were \$14.3 million, compared to \$11.9 million for the three months ended December 31, 2019. The increase of \$2.4 million was due primarily to an increase of approximately \$3.5 million in direct research costs, off set by an approximately \$1.2 million decrease 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 December 31, 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 costs associated with RP2 and RP3 are primarily associated with the continued clinical trial development of these product candidates.

The decrease in unallocated research and development expenses reflected an increase of \$1.3 million in personnel-related 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 in multiple indications. Personnel related costs for the three months ended December 31, 2020 and 2019 included stock-based compensation expense of \$1.5 million and \$1.3 million, respectively. Other costs decreased primarily due to our manufacturing operations focused on the potential registrational studies associated with our RP1 development plan with multiple cohorts.

General and administrative expenses

General and administrative expenses were \$6.0 million for the three months ended December 31, 2020, compared to \$4.7 million for the three months ended December 31, 2019. The increase of \$1.2 million primarily reflected increases of \$0.9 million in personnel related costs, including stock-based compensation of \$0.6 million, and increases of \$0.2 million in facility and other variable costs. 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 facility and other variable costs was due primarily to an increase in costs associated with our directors and officers insurance.

Total other income (expense), net

Other income (expense) was \$(1.5) million for the three months ended December 31, 2020, compared to \$0.5 million for the three months ended December 31, 2019. The decrease of \$2.0 million was primarily attributable to a \$0.9 million increase associated with the loss from extinguishment of debt under our term loan facility with Hercules, a \$0.2 million increase in interest expense on debt obligations related to our term loan facility with Hercules, a \$0.3 decrease in other income due primarily to the changes in foreign exchange rates of the Great British Pounds to United States Dollar, a \$0.4 million decrease in investment income due to fluctuations in the rate of return on investments, and a \$0.4 million decrease in research and development incentives.

Comparison of the nine months ended December 31, 2020 and 2019

The following table summarizes our results of operations for the nine months ended December 31, 2020 and 2019:

Research and development expenses

	Nine Months Ended December 31,		Change
	2020	2019	
	(Amounts in thousands)		
Operating expenses:			
Research and development	\$ 40,529	\$ 27,573	\$ 12,956
General and administrative	17,242	12,240	5,002
Total operating expenses	<u>57,771</u>	<u>39,813</u>	<u>17,958</u>
Loss from operations	(57,771)	(39,813)	(17,958)
Other income (expense):			
Research and development incentives	1,991	2,192	(201)
Investment income	821	1,804	(983)
Interest expense on finance lease liability	(1,683)	(1,029)	(654)
Interest expense on debt obligations	(817)	-	(817)
Loss on extinguishment of debt	(913)	-	(913)
Other income (expense)	(999)	10	(1,009)
Total other income (expense), net	<u>(1,600)</u>	<u>2,977</u>	<u>(4,577)</u>
Net loss	<u>\$ (59,371)</u>	<u>\$ (36,836)</u>	<u>\$ (22,535)</u>

	Nine Months Ended December 31,		Change
	2020	2019	
	(Amounts in thousands)		
Direct research and development expenses by program:			
RP1	\$ 20,185	\$ 10,660	\$ 9,525
RP2 and RP3	2,143	627	1,516
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	15,889	10,776	5,113
Other	2,312	5,510	(3,198)
Total research and development expenses	<u>\$ 40,529</u>	<u>\$ 27,573</u>	<u>\$ 12,956</u>

Research and development expenses for the nine months ended December 31, 2020 were \$40.5 million, compared to \$27.6 million for the nine months ended December 31, 2019. The increase of \$13.0 million was due primarily to an increase of approximately \$9.5 million in direct research costs associated with RP1, \$1.5 million in direct research costs associated with RP2 and RP3, and approximately \$1.9 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 nine months ended December 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 costs associated with RP2 and RP3 is primarily associated with the continued clinical trial development of these product candidates.

The increase in unallocated research and development expenses reflected an increase of \$5.1 million in personnel-related costs, including stock-based compensation of \$0.8 million, partially offset by a decrease of \$3.2 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 in multiple indications. Personnel related costs for the nine months ended December 31, 2020 and 2019 included stock-based compensation expense of \$3.8 million and \$3.0 million, respectively. Other costs decreased primarily due to our manufacturing operations focused on the potential registrational studies associated with our RP1 development plan with multiple cohorts.

General and administrative expenses

General and administrative expenses were \$17.2 million for the nine months ended December 31, 2020, compared to \$12.2 million for the nine months ended December 31, 2019. The increase of \$5.0 million primarily reflected increases of \$2.8 million in personnel related costs, including stock-based compensation of \$1.6 million, increases of \$1.3 million in facility and other variable costs and increases of \$0.8 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 of approximately \$0.4 million and depreciation expense of \$0.4 million associated with our corporate headquarters.

Total other income (expense), net

Other income (expense) was \$(1.6) million for the nine months ended December 31, 2020, compared to \$3.0 million for the nine months ended December 31, 2019. The decrease of \$4.6 million was primarily attributable to a \$0.7 million increase in interest expense related to our finance lease liability, a \$0.8 million increase in interest expense on debt obligations related to our term loan facility with Hercules, a \$0.9 million increase associated with the loss from extinguishment of debt under our term loan facility with Hercules a \$1.0 million increase in other expense due primarily to the changes in foreign exchange rates of the Great British Pounds to United States Dollar, a \$1.0 million decrease in investment income due to fluctuations in the rate of return on investments, and a \$0.2 million decrease in research and development incentives.

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 December 31, 2020, we had received gross proceeds of approximately \$706.5 million from our sales of equity instruments and \$10.0 million from our incurrence debt under the term loan facility with Hercules, which was repaid in full in December 2020. As of December 31, 2020, we had cash and cash equivalents and short-term investments of \$493.3 million.

In July 2018, we completed our IPO and issued and sold 7,407,936 shares of our common stock at a public offering price of \$15.00 per share, resulting in net proceeds of \$103.4 million after deducting underwriting discounts and commissions but before deducting offering costs. In the fourth calendar quarter of 2019, we closed a registered public offering for the issuance and sale of 4,516,561 shares of our common stock at a public offering price of \$13.61 per share and 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. We received aggregate net proceeds of approximately \$85.6 million after deducting underwriting discounts, commissions and other offering expenses of approximately \$5.8 million. In June 2020, we closed a second public offering for the issuance and sale of 3,478,261 shares of our common stock at a public offering price of \$23.00 per share and 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. We received aggregate net proceeds of approximately \$107.8 million after deducting underwriting discounts, commissions and other offering expenses of approximately \$7.2 million. On October 26, 2020, we closed a third public offering for the issuance and sale of 5,625,000 shares of our common stock at a public offering price of \$40.00 per share and pre-funded warrants to purchase 1,562,500 shares of our common stock at a purchase price of \$39.99 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. We received aggregate net proceeds of approximately \$270.0 million after deducting underwriting discounts, commissions and other offering expenses of approximately \$17.5 million.

In addition to registered public equity offerings, we also established an at-the-market offering program pursuant to a sales agreement that we entered into with SVB Leerink LLC, or the Agent, on August 8, 2019, or the 2019 Sales Agreement. Under the 2019 Sales Agreement, and prior to its amendment in June 2020, we could sell from time to time, at our option, up to an aggregate of \$75.0 million of shares of our common stock. In June 2020, we amended the 2019 Sales Agreement to reduce the aggregate offering amount thereunder from \$75.0 million to \$30.0 million. We sold 287,559 shares of our common stock under the 2019 Sales Agreement for net proceeds of approximately \$4.4 million. On August 11, 2020, in connection with our entry into separate sales agreement with the Agent, or the 2020 Sales Agreement, we and the Agent mutually agreed to terminate the 2019 Sales Agreement. Under the 2020 Sales Agreement, and prior to its amendment in October 2020, we could sell from time to time, at our option, up to an aggregate of \$75.0 million of shares of our common stock. In October 2020, we amended the 2020 Sales Agreement to reduce the aggregate offering amount thereunder from \$75.0 million to \$62.5 million. We have not sold any shares of our common stock under the 2020 Sales Agreement.

Our incurrence of debt was conducted entirely under the Hercules Loan Agreement, as amended, pursuant to which we borrowed \$10.0 million of a maximum of \$40.0 million. On December 15, 2020, we entered into a Payoff Letter with Hercules and paid a total of \$10.8 million to Hercules representing the outstanding principal, accrued and unpaid interest, fees, costs and expense due and owed to Hercules, thereby terminating the Hercules Loan Agreement and the related loan documents.

Cash flows

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

	Nine Months Ended December 31,	
	2020	2019
	(Amounts in thousands)	
Net cash used in operating activities	\$ (45,261)	\$ (49,290)
Net cash provided by (used in) investing activities	(62,503)	(13,074)
Net cash provided by financing activities	371,677	100,132
Effect of exchange rate changes on cash and cash equivalents	1,062	(20)
Net increase (decrease) in cash and cash equivalents	<u>\$ 264,975</u>	<u>\$ 37,748</u>

Operating activities

During the nine months ended December 31, 2020, net cash used in operating activities was \$45.3 million, primarily resulting from our net loss of \$ 59.4 million, partially offset by the net cash provided by changes in our operating assets and liabilities of \$2.6 million and non-cash charges of \$11.4 million. Net cash used by our changes in our operating assets and liabilities for the nine months ended December 31, 2020 consisted primarily of a \$1.1 million decrease in research and development incentive receivables, partially from the United Kingdom government due to the timing and amount of our qualifying expenditures, \$1.2 million increase in prepaid expenses and other current assets and \$1.0 million decrease in accounts payable, partially offset by \$1.9 million increase in accrued expenses and other current liabilities and \$1.9 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 nine months ended December 31, 2019, net cash used in operating activities was \$49.3 million, primarily resulting from our net loss of \$36.8 million and net cash used by changes in our operating assets and liabilities of \$17.8 million, partially offset by net non-cash charges of \$5.3 million. Net cash used by changes in our operating assets and liabilities for the nine months ended December 31, 2019 consisted primarily of a \$14.1 million increase in long-term prepaid rent, a \$2.6 million decrease in accounts payable, a \$2.2 million increase in research and development incentives receivable, partially from the United Kingdom government due to the timing and amount of our qualifying expenditures, a \$1.5 million increase in prepaid expenses and other current assets and a \$0.3 million decrease in operating lease liabilities offset by a \$1.8 million increase in accrued expenses and other current liabilities, \$0.7 million decrease in operating lease, right-of-use asset and \$0.4 million decrease in financing lease, right-of-use-asset.

Investing activities

During the nine months ended December 31, 2020, net cash used in investing activities was \$62.5 million, consisting of \$225.0 million in purchases of available for sale securities and \$1.6 million in purchases of property, plant and equipment, partially offset by \$164.1 million in proceeds from sales and maturities of short-term investments.

During the nine months ended December 31, 2019, net cash used in investing activities was \$13.1 million, consisting of \$119.6 million in purchases of available for sale securities and \$5.2 million in purchases of property, plant and equipment, partially offset by \$111.7 million in proceeds from sales and maturities of short-term investments.

Financing Activities

During the nine months ended December 31, 2020, net cash provided by financing activities was \$371.7 million, consisting of \$286.1 million from the issuance of common stock, \$91.7 million from the issuance of pre-funded warrants to purchase common stock, \$4.9 million in proceeds from the exercise of stock options, partially offset by \$10.0 million in debt payments under the Hercules Loan Agreement and \$0.8 million of fees associated with the extinguishment of the obligations under the Hercules Loan Agreement.

During the nine months ended December 31, 2019, net cash provided by financing activities was \$100.1 million, consisting of \$57.5 million in proceeds from the issuance of common stock, \$28.1 million in proceeds from issuance of pre-funded warrants to purchase common stock, \$10.0 million in proceeds from the long-term debt, \$4.4 million in proceeds from the issuance of common stock through sales under the 2019 Sales Agreement and \$0.5 million in proceeds from the exercise of stock options, partially offset by \$0.4 million in payments of issuance costs and \$22,000 in principal payments of finance lease obligations.

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, 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 and, subject to the achievement of certain milestones, had the ability to borrow the unused \$30.0 million available thereunder in three separate \$10.0 million advances between October 1, 2020 and December 15, 2020, July 1, 2020 and June 30, 2021, and July 1, 2021 and December 15, 2021, respectively.

On December 15, 2020, we entered into a Payoff Letter with respect to the Hercules Loan Agreement. Pursuant to the Payoff Letter, we paid a total of \$10.8 million to Hercules, representing the outstanding principal, accrued and unpaid interest, fees, costs and expenses due and owed to Hercules under the Hercules Loan Agreement. Upon the execution of the Payoff Letter, in repayment of all of our outstanding obligations thereunder, the Hercules Loan Agreement and the related loan documents were terminated.

Borrowings under the Hercules Loan Agreement bore interest at a rate per annum equal to 8.75%. Under the Hercules Loan Agreement, we were required to make monthly interest-only payments through September 1, 2022. As of December 31, 2020, there was no amount of outstanding principal under the Hercules Loan Agreement due and owing.

The term loan facility with Hercules was secured by substantially all of our assets, excluding our intellectual property, and subject to certain exceptions and exclusions. All liens on our assets held by Hercules were released in connection with the our execution of the Payoff Letter.

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 with RP1, RP2 and RP3;
- further preclinical development of our platform;
- 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 limited manufacturing by third parties 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, any future commercialization efforts and operations as a public company.

As of December 31, 2020, we had cash and cash equivalents and short-term investments of \$493.3 million. We believe that our existing cash, cash equivalents and short-term investments as of December 31, 2020, will enable us to fund our overall operations into the second half of 2024. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

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 nine months ended December 31, 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 SEC 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 failed 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, 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 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.

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 3. Quantitative and Qualitative Disclosures about Market Risks.

Not applicable.

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 December 31, 2020, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 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 Quarterly Report 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

During the three months ended December 31, 2020, we continued to test the operating effectiveness of our formal policies, processes and internal controls for compliance with the Sarbanes-Oxley Act, including processes and internal controls to analyze, account for and disclose complex transactions.

The process of implementing and maintaining an effective financial reporting system is a continuous effort that requires management to anticipate and react to changes in our business, 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 our internal control environment, we may take additional actions to address control deficiencies or modify the remediation measures described above.

While significant progress has been made to enhance our internal control over financial reporting, we are still in the process of testing these processes, procedures and controls to ensure they are operating effectively. Additional time is required to complete our assessment to ensure these new procedures are sustainable. While we will continue to devote significant time and attention to these efforts, the material weaknesses previously identified cannot be considered fully 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

There have been no changes in our internal control over financial reporting during the three months ended December 31, 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.

Summary of Risk Factors

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- the timing, progress, and results of our preclinical studies and clinical trials for our product candidates, and the timing, scope or likelihood of regulatory filings and approvals for any of our other product candidates;
- our ability to develop and advance any future product candidates based on our Immulytic platform and successfully complete clinical trials;
- our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;
- our ability to successfully commercialize any product candidate for which we receive regulatory approval and our expectations regarding the size of the patient populations our product candidates if approved for commercial use;
- our ability to compete with other biopharmaceutical, biotechnology companies and other third parties and risks associated with such third parties developing or commercializing products more quickly or marketing them more successfully than us;
- negative developments in the field of immuno-oncology;
- our history of losses, the likelihood that we will continue to incur substantial and increasing net losses in the future, and the likelihood that we will require additional financing to achieve our goals;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation of any third-party intellectual property rights;
- the costs of operating our in-house manufacturing facility and our reliance on third-party collaborators and clinical trial service providers;
- our compliance with domestic and foreign laws, rules and regulations and the consequences in the event that we fail to comply with such laws, rules and regulations;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our competitive position, and developments and projections relating to our competitors and our industry;

- the impact of the COVID-19 coronavirus, or COVID-19, as a global pandemic and related public health issues; and
- our ability to remediate the material weaknesses in internal control over financial reporting and to maintain effective internal control over financial reporting.

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.

An underlying problem with our Immulytic platform would adversely affect our business and may require us to discontinue development of product candidates based on the same or similar therapeutic approaches.

Since all of the product candidates in our current pipeline are based on our Immulytic platform, if any of our product candidates fail 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 our product candidates that are based on our therapeutics approach, 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 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:

- 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;
- 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;
- 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 combination with and for the continued 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 have opened a clinical trial for use of RP1 as a monotherapy, we are generally developing RP1 and our other product candidates for use in combination with anti-PD-1 or potentially 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 therapy with which our products were combined 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 or at all, 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.

There can be no assurance that 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 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.

Certain 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 our 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 our product candidates. 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 our 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 our 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 and pre-funded warrants 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. 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 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. 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 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. 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 into the second half of 2024. 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.

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.

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 and subject to change with regulatory agencies and court decisions. 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, use by third parties of our products or infringement of our intellectual property rights, both inside and outside of the United States.

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, our issued patents and issued patents that we license from third parties or may own in the future may be challenged in the courts or patent offices in the United States and abroad. 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 interpreted or 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. 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. 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. If we are unable to obtain and maintain patent protection for our technology or inventions, 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 or inventions may be adversely affected.

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 our 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.

Filing, prosecuting and defending patents on our technology or inventions in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries or regions outside the United States can be less protective of our products 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. 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. 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 or inventions 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.

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 or misappropriation 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.

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. Although we enter into confidentiality agreements with our employees, consultants, collaborators, suppliers, manufacturers and other third parties who have access to our trade secrets, and 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, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms or may have conflicting agreements with third parties. 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. If any of our trade secrets, know-how or confidential or proprietary information were to be lawfully obtained, patented 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 and may be blocked from using such trade secrets, know-how or confidential or proprietary information ourselves. 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, and 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.

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. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be filed and/or 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. Such a license may not be available 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 and inventions 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 or we could be found liable for significant monetary damages 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 know-how, confidential or proprietary information or trade secrets could have a similar material adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology or inventions, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. 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, financial condition, results of operations, stock price and prospects.

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. Although we take steps to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, confidential or proprietary information, know-how or trade secrets 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, know-how or other confidential or 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.

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 may 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 license may not be available on commercially reasonable terms, or at all.

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.

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. 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 trade secrets, know-how, or proprietary or 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.

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 Phase 2 clinical trial 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.

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, 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.

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 may result in delays that 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.

We continue to rely on third-party contract manufacturers to manufacture our clinical trial product supplies. As a result, 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.

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. 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. 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.

If our manufacturers do not perform as agreed or encounter difficulties in production costs and yields, quality control, shortages of qualified personnel or key raw materials, compliance with strictly enforced federal, state, and foreign regulations, or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

In addition, 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.

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. 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.

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.

Our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts is now fully operational. This facility is intended to give us control over key aspects of the supply chain for our products and product candidates. However, 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. 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, raw material supply, 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. If we experience any unanticipated shortages of key raw materials, or other difficulties related to our raw material supply, we may not be able to effectively manage our ongoing manufacturing timelines which may negatively affect our product development schedule and our ability to provide clinical trial supplies to patients in our clinical trials.

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.

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. 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. 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. 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. 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. 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.

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, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

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.

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. 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. 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 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. 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, our commercialization processes and the conduct and the enrollment 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 and continues to be slower than expected as a result, in part, of the COVID-19 pandemic. 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 and fluctuation in infection rates in the regions in which we operate has resulted in periodic changes in restrictions that vary from region to region and require vigilant attention and rapid response to new or reinstated orders. 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. While vaccines for COVID-19 are being, and have been developed, there is no guarantee that any such vaccine will be effective, work as expected or be made available or will be accepted on a significant scale and in a timely manner.

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. 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, which would impose significant additional responsibilities on members of management and may divert their attention away from day-to-day 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. If the services of independent organizations, advisors and consultants become unavailable to us or we are unable to effectively manage our outsourced activities, or if the quality or accuracy of such services 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.

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, 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. 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. Additionally, 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.

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 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, 2018 and 2017 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, 2018 or 2017. 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, legal 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 December 31, 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 December 31, 2020, we concluded that, as of December 31, 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.

Risks Related to Our Common Stock and General Risks

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 COVID-19, 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.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own 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, a significant number of 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 \$62.5 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 11, 2020 and as amended on October 21 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.

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, exercisable 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.

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.

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, 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.

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 10, 2020	4.1
10.1*	Payoff Letter to Loan and Security Agreement by and among Replimune Group, Inc., Replimune, Inc., Replimune Limited and Hercules Capital, Inc., dated December 15, 2020.			
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.

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: February 4, 2021

By: /s/ Philip Astley-Sparke

Name: Philip Astley-Sparke

Title: Chief Executive Officer and Director

(Principal Executive Officer)

Dated: February 4, 2021

By: /s/ Jean Franchi

Name: Jean Franchi

Title: Chief Financial Officer

(Principal Financial Officer)



December 15, 2020

Replimune Group, Inc.
Attention: Philip Astley-Sparke, Executive Chairman and Director
18 Commerce Way
Woburn, MA 01801

Re: Payoff of Loan and Security Agreement

Reference is hereby made to that certain Loan and Security Agreement (as amended from time to time, the "Loan Agreement"), entered into and effective as of August 7, 2019, by and among Replimune Group, Inc., a Delaware corporation, and each of its Subsidiaries (other than Excluded Subsidiaries and the MSC Subsidiary (collectively referred to as the "Borrower"), the several banks and other financial institutions or entities from time to time parties thereto (collectively referred to as the "Lender"), and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the Lender (in such capacity, the "Agent"). Capitalized terms used herein, but not otherwise defined, shall have the meaning set forth in the Loan Agreement.

We have been advised that the Borrower (a) intends to pay off all of its indebtedness to the Lender, including principal, accrued and unpaid interest, fees, costs and expenses (collectively, together with the Secured Obligations, the "Obligations") payable under the Loan Agreement and (b) wishes to terminate the Term Loan Commitments of the Lender under the Loan Agreement. This letter (the "Payoff Letter") will confirm that, upon receipt by the Lender of the Payoff Amount (together with any applicable Per Diem Amount; both as defined below) from or on behalf of the Borrower, all of the Obligations shall be paid in full, released, and discharged.

Payoff Amount; Wiring Instructions. The "Payoff Amount" is U.S. \$10,838,819.44 through and until 1:00 p.m. Eastern time on December 18, 2020 (the "Payoff Date"). If the Lender does not receive funds in an amount sufficient to repay the Payoff Amount in full by 1:00 p.m. Eastern time on the Payoff Date, additional interest and fees shall accrue and be payable in the amount of U.S. \$2,430.56 per day (the "Per Diem Amount") until the Payoff Amount is paid in full. The Payoff Amount must be received, in immediately available funds, by 1:00 p.m. Eastern time on the Payoff Date in order for the Borrower to avoid the accrual of the Per Diem Amount. The Payoff Amount and Per Diem Amount quoted herein are effective through December 31, 2020.

The Payoff Amount (together with any applicable Per Diem Amount) should be paid by or on behalf of the Borrower as two (2) separate wire transfer in accordance with the following instructions:

- 1. \$100,000.00 shall be wired as follows:

Bank Name: Wells Fargo NA
Address: PO Box 63020
San Francisco, CA 94163
ABA#: #####
Account Name: HERCULES CAPITAL INC
Account #: #####
Contact: Peter Fishman (###) ###-####

2. \$10,738,819.44 (plus Per Diem Amount of \$2,430.56 per day, if applicable) shall be wired as follows:

Bank Name:	US Bank N.A.
Address:	5065 Wooster PK
	Cincinnati, OH 45226
ABA#:	#####
Account Name:	Hercules Capital Funding Trust 2019 1
Account #:	#####
Reference:	Hercules 2019 1
Contact:	Peter Fishman (###) ###-####
ACH Company ID:	#####

Termination of Obligations. Upon the acceptance of this Payoff Letter by the Borrower as evidenced by their countersignature hereto and the Lender's receipt of the Payoff Amount (together with any applicable Per Diem Amount), (a) the Lender's commitments (including, without limitation, the Term Loan Commitments) to extend further credit to the Borrower under the Loan Agreement shall automatically terminate, all obligations (including, without limitation, the Obligations), covenants, debts and liabilities of the Borrower under the Loan Agreement shall be satisfied, released, and discharged in full, and the Loan Agreement and all other documents (including, without limitation, the Loan Documents) entered into in connection with the Loan Agreement shall be automatically terminated, (b) all liens or security interests granted to secure the obligations (including, without limitation, the Obligations) under the Loan Agreement shall be released and automatically terminate, and (c) all guaranties of the obligations (including, without limitation, the Obligations) under the Loan Agreement shall be released and automatically terminate. Notwithstanding the foregoing, provisions set forth in Sections 6.3, 8.1, 11.15 and 11.18 of the Loan Agreement shall survive the termination of the Loan Agreement.

Lender's Agreements. Upon the Lender's receipt of the Payoff Amount (together with any applicable Per Diem Amount):

(a) The undersigned hereby agrees that upon the payment in full of the Payoff Amount, this Payoff Letter shall be deemed to be an authorization for the Borrower or any agent or other designee of the Borrower (i) to file UCC-3 financing statement terminations with respect to each financing statement filed against the Borrower and its Subsidiaries for the benefit of the Lender, and (ii) to deliver a copy of this letter or any other termination or release contemplated hereby to any insurance company, insurance broker, bank, landlord, tenant, warehouseman or other Person to evidence (and/or reflect on public record) the termination and release of all security interests, pledges, liens, assignments or other encumbrances which the Borrower or any guarantor or other obligor has granted to the Lender to secure the Obligations, and thereafter any contract, agreement, mortgage, commitment to deliver insurance certificates and proceeds and the like executed by any such party in favor of the Agent and/or Lender in connection with the transactions contemplated by the Loan Agreement shall be automatically terminated, without further action of or consent by the Agent and/or Lender.

(b) The Agent and/or Lender will immediately return to Borrower for the benefit of the Borrower and its Subsidiaries all of the collateral it has in its possession including, without limitation all promissory notes, certificates representing the Collateral, any transfers therefore and any other instruments.

(c) The Agent shall execute and deliver the Termination of Control Agreement attached hereto as Schedule A for each agreement by which the Agent obtained control of a deposit account and/or a securities account to terminate its control over such deposit and/or securities account.

(d) Lender shall execute and deliver the Confirmation of Receipt of Full Payment of the Payoff Amount attached hereto as Schedule B.

The Agent and/or Lender further agree that, at any time and from time to time following the Lender's receipt of the Payoff Amount, the Agent and/or Lender will promptly execute and deliver such other termination statements or other documents, agreements and instruments in form and substance reasonably satisfactory to the Borrower and take such other actions as the Borrower or its counsel may reasonably request to evidence, effect or reflect on public record the release of the security interests, pledges, liens and other encumbrances granted to the Agent and/or Lender pursuant to the Loan Agreement or any other agreement executed and/or delivered in connection therewith (including, without limitation, the Loan Documents).

Release. For and in consideration of the agreements of the Agent and Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Borrower hereby forever releases and discharges the Agent and Lender, each of their respective officers, directors, employees, agents, affiliates, representatives, successors and assigns (collectively, the "**Released Parties**") from any and all claims, causes of actions, damages and liabilities of any nature whatsoever, known or unknown, which the Borrower ever had, now has or might hereafter have against one or more of the Released Parties which relates, directly or indirectly, to the Loan Documents or the transactions relating thereto, to the extent that any such claim, cause of action, damage or liability shall be based in whole or in part upon facts, circumstances, actions or events existing on or prior to the Payoff Date.

Counterparts; Facsimile Delivery. Agent and Lender hereby request that the Borrower acknowledges its receipt and acceptance of and agreement to the terms and conditions set forth in this Payoff Letter by signing a copy of it in the appropriate space indicated below and returning it to the Agent and Lender. This Payoff Letter may be signed by the parties hereto in several counterparts. Delivery of a photocopy or facsimile of an executed counterpart of this Payoff Letter shall be effective as delivery of a manually executed original counterpart of this Payoff Letter.

Governing Law. The validity, construction and effect of this Payoff Letter shall be governed by the laws of the State of California (without giving effect to principles of conflicts of law).

[Signature Pages Follow]



Very truly yours,

AGENT:

HERCULES CAPITAL, INC.

By: /s/ Jennifer Choe

Name: Jennifer Choe

Title: Associate General Counsel

LENDER:

HERCULES CAPITAL, INC., as Lender

By: /s/ Jennifer Choe

Name: Jennifer Choe

Title: Associate General Counsel

**HERCULES CAPITAL FUNDING TRUST 2019-1,
as Lender**

By: /s/ Jennifer Choe

Name: Jennifer Choe

Title: Associate General Counsel



ACCEPTED AND AGREED:

BORROWER:

REPLIMUNE GROUP, INC.

By: /s/ Jean Franchi

Name: Jean Franchi

Title: CFO

REPLIMUNE, INC.

By: /s/ Philip Astley-Sparke

Name: Philip Astley-Sparke

Title: CEO

REPLIMUNE LIMITED

By: /s/ Philip Astley-Sparke

Name: Philip Astley-Sparke

Title: CEO

400 HAMILTON AVENUE, SUITE 310, PALO ALTO, CA 94301

TEL: 650-289-3060 | FAX: 650-473-9194 | [WWW.HTGC.COM](http://www.htgc.com)

Schedule A



Termination Letter for Deposit Account Control Agreement

December 17, 2020

Silicon Valley Bank
Global Deposit Operations
80 East Rio Salado Parkway, Mail Sort AZ145
Tempe, AZ 85281

Re: Consent for Termination of a Deposit Account Control Agreement for

Name of Client: Replimune Inc.
Deposit Account Number: #####
Creditor: Hercules Capital, Inc., as administrative and collateral agent
Execution Date of DACA: August 5, 2019

Ladies and Gentlemen:

Hercules Capital, Inc., as Creditor, is hereby terminating the Deposit Account Control Agreement with Silicon Valley Bank and Client referenced above. Silicon Valley Bank can rely on a faxed copy of this termination letter.

Creditor hereby certifies that the person executing this letter is an officer, representative or agent of Creditor authorized to act on behalf of the Creditor and to make representations and agreements contained in this letter.

Sincerely,

HERCULES CAPITAL, INC., as administrative and collateral agent

By: /s/ Jennifer Choe
Name: Jennifer Choe
Title: Associate General Counsel

400 HAMILTON AVENUE, SUITE 310, PALO ALTO, CA 94301

TEL: 650-289-3060 | FAX: 650-473-9194 | WWW.HTGC.COM

Schedule B



**CONFIRMATION OF RECEIPT OF FULL PAYMENT
OF THE PAYOFF AMOUNT**

By its signature below, the undersigned hereby confirms its receipt of full payment of the Payoff Amount on the Payoff Date and releases its security interest in all of the Collateral as provided in our Payoff Letter dated as of December 15, 2020 (the "**Payoff Letter**") to Replimune Group, Inc. All terms used herein and not defined shall have the meaning attributed to them in the Payoff Letter.

LENDER:

HERCULES CAPITAL, INC., as Lender

By: /s/ Jennifer Choe

Name: Jennifer Choe

Title: Associate General Counsel

HERCULES CAPITAL FUNDING TRUST 2019-1,
as Lender

By: /s/ Jennifer Choe

Name: Jennifer Choe

Title: Associate General Counsel

400 HAMILTON AVENUE, SUITE 310, PALO ALTO, CA 94301

TEL: 650-289-3060 | FAX: 650-473-9194 | www.htgc.com

**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: February 4, 2021

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

**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: February 4, 2021

BY: /s/ JEAN FRANCHI

Jean Franchi
Chief Financial Officer
(Principal Financial Officer)

**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 December 31, 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: February 4, 2021

By: /s/ PHILIP ASTLEY-SPARKE

Philip Astley-Sparke
Chief Executive Officer
(Principal Executive Officer)

**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 December 31, 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: February 4, 2021

By: /s/ JEAN FRANCHI

Jean Franchi
Chief Financial Officer
(Principal Financial Officer)
