

**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 June 30, 2023

OR

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

For the transition period from            to

Commission file number 001-38596

**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 Drive**

**Suite 303**

**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 July 31, 2023 was 58,996,326.

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REPLIMUNE GROUP, INC.

FORM 10-Q

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**PART I - FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

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

	<u>June 30, 2023</u>	<u>March 31, 2023</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 106,481	\$ 146,590
Short-term investments	432,619	436,796
Research and development incentives receivable	3,047	2,939
Prepaid expenses and other current assets	7,895	6,278
Total current assets	<u>550,042</u>	<u>592,603</u>
Property, plant and equipment, net	7,616	7,479
Restricted cash	1,636	1,636
Research and development incentives receivable, non-current	402	—
Right-to-use asset - operating leases	5,137	5,208
Right-to-use asset - financing leases	39,058	39,665
Total assets	<u>\$ 603,891</u>	<u>\$ 646,591</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 4,883	\$ 5,364
Accrued expenses and other current liabilities	23,562	24,704
Operating lease liabilities, current	1,139	1,118
Financing lease liabilities, current	2,658	2,639
Total current liabilities	<u>32,242</u>	<u>33,825</u>
Operating lease liabilities, non-current	4,295	4,389
Financing lease liabilities, non-current	23,842	23,965
Long term debt, net of discount	28,905	28,648
Other liabilities, non-current	578	472
Total liabilities	<u>\$ 89,862</u>	<u>\$ 91,299</u>
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, \$0.001 par value; 150,000,000 shares authorized as of June 30, 2023 and March 31, 2023; 58,976,325 and 56,676,313 shares issued and outstanding as of June 30, 2023 and March 31, 2023, respectively	57	57
Additional paid-in capital	1,045,049	1,034,994
Accumulated deficit	(535,043)	(485,488)
Accumulated other comprehensive income	3,966	5,729
Total stockholders' equity	<u>514,029</u>	<u>555,292</u>
Total liabilities and stockholders' equity	<u>\$ 603,891</u>	<u>\$ 646,591</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)**

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 40,437	\$ 29,478
Selling, general and administrative	15,211	11,398
Total operating expenses	55,648	40,876
Loss from operations	(55,648)	(40,876)
Other income (expense):		
Research and development incentives	393	851
Investment income	6,186	343
Interest expense on finance lease liability	(544)	(552)
Interest expense on debt obligations	(1,115)	—
Other income (expense)	1,374	(2,019)
Total other income (expense), net	6,294	(1,377)
Loss before income taxes	\$ (49,354)	\$ (42,253)
Income tax provision	201	\$ —
Net loss	\$ (49,555)	\$ (42,253)
Net loss per common share, basic and diluted	\$ (0.75)	\$ (0.78)
Weighted average common shares outstanding, basic and diluted	66,367,702	54,211,446

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)**

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Net loss	\$ (49,555)	\$ (42,253)
Other comprehensive loss:		
Foreign currency translation (loss) gain	(1,305)	1,737
Net unrealized loss on short-term investments, net of tax of \$0	(458)	(244)
Comprehensive loss	<u>\$ (51,318)</u>	<u>\$ (40,760)</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				
<b>Balances as of March 31, 2023</b>	56,676,313	\$ 57	\$ 1,034,994	\$ (485,488)	\$ 5,729	\$ 555,292
Foreign currency translation adjustment	—	—	—	—	(1,305)	(1,305)
Unrealized loss on short-term investments	—	—	—	—	(458)	(458)
Exercise of pre-funded warrants	1,922,655	—	—	—	—	—
Exercise of stock options	96,146	—	1,209	—	—	1,209
Vesting of RSUs	281,211	—	—	—	—	—
Stock-based compensation expense	—	—	8,846	—	—	8,846
Net loss	—	—	—	(49,555)	—	(49,555)
<b>Balances as of June 30, 2023</b>	58,976,325	57	1,045,049	(535,043)	3,966	514,029
<b>Balances as of</b>						
<b>Balances as of March 31, 2022</b>	47,338,660	\$ 47	\$ 723,359	\$ (311,204)	\$ (973)	\$ 411,229
Issuance of common stock through ATM sales, net of offering costs	1,686,438	2	31,035	—	—	31,037
Foreign currency translation adjustment	—	—	—	—	1,737	1,737
Unrealized loss on short-term investments	—	—	—	—	(244)	(244)
Exercise of stock options	124,028	—	1,562	—	—	1,562
Vesting of RSUs	149,341	—	—	—	—	—
Stock-based compensation expense	—	—	7,194	—	—	7,194
Net loss	—	—	—	(42,253)	—	(42,253)
<b>Balances as of June 30, 2022</b>	49,298,467	49	763,150	(353,457)	520	410,262

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)

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (49,555)	\$ (42,253)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,846	7,194
Depreciation	621	620
Net amortization of premiums and discounts on short-term investments	(4,091)	243
Noncash interest expense	257	—
Unrealized foreign currency transaction losses	(1,374)	—
Changes in operating assets and liabilities:		
Research and development incentives receivable	(393)	(850)
Prepaid expenses and other current assets	(1,577)	1,158
Operating lease, right-of-use-asset	148	126
Finance lease, right-of-use-asset	607	607
Accounts payable	(816)	895
Accrued expenses and other current liabilities	(1,215)	(1,067)
Operating lease liabilities	(153)	(128)
Other non-current liabilities	107	—
Net cash used in operating activities	(48,588)	(33,455)
<b>Cash flows from investing activities:</b>		
Purchases of property, plant and equipment	(449)	(1,068)
Purchase of short-term investments	(169,330)	(60,617)
Proceeds from sales and maturities of short-term investments	177,140	67,000
Net cash provided by investing activities	7,361	5,315
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock through ATM sales, net of offering costs	—	31,037
Principal payment of finance lease obligation	(104)	(77)
Proceeds from exercise of stock options	1,209	1,562
Net cash provided by financing activities	1,105	32,522
<b>Effect of exchange rate changes on cash, cash equivalents and restricted cash</b>	<b>13</b>	<b>1,915</b>
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<b>(40,109)</b>	<b>6,297</b>
Cash, cash equivalents and restricted cash at beginning of period	148,226	107,584
Cash, cash equivalents and restricted cash at end of period	\$ 108,117	\$ 113,881
<b>Supplemental disclosure of cash flow information:</b>		
<b>Cash paid during the period for interest</b>	<b>653</b>	<b>—</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Purchases of property and equipment included in accounts payable	412	318

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 committed to applying its leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients through its novel tumor-directed oncolytic immunotherapies. The Company's proprietary tumor-directed oncolytic immunotherapy product candidates are designed and intended to maximally activate the immune system against 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, third-party intellectual property, 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 \$49.6 million and \$42.3 million for the three months ended June 30, 2023 and 2022, respectively. In addition, as of June 30, 2023, the Company had an accumulated deficit of \$535.0 million. 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 these consolidated financial statements.

## **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 (“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.

### ***Unaudited interim financial information***

The accompanying consolidated balance sheet as of June 30, 2023, the consolidated statements of operations, of comprehensive loss and of stockholders' equity for the three months ended June 30, 2023 and 2022 and the consolidated statements of cash flows for the three months ended June 30, 2023 and 2022 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the

opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of June 30, 2023 and the results of its operations for the three months ended June 30, 2023 and 2022 and its cash flows for the three months ended June 30, 2023 and 2022. The financial data and other information disclosed in these consolidated notes related to the three months ended June 30, 2023 and 2022 are unaudited. The results for the three months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending March 31, 2024, 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, 2023, which was filed with the Securities and Exchange Commission on May 18, 2023 (the "Annual Report").

During the three months ended June 30, 2023, there have been no changes to the Company's significant accounting policies as described in the Annual Report, except as described below.

### 3. Fair value of financial assets and liabilities

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

	Fair Value Measurements as of June 30, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ —	\$ 26,928	\$ —	\$ 26,928
US Government Agency bonds	—	15,928	—	15,928
Short-term investments				
US Government Agency bonds	—	307,583	—	307,583
US Treasury bonds	—	125,036	—	125,036
	<u>\$ —</u>	<u>\$ 475,475</u>	<u>\$ —</u>	<u>\$ 475,475</u>
	Fair Value Measurements as of March 31, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	\$ —	\$ 121,455	\$ —	\$ 121,455
Short-term investments				
US Government Agency bonds	—	240,355	—	240,355
US Treasury bonds	—	196,441	—	196,441
	<u>\$ —</u>	<u>\$ 558,251</u>	<u>\$ —</u>	<u>\$ 558,251</u>

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

During the three months ended June 30, 2023 and 2022, there were no transfers between levels.

#### Valuation of cash equivalents and short-term investments

Money market funds, U.S. Government Agency bonds and U.S. Treasury bonds 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 and U.S. Government Agency bonds at June 30, 2023 and money market funds at March 31, 2023.

### 4. Short-term investments

As of June 30, 2023 and March 31, 2023, the Company's available-for-sale investments by type consisted of the following:

	<b>June 30, 2023</b>				
	<b>Amortized cost</b>	<b>Gross unrealized gains</b>	<b>Gross unrealized losses</b>	<b>Credit Losses</b>	<b>Fair value</b>
US Government agency bonds	\$ 307,935	\$ 84	\$ (436)	\$ —	\$ 307,583
US Treasury bonds	125,205	3	(172)	—	125,036
Total	<u>\$ 433,140</u>	<u>\$ 87</u>	<u>\$ (608)</u>	<u>\$ —</u>	<u>\$ 432,619</u>

  

	<b>March 31, 2023</b>				
	<b>Amortized cost</b>	<b>Gross unrealized gains</b>	<b>Gross unrealized losses</b>	<b>Credit Losses</b>	<b>Fair value</b>
US Government agency bonds	240,371	187	(203)	\$ —	240,355
US Treasury bonds	196,488	77	(124)	—	196,441
Total	<u>\$ 436,859</u>	<u>\$ 264</u>	<u>\$ (327)</u>	<u>\$ —</u>	<u>\$ 436,796</u>

As of June 30, 2023, available-for-sale securities consisted of investments that mature within one year. As of March 31, 2023, available-for-sale securities consisted of investments that mature within one year, with the exception of certain U.S. Government agency bonds and U.S. Treasury bonds which had maturities between one and two years and an aggregate fair value of \$15.1 million.

## 5. Property, plant and equipment, net

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

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
Office equipment	\$ 1,245	\$ 1,240
Computer equipment	1,806	1,806
Plant and laboratory equipment	9,337	9,186
Leasehold improvements	1,706	1,706
Construction in progress	1,385	783
Total property, plant and equipment	15,479	14,721
Less: Accumulated depreciation	(7,863)	(7,242)
Property, plant and equipment, net	<u>\$ 7,616</u>	<u>\$ 7,479</u>

Depreciation expense was \$621 and \$620 for the three months ended June 30, 2023 and 2022, respectively. Depreciation expense is recorded within research and development and selling, 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:

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
Accrued research and development costs	\$ 14,959	\$ 11,261
Accrued compensation and benefits costs	5,204	9,909
Accrued professional fees	402	540
Other	2,997	2,994
Total accrued expenses and other current liabilities	<u>\$ 23,562</u>	<u>\$ 24,704</u>

## 7 Debt

On October 6, 2022, the Company entered into a Loan and Security Agreement (the "Loan Agreement"), with Hercules Capital, Inc., as administrative agent, collateral agent and as a lender ("Hercules"). Pursuant to the Loan Agreement, the Company can borrow term loans in an aggregate maximum principal amount of up to \$200.0 million under multiple tranches (the "Term Loan Facility"). Under the Loan Agreement, the Company borrowed an initial amount of \$30.0 million on the Closing Date, and at the Company's sole option, could draw down an additional \$30.0 million on or prior to September 30, 2023, as well as additional term loan advances in an aggregate principal amount of up to \$115.0 million during the term of the Term Loan Facility subject to achievement of specified performance milestones, and two additional term loan advances up to an aggregate principal amount of \$25.0 million subject to certain terms and conditions, on or prior to the end of the interest-only period. The Company intends to use the proceeds of the Term Loan Facility for working capital and general corporate purposes.

The Loan Agreement was subsequently amended (the "Amendment") on June 28, 2023 and the agreement, as amended, states that the Company agrees to draw an initial term loan advance in an aggregate principal amount not less than \$30.0 million, provided that the aggregate amount of the term loan advances made under tranche 1 do not exceed \$30.0 million, which is a decrease of \$30 million from the \$60.0 million in the original Loan Agreement. The total amount of the Loan Agreement, as well as the outstanding balance of the loan, is unchanged, but the option to borrow an additional \$30.0 million is moved from tranche 1 to tranche 2. Therefore, the amendment states that the Company can draw down an additional \$45.0 million on or prior to December 31, 2023, which is an increase of \$30.0 million from the \$15.0 million in the original Loan Agreement for tranche 2. The impact of this amendment is not a modification, as it does not relate to outstanding debt, but is rather an amendment that provides for a future potential benefit. There is no material impact to the financial statements.

The Term Loan Facility will mature on October 1, 2027 (the "Maturity Date"). The outstanding principal balance of the Term Loan Facility bears interest payable in cash at a floating rate per annum equal to the greater of (i) 7.25% and (ii) the sum of the Prime Rate (which is capped at 7.25%) and 1.75%. Accrued interest is payable monthly following the funding of each term loan advance. In addition, the principal balance of the Term Loan Facility will bear "payment-in-kind" interest at the rate of 1.50% ("PIK Interest"), which PIK Interest will be added to the outstanding principal balance of the Term Loan Facility on each interest payment date.

Borrowings under the Loan Agreement are repayable in monthly interest-only payments through September 2026. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until October 2027. At the Company's option, the Company may prepay all or a portion of the outstanding borrowings, subject to a prepayment fee of 3.0% of the principal amount if prepayment occurs during the 12 months following the Closing Date, 2.0% after 12 months following the Closing Date but prior to 36 months following the Closing Date, and 1.0% thereafter.

The Loan Agreement contains customary facility fees, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring us to maintain unrestricted cash in an amount not less than 35% of the aggregate outstanding secured obligations under the Loan Agreement, in accounts subject to a control agreement in favor of the Agent (the "Unrestricted Cash") at all times commencing on January 1, 2024. In addition, the Loan Agreement also contains a financial covenant that beginning on the later of (i) July 1, 2024 and (ii) the date on which the aggregate outstanding principal amount of the Term Loan Facility is equal to or greater than \$100.0 million, the Company is required to satisfy one of the following requirements: (1) achieve a minimum amount of trailing three-month net product revenue tested on a monthly basis, (2) maintain a market capitalization in excess of \$1.2 billion and Unrestricted Cash in an amount no less than 50% of the outstanding amount under the Term Loan Facility, or (3) maintain Unrestricted Cash in an amount no less than 85% of the outstanding amount under the Term Loan Facility.

The Company paid a \$0.5 million facility charge and incurred debt issuance costs of \$1.5 million upon closing of the Loan Agreement. The Loan Agreement also provides for a final payment, payable upon maturity or the repayment of the obligations in full or in part (on a pro rata basis), equal to 4.95% of the aggregate principal amount of Term Loans advanced to the Borrower and repaid on such date, which is being accrued on the Company's consolidated balance sheet. As of June 30, 2023 and March 31, 2023, the amount accrued for the final payment is \$0.2 million.

Unamortized debt issuance costs are recorded as a reduction of the carrying amount on the term loan and amortized as interest expense using the effective-interest method. In addition, unamortized deferred financing costs related to the Company's right to borrow additional amounts from Hercules in the future were recorded in other assets and amortized to interest expense over the relevant draw period on a straight-line basis. As a result of the Amendment, the Company recorded \$0.1 million of the remaining unamortized deferred financing costs related to the Tranche 1 delayed draw to interest expense as of June 30, 2023. Interest expense for the three months ended June 30, 2023 was \$1.1 million.

The summary of obligations under the term loan as of June 30, 2023 and March 31, 2023 consisted of the following (in thousands):

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
Principal loan balance	\$ 30,337	\$ 30,222
Facility charge and diligence fee	(304)	(315)
Unamortized issuance costs	(1,358)	(1,410)
Accumulated end of term fee	230	151
Long term debt, net	<u>\$ 28,905</u>	<u>\$ 28,648</u>

The annual principal payments due under the Loan Agreement as of June 30, 2023 and March 31, 2023 were as follows:

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
2024	—	—
2025	—	—
2026	—	—
2027	13,438	13,438
Thereafter	18,701	18,701
Total	<u>\$ 32,139</u>	<u>\$ 32,139</u>

The table of future payments of long-term debt excludes the end of term charge of \$1.5 million, which is due upon the maturity of the loan

## 8 Stockholders' equity

### *Common stock*

As of June 30, 2023 and March 31, 2023, 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.

The Company had reserved for common stock for the exercise of outstanding stock options and the vesting of restricted share units, 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 10) and the exercise of the outstanding warrants to purchase shares of common stock as follows:

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
Stock options, issued and outstanding	9,067,305	7,438,000
Restricted stock units	2,069,415	1,338,000
Stock options and restricted stock units, future issuance	2,148,050	2,200,000
Employee stock purchase plan, available for future grants	2,738,208	2,000,000
Pre-IPO warrants to purchase common stock	497,344	497,344
Pre-funded warrants	7,561,583	9,438,000
Total shares of common stock reserved for future issuance	<u>24,081,905</u>	<u>23,011,344</u>

### *Undesignated preferred stock*

As of June 30, 2023, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value \$0.001 per share. There were no undesignated preferred shares issued or outstanding as of June 30, 2023.

### *ATM program*

On August 11, 2020, the Company and the SVB Leerink LLC (the "Agent") entered into a sales agreement, which was subsequently amended on October 21, 2020 (as amended, the "2020 Sales Agreement"), pursuant to which the Company could sell, from time to time, at its option, up to an aggregate of \$62.5 million of shares of the Company's common stock, \$0.001 par value per share, through the Agent, as the Company's sales agent.

During the three months ended June 30, 2022 the Company settled transactions that occurred pursuant to the 2020 Sales Agreement, whereby the Company issued and sold an aggregate of 1,686,438 shares of its common stock, resulting in gross proceeds of \$32.0 million, before deducting fees of \$1.0 million.

On June 23, 2022, the 2020 Sales Agreement was terminated by the execution by the Company and the Agent of a new sales agreement (the "2022 Sales Agreement"). Under the 2022 Sales Agreement, the Company may sell, from time to time, at its option, up to an aggregate of \$93.3 million 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 2022 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 if authorized by the Company, in negotiated transactions or block trades, and (ii) pursuant to a registration statement on Form S-3 filed by the Company with the Securities and Exchange Commission on June 23, 2022 for an offering of up to \$400.0 million 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 2022 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 will pay the Agent a commission of up to 3.0% of the gross proceeds from the sale of the Shares. The Company has also agreed to provide the Agent with customary indemnification rights.

During the three months ended June 30, 2023, and 2022, the Company did not issue or sell any shares under the 2022 Sales Agreement. During the year ended March 31, 2023, pursuant to the 2022 Sales Agreement, the Company issued and sold an aggregate of 340,000 shares of its common stock, resulting in gross proceeds of \$6.7 million, before deducting fees of \$0.3 million. The Company cannot provide any assurances that it will issue any additional Shares pursuant to the 2022 Sales Agreement.

#### ***Equity offerings***

In November 2019, the Company completed a public offering of (a) 4,516,561 shares of the Company's common stock at a public offering price of \$13.61 per share, inclusive of the underwriter's partially exercised 30-day option to purchase an additional 838,530 shares of the Company's common stock, and (b) pre-funded warrants to purchase 2,200,000 shares of the Company's common stock at a public offering price of \$13.6099 per warrant. The Company received aggregate net proceeds of approximately \$85.6 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$5.8 million.

In June 2020, the Company completed a public offering of (a) 3,478,261 shares of the Company's common stock, inclusive of the June 2020 Underwriters fully exercised 30-day option to purchase 652,173 shares of the Company's common stock at a public offering price of \$23.00 per share, and (b) pre-funded warrants to purchase 1,521,738 shares of the Company's common stock at a public offering price of \$22.9999 per warrant. The Company received aggregate net proceeds of approximately \$107.8 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$7.2 million.

In October 2020, the Company completed a public offering of (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, at a public offering price of \$40.00 per share and (b) pre-funded warrants to purchase 1,562,500 shares of the Company's common stock at a public offering price of \$39.9999 per warrant. The Company received aggregate net proceeds of approximately \$270.0 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$17.5 million.

In December 2022, the Company completed a public offering of (a) 6,810,658 shares of the Company's common stock, inclusive of the underwriters 30-day option to purchase up to an additional 1,436,172 shares of the Company's common stock, at a public offering price of \$23.50 per share and (b) pre-funded warrants to purchase 4,200,000 shares of the Company's common stock at a public offering price of \$23.4999 per warrant. The Company received aggregate net proceeds of

approximately \$242.6 million after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$16.1 million.

## 9 Pre-funded Warrants

The pre-funded warrants described above are exercisable at any time after the date of issuance. Unless otherwise modified by a holder of a pre-funded warrant, no holder may exercise a pre-funded warrant if such 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 a pre-funded warrant may increase or decrease this percentage up to 19.99% by providing at least 61 days' prior notice to the Company.

The 7,561,583 shares of the Company's common stock underlying the above described pre-funded warrants, are not included in the number of issued and outstanding shares of the Company's common stock outstanding as reported on the consolidated balance sheet, though they are included in the Company's annual pool increase calculation as well as the weighted average outstanding common stock in the calculation of basic and diluted net loss per share, as noted below in Note 11.

During the three months ended June 30, 2023, a holder of the Company's pre-funded warrants exercised 1,922,655 of its pre-funded warrants and the Company issued 1,922,655 shares of common stock.

## 10 Stock-based compensation

### *Stock-based compensation expense*

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

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Research and development	\$ 3,298	\$ 2,614
Selling, general and administrative	5,548	4,580
	<u>\$ 8,846</u>	<u>\$ 7,194</u>

The following table summarizes stock-based compensation expense by award type for the three months ended June 30, 2023 and 2022:

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Stock options	\$ 5,614	\$ 5,159
Restricted stock units	3,232	2,035
	<u>\$ 8,846</u>	<u>\$ 7,194</u>

### *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 were granted under the 2015 Plan only to the Company's employees, including officers and directors who were also employees. Non-statutory stock options were granted under the 2015 Plan 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 reorganization by Replimune Limited, pursuant to which each shareholder thereof exchanged their outstanding shares in Replimune Limited for shares in Replimune Group, Inc., on a one-for-one basis (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 have been or will be made under the 2015 Plan and any outstanding awards under the 2015 Plan have continued, and 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 were granted under the 2017 Plan only to the Company's employees, including officers and directors who were also employees. Restricted stock awards and non-statutory stock options were granted under the 2017 Plan 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 June 30, 2023. 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 2018 Plan referenced below. 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 filed in connection with 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 of common stock 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 the 2018 Plan. The number of shares reserved for issuance under the 2018 Plan will increase automatically on the first day of each April equal to 4.0% of the total number of shares of common stock outstanding on the last trading day in the immediately preceding fiscal year, which includes for these purposes, the 9,484,238 shares issuable upon exercise of those pre-funded warrants as of March 31, 2023, as described in Note 9 to these consolidated financial statements, or such lesser amount as determined by the Board. On April 1, 2023, the number of shares reserved for issuance under the 2018 Plan automatically increased by 2,646,422 shares pursuant to the terms of the 2018 Plan and based on total number of shares of common stock outstanding on March 31, 2023. On April 1, 2022, the number of shares reserved for issuance under the 2018 Plan automatically increased by 2,104,915 shares pursuant to the terms of the 2018 Plan. As of June 30, 2023, 2,148,050 shares remained available for future grants under the 2018 Plan.

The 2015 Plan, the 2017 Plan and the 2018 Plan are 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 the 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. In 2021 the board of directors initiated the award of restricted stock units ("RSUs"), under the 2018 Plan in addition to stock option awards available as part of the Company's equity incentive for employees, officers, advisors and consultants of the Company. The RSUs typically vest over four approximately equal annual installments with the first such installment occurring on a designated vesting date that is approximately on the one year anniversary of the date of grant and the subsequent installments occurring on the subsequent three annual anniversaries of the designated vesting date.



### ***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 that was filed in connection with the Company's IPO. The total shares of common stock initially reserved for issuance under the ESPP is 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, which includes for these purposes, the 7,561,583 shares issuable upon exercise of those pre-funded warrants described in Note 9 to these consolidated financial statements, 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 with the terms of the ESPP, on April 1, 2023 and 2022, the number of shares reserved for issuance under the ESPP automatically increased by 661,605 and 526,228 shares respectively, for a total of 2,738,208 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.

### ***Out-of-Plan Inducement Grants***

In May 2021, the Company granted an equity award to a newly hired executive as a material inducement to enter into employment with the Company. The grant constitutes an "employment inducement grant" in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules and was issued outside of the 2018 Plan and each of the other stock incentive plans described above. The inducement grant included a nonqualified stock option to purchase up to 125,000 shares of the Company's common stock, as well as a restricted stock unit grant representing 88,333 shares of the Company's common stock. These stock option and restricted stock unit inducement grants have terms and conditions consistent with those set forth under the 2018 Plan and vest under the same respective vesting schedules as stock option and restricted stock unit awards granted under the 2018 Plan. The inducement grant is included in the stock option and RSU award tables below.

In December 2022, the Company granted an equity award to a newly hired executive as a material inducement to enter into employment with the Company. The grant constitutes an "employment inducement grant" in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules and was issued outside of the 2018 Plan and each of the other stock incentive plans described above. The inducement grant included a nonqualified stock option to purchase up to 82,500 shares of the Company's common stock, as well as a restricted stock unit grant representing 55,000 shares of the Company's common stock. These stock option and restricted stock unit inducement grants have terms and conditions consistent with those set forth under the 2018 Plan and vest under the same respective vesting schedules as stock option and restricted stock unit awards granted under the 2018 Plan. The inducement grant is included in the stock option and RSU award tables below.

### ***Stock option valuation***

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

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

	Three Months Ended June 30,	
	2023	2022
Risk-free interest rate	3.60 %	2.59 %
Expected term (in years)	6.0	6.0
Expected volatility	74.1 %	75.6 %
Expected dividend yield	0 %	0 %

### **Stock options**

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of March 31, 2023	7,454,828	\$ 17.24	6.88	\$ 31,244
Granted	1,802,406	\$ 17.94		
Exercised	(96,146)	\$ 12.58		
Cancelled	(93,783)	\$ 24.80		
Outstanding as of June 30, 2023	<u>9,067,305</u>	\$ 17.35	6.94	\$ 69,685
Options exercisable as of June 30, 2023	<u>5,254,968</u>	\$ 15.03	5.77	\$ 52,342
Options vested and expected to vest as of June 30, 2023	<u>9,067,305</u>	\$ 17.35	6.94	\$ 69,685

As of June 30, 2023, there was \$49.6 million of unrecognized compensation cost related to unvested common stock options, which is expected to be recognized over a weighted average period of 2.7 years.

The weighted average grant-date fair value of stock options granted during the three months ended June 30, 2023 and 2022 was \$12.09 and \$12.15, respectively. The aggregate intrinsic value of stock options exercised during the three months ended June 30, 2023 was \$0.5 million.

### **Restricted stock units**

A summary of the changes in the Company's RSUs during the three months ended June 30, 2023 is as follows:

	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Outstanding as of March 31, 2023	1,351,280	24.38
Granted	1,041,856	17.96
Vested	(281,211)	25.36
Cancelled	(42,510)	21.98
Outstanding as of June 30, 2023	<u>2,069,415</u>	<u>21.06</u>

As of June 30, 2023, there was \$40.3 million of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 3.2 years.

## **11 Net loss per share**

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

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Numerator:</b>		
Net loss	\$ (49,555)	\$ (42,253)
<b>Denominator:</b>		
Weighted average common shares outstanding, basic and diluted	66,367,702	54,211,446
Net loss per share, basic and diluted	\$ (0.75)	\$ (0.78)

The 7,561,583 shares of the Company's common stock issuable upon exercise of Pre-Funded Warrants described in Note 9 to these consolidated financial statements are included as outstanding common stock in the calculation of basic and diluted net loss per share.

The Company's potentially dilutive securities, which include stock options and warrants to purchase shares of common stock that resulted from the conversion of warrants to purchase shares of series seed preferred stock existing before the Company's IPO, 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 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 for the periods indicated because including them would have had an anti-dilutive effect:

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Options to purchase common stock	9,067,305	7,511,559
Unvested restricted stock units	2,069,415	1,256,123
Warrants to purchase common stock	497,344	497,344
	11,634,064	9,265,026

## 12 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 (x) in the event of an uncured material breach by the other party, (y) in the event the other party is insolvent or in bankruptcy proceedings or (z) 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.

### *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 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, agreed in June 2018, 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 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 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.

The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain time-based 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.

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 and 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 (ii) in the event of a material breach.

The agreement with Regeneron is accounted for under ASC 808, *Collaborative Arrangements* (“ASC 808”), as both parties are active participants and each party pays its own compound costs and shares equally in development costs in accordance with and up to the amount in the agreed upon first study plan. 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.

In July 2022, Regeneron informed the Company that the costs of the study have reached the initial budget for the initial study plan of June 2018 and that Regeneron’s reimbursement of CERPASS study costs to the Company have completed in the period ending June 30, 2022 in relation to the initial study budget. As a result of this notice from, and the ongoing communications with, Regeneron, we have not recorded any cost-sharing reimbursements from Regeneron in prepaid expenses and other current assets in the consolidated balance sheet or as an offset to research and development expense within the consolidated statement of operations since Regeneron informed us that Regeneron’s reimbursement of CERPASS study costs have completed. The Company does not expect any further reimbursements from Regeneron related to the initial study plan of June 2018.

During the three months ended June 30, 2023 and 2022, the Company did not make any payments to Regeneron under the terms of the agreement. The Company did not record any costs as an offset to research and development expenses during the three months ended June 30, 2023 and 2022. During the three months ended June 30, 2023 and 2022, the Company received payments under the terms of the agreement from Regeneron of \$0.0 million and \$2.0 million, respectively. No receivables from Regeneron were booked in connection with this agreement as of June 30, 2023 or March 31, 2023.

### 13 Commitments and contingencies

#### *Leases*

The table below presents the lease-related costs which are included in the consolidated statements of operations for the three months ended June 30, 2023 and 2022:

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Lease cost</b>		
Finance lease costs:		
Amortization of right-to-use asset	\$ 607	\$ 607
Interest on lease liabilities	544	552
Operating lease costs	280	259
<b>Total lease cost</b>	<b>\$ 1,431</b>	<b>\$ 1,418</b>

The following table summarizes the classification of lease costs in the consolidated statement of operations for the three months ended June 30, 2023 and 2022 as follows:

	<b>Three Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Finance Lease Costs</b>		
Research and development	\$ 607	\$ 518
Selling, general and administrative	—	89
Other income (expense)	544	552
<b>Operating Lease Costs</b>		
Research and development	229	110
Selling, general and administrative	51	149
<b>Total lease cost</b>	<b>\$ 1,431</b>	<b>\$ 1,418</b>

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 its balance sheet as of June 30, 2023:

	<b>June 30, 2023</b>		
	<b>Operating leases</b>	<b>Financing lease</b>	<b>Total</b>
2024 (remaining nine months)	\$ 848	\$ 1,990	\$ 2,838
2025	1,170	2,718	3,888
2026	1,179	2,799	3,978
2027	1,144	2,883	4,027
2028	1,093	2,969	4,062
Thereafter	1,943	35,054	36,997
<b>Total lease payments</b>	<b>7,377</b>	<b>48,413</b>	<b>55,790</b>
Less: interest	1,943	21,913	23,856
<b>Total lease liabilities</b>	<b>\$ 5,434</b>	<b>\$ 26,500</b>	<b>\$ 31,934</b>

The following table provides lease disclosure as of June 30, 2023 and March 31, 2023:

	June 30, 2023	March 31, 2023
<b>Leases</b>		
Right-to-use operating lease asset	\$ 5,137	\$ 5,208
Right-to-use finance lease asset	39,058	39,665
Total lease assets	<u>\$ 44,195</u>	<u>\$ 44,873</u>
Operating lease liabilities, current	\$ 1,139	\$ 1,118
Finance lease liabilities, current	2,658	2,639
Operating lease liabilities, non-current	4,295	4,389
Finance lease liabilities, non-current	23,842	23,965
Total lease liabilities	<u>\$ 31,934</u>	<u>\$ 32,111</u>

The following table provides lease disclosure for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,	
	2023	2022
<b>Other information</b>		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 263	\$ 261
Operating cash flows from finance leases	\$ 544	\$ 552
Financing cash flows from finance leases	\$ 104	\$ 77
Right-to-use asset obtained in exchange for new operating lease liabilities	\$ —	\$ —
Weighted-average remaining lease term - operating leases	6.3	7.6
	years	years
Weighted-average remaining lease term - financing leases	16.1	17.3
	years	years
Weighted-average discount rate - operating leases	10.3 %	10.0 %
Weighted-average discount rate - financing leases	8.3 %	8.3 %

The variable lease costs and short-term lease costs were insignificant for the three months ended June 30, 2023 and 2022.

#### ***Manufacturing commitments***

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of June 30, 2023 and March 31, 2023, the Company had committed to minimum payments under these arrangements totaling \$0.9 million and \$1.0 million, respectively.

#### ***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 June 30, 2023 or March 31, 2023.

#### ***Legal proceedings***

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

#### 14 Income taxes

During the three months ended June 30, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses incurred in the United Kingdom in each period due to its uncertainty of realizing a benefit from those items. During the three months ended June 30, 2023, the Company recorded a tax expense of \$0.2 million primarily related to the Company's interest income in the United States, partially offset by discrete share-based compensation items.

The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate ("AETR"), adjusted for the effect of discrete items arising in that quarter. The impact of such inclusions could result in a higher or lower effective tax rate during a particular quarter, based upon the mix and timing of actual earnings or losses versus annual projections. In each quarter, the Company updates its estimate of the annual effective tax rate, and if the estimated annual tax rate changes, a cumulative adjustment is made in that quarter. For the three months ended June 30, 2023 and 2022, the Company excluded the United Kingdom from the calculation of the AETR as the Company anticipates an ordinary loss in this jurisdiction for which no tax benefit can be recognized.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets both in the United States and United Kingdom, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of June 30, 2023 and March 31, 2023, the Company has recorded a full valuation allowance against its net deferred tax assets.

#### 15 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:

	<b>June 30, 2023</b>	<b>March 31, 2023</b>
United States	\$ 5,835	\$ 5,836
United Kingdom	1,781	1,643
	<u>\$ 7,616</u>	<u>\$ 7,479</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, 2023, included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2023.

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 Securities Exchange Commission, or 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 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 through our novel tumor-directed oncolytic immunotherapies. Our proprietary tumor-directed oncolytic immunotherapy product candidates are designed and 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 other approaches to inducing anti-tumor immunity, including personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will increase clinical efficacy and 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.

Our proprietary RPx platform is based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a dual local and systemic mechanism of action, or MOA, consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor-derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform is expected to have the versatility to be developed alone or combined with a variety of other treatment options. We currently have three RPx product candidates in our development pipeline, RP1 (vusolimogene oderparepvec), our lead product candidate, RP2 and RP3. Although our fiscal year ends March 31<sup>st</sup>, our programs and program updates are reported on a calendar year basis.

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 establishing a major skin cancer franchise. We have completed enrolling patients in a randomized, controlled Phase-2 clinical trial of RP1 with cutaneous squamous cell carcinoma, or CSCC, RP1's lead indication, which is referred to herein as CERPASS or the CERPASS trial, under an agreement with our partner Regeneron Pharmaceuticals, Inc.,



or Regeneron. CERPASS is a registration directed clinical trial evaluating RP1 in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, versus cemiplimab alone. Regeneron has granted to us a non-exclusive royalty-free license to cemiplimab for use in this trial, is supplying cemiplimab at no cost and funded one-half of the clinical trial costs up to the amount agreed in the first study plan. CERPASS enrolled 211 patients with locally advanced or metastatic CSCC who are naïve to anti-PD1 therapy. An additional 20 patients were also dosed with RP1 made at our in-house manufacturing facility. The CERPASS protocol evaluates complete response, or CR rate, and overall response rate, or ORR, as its two independent primary efficacy endpoints as assessed by independent review, as well as duration of response, progression-free survival, or PFS, and overall survival, or OS, as secondary endpoints. As previously reported, we met with the FDA in the first quarter and discussed the rationale for the changes to the study design we made in 2020 reducing the study size from 240 to 180 patients and adding CR as a dual independent primary endpoint (the study subsequently over enrolled with 211 patients randomized, as reported in November 2022). No changes were made to the protocol as a result of the meeting. Topline data from the CERPASS trial is now expected to be announced in early Q4 2023, updated from Q3 2023, as a result of the independent review read rate tracking behind projections. Assuming positive primary analysis data is generated, including demonstrating overall clinical benefit, we continue to expect to make a Biologics License Application submission for RP1 in Q1/Q2 2024, with the potential to combine the filings for both the CERPASS clinical trial and the IGNUYTE anti-PD-1 failed melanoma cohort.

We continue our collaboration with Bristol Myers Squibb Company, or BMS, under which BMS 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 which is referred to herein as IGNUYTE, or the IGNUYTE trial. The leading tumor specific cohort in the IGNUYTE trial is our registration directed Phase 2 expansion cohort enrolling 125 patients with anti-PD-1 failed cutaneous melanoma who are being treated with RP1 in combination with nivolumab. We are also continuing enrollment into the cohorts of patients with anti-PD-1 failed non-melanoma skin cancers, or NMSC, which includes patients with both naïve and anti-PD-1 failed disease, including CSCC.

We initiated the registration directed Phase 2 expansion cohort in the IGNUYTE trial enrolling 125 patients with anti-PD-1 failed cutaneous melanoma after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma, which demonstrated the tolerability and clinical activity of the combination of RP1 and nivolumab in patients with melanoma, including those who had failed prior anti-PD-1 when given alone or in combination with CTLA-4 blockade. In March 2021, we held a Type B meeting with the FDA to discuss the design of the 125 patient expansion cohort in the IGNUYTE trial. In this meeting, the FDA expressed that while a randomized controlled clinical trial would always be preferred for registration purpose, that in this patient population with no clear standard of care, if the clinical data is sufficiently compelling then the data could be considered for submission by the FDA under the accelerated approval pathway. The FDA also indicated that a randomized confirmatory trial would also be needed as is required under the accelerated approval pathway. The design of the confirmatory trial is intended to be discussed with the FDA prior to a BLA submission. In December 2022, we reported data from the first 75 patients with at least six months follow-up. The data snapshot based on investigator response showed a 20% CR rate and a 36% ORR with activity across all disease stages and strong durability. In January 2023, we completed target enrollment of 125 patients with patients in screening at that time continuing to be enrolled. We completed enrollment in this cohort in March 2023, ultimately enrolling 141 patients. In June 2023, further updated data from the initial 75 patients was presented at the American Society of Clinical Oncology, or ASCO, showing RP1 combined with nivolumab continued to demonstrate deep and durable responses with a well-tolerated safety profile and no progression in responding patients since the prior data snapshot. The updated data also showed overall response rate (ORR) of 37.4%, with clinically meaningful activity across the range of anti-PD1 failed cutaneous melanoma settings enrolled, including in patients with moderate-high tumor burden and visceral disease. We remain on track to announce snapshot data for all patients (N=141) in Q4 2023 by which point all patients will have had at least 6 months follow up. The data snapshot for all 141 patients with a minimum of 6 months follow-up will be evaluated for the potential to align a dual launch with CERPASS, assuming both indications for RP1 are timely approved, however, the per protocol primary analysis continues to be expected 12 months after enrollment of the last patient, March 2024.

In NMSC, enrollment in the anti-PD-1 naïve NMSC cohort has completed, included patients with cutaneous squamous cell carcinoma, or CSCC, basal cell carcinoma, or BCC, merkel cell carcinoma, or MCC, and angiosarcoma. Updated data from the CSCC patients in the anti-PD-1 naïve NMSC cohort, presented in March 2022, continued to show nearly half of the patients achieving a complete response and nearly 65% achieving a complete or partial response. We are currently enrolling an extension of the NMSC cohort of RP1 in combination with nivolumab in NMSC patients who have failed prior treatment with anti-PD(L)-1. In March 2022, we reported initial data (N=12) from this extension cohort where responses had been observed in anti-PD(L)-1 failed CSCC, MCC and angiosarcoma tumors. We believe the activity of RP1 combined with nivolumab in this anti-PD(L)-1 failed cohort represents a new potential therapeutic option for these patients and supports the broad potential for RP1 in anti-PD(L)-1 failed skin cancers beyond melanoma. Recruitment remains ongoing, with a data update expected from the first 30 patients with at least 6 months follow up in early Q4 2023.

We also have open for enrollment a Phase 1b/2 clinical trial of single agent RP1 in solid organ transplant recipients with skin cancers, including CSCC, which is referred to herein as ARTACUS or the ARTACUS trial, 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 up to 65 patients in the ARTACUS trial to assess the safety and efficacy of RP1 in liver, kidney, heart, lung, and hematopoietic cell transplant patients transplant recipients with skin cancers. Enrollment in this clinical trial had been impacted by COVID-19, as the patient population is severely immune-compromised and considered very high risk, however, more recently we have seen enrollment increase in the ARTACUS trial. As reported at the American Transplant Congress (ATC) Meeting in June 2023, the data demonstrated an ORR of 27.3%, with all responders achieving confirmed CR. RP1 monotherapy was well tolerated in these patients and the safety profile was similar to that observed in our other RP1 clinical trials in patients who are not immune suppressed. No immune-mediated adverse events or evidence of allograft rejection were observed.

In addition to these ongoing trials with RP1, we are currently evaluating all strategic opportunities for RP1 in skin cancers, including the setting for the confirmatory clinical trial in melanoma which is expected to be required to support a potential accelerated approval of RP1 in anti-PD1 failed melanoma.

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, including traditionally less immune responsive tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF as in RP1, 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 has been engineered with the intent to further stimulate an anti-tumor immune response through activation of immune co-stimulatory pathways through the additional expression of the ligands for CD40 and 4-1BBL, as well as anti-CTLA-4 and GALV-GP R(-), but without the expression of GM-CSF.

We initiated a Phase-1 clinical trial of RP2 alone and in combination with nivolumab in the second half of 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 have presented data from the single agent RP2 portion of this clinical trial that showed deep and durable responses, including demonstration of tumor response in uninjected lesions and in patients with difficult to treat advanced cancers. We believe that 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. We have also presented combination data from both the clinical trial that showed compelling activity in patients with immune insensitive tumors and with anti-PD-1 failed disease. In the second half of 2021, we reported full enrollment in the initial 30 patient combination with nivolumab part of the Phase 1 clinical trial following which a protocol amendment was made to expand this clinical trial to enroll additional patients who are required to have specific tumor types of interest, including gastro-intestinal cancers, breast cancer, lung cancer, head and neck cancer and uveal melanoma, rather than any type of tumor as were eligible for the initial 30 patient group. In December 2022, we reported that of 14 patients with uveal melanoma for which sufficient follow-up was available for assessment, 4 patients had achieved a response. More recently, at ASCO in June 2023, we reported 17 patients have received RP2 as monotherapy (N=3) or in combination with nivolumab (N=14), completing enrollment of uveal melanoma patients in the Phase 1b trial. Four of the 14 evaluable patients had responded to treatment (28.6%), including metastatic tumors in the liver and bone. The final three of 17 patients remained on treatment, but had insufficient follow-up data to determine response outcome as of the cut-off date. Three of the four responses are ongoing at 9, 12 and 21 months, including for patients with liver and bone metastases, with the fourth patient having progressed at 15 months.

Enrollment continues in our clinical trial designed to evaluate RP3 alone and combined with anti-PD-1 therapy in advanced solid tumor patients, focusing on enrolling patients with gastro-intestinal cancers, breast cancer, lung cancer and head and neck cancer. In December 2022, the Company presented data from its Phase 1 trial of RP3 in combination with nivolumab (N=5) in patients with multiple soft tissue sarcomas including in leiomyosarcoma, osteosarcoma, chondrosarcoma, and epithelioid sarcomas who have all failed standard of care. At the data cut-off date, 3 of 5 patients had sufficient follow-up for response assessment, and all three were responding to therapy in settings with no viable alternative treatment option, indicating the potential utility of RP3 in treating this difficult to treat tumor type.

Enrollment in the Phase 1 programs with both RP2 and RP3 are expected to materially complete in Q3 2023. Any additional Phase 2 development programs not already announced which are driven by data from the full Phase 1 data and other opportunistic considerations are expected to be disclosed by year-end 2023.

We continue to plan for, and are initiating, our previously announced Phase 2 development program for RP2 and/or RP3. As previously announced, our initial signal finding single arm Phase 2 clinical trials are planned in the following tumor types: squamous cell carcinoma of the head and neck, or SCCHN, locally advanced and recurrent/metastatic; hepatocellular carcinoma, or HCC, both first and second line; and colorectal cancer, or CRC, third line; with additional studies in other tumor types intended to follow. As we announced in December 2022, our signal finding studies in HCC and CRC are being developed in combination with atezolizumab and bevacizumab under a supply and cost share clinical collaboration arrangement with Roche Holding AG, or Roche. Our signal finding studies in SCCHN are being developed in combination with nivolumab under our collaboration agreement with BMS.

- In CRC, we have initiated the clinical trial investigating two signal finding cohorts of 30 patients each in collaboration with Roche. The first cohort will enroll 3L patients to be treated with atezolizumab combined with

bevacizumab and RP2 and the second cohort with atezolizumab and bevacizumab and RP3. We believe that data with both RP2 and RP3 in CRC will allow the comparative efficacy of RP2 and RP3 to be evaluated in a particularly difficult to treat patient population.

– In HCC, two signal finding cohorts of 30 patients each will be enrolled in collaboration with Roche. The first cohort will enroll 1L patients treated with SOC atezolizumab combined with bevacizumab and RP3, and the second cohort will enroll patients who have progressed on 1L immunotherapy (including atezolizumab/bevacizumab), and will be treated with atezolizumab combined with bevacizumab and RP3. This clinical trial is expected to initiate this quarter.

– In SCCHN, the trial will be conducted under our collaboration with BMS. This study is intended to include two cohorts of patients, the first with locally advanced disease is planned to enroll approximately 100 patients randomized 1:1 to either SOC chemotherapy combined with radiation, or SOC combined with RP3 followed by adjuvant nivolumab therapy. The second, signal finding cohort, will enroll 30 patients with recurrent or metastatic SCCHN with low PD-L1 levels (CPS<20) who will be treated with chemotherapy, nivolumab and RP3. Due to the global shortage of cisplatin and carboplatin, initiation of this study is currently on hold until sufficient supplies of these agents are available.

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 proprietary RPx 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 incurred significant operating losses and 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. 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. 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 20, 2018, we have raised an aggregate of approximately \$849.1 million in net proceeds to fund our operations, of which \$101.2 million was from our IPO, \$706.0 million was from four separate follow-on offerings, or the Public Offerings, that we closed in November 2019, June 2020, October 2020 and December 2022, respectively, and \$41.9 million was from at-the-market offerings. We sold 7,407,936 shares of common stock in our IPO, an aggregate of 20,430,480 shares of our common stock and pre-funded warrants to purchase 9,484,238 shares of common stock in the Public Offerings, and 2,313,997 shares of common stock through our at-the-market facilities.

Our net losses were \$49.6 million and \$42.3 million for the three months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of \$535.0 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 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, protect and defend our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and general and administration personnel;
- acquire or in-license other drugs, technologies or intellectual property rights; 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.

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

As of June 30, 2023, we had cash and cash equivalents and short-term investments of \$539.1 million. Based on our current operating plan, 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.”

## **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 engaged in research and development functions, including their fees, stock-based compensation and related travel expenses;

- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs related to compliance with regulatory requirements in connection with the development of our product candidates; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

These costs may be partially offset by cost-sharing arrangements under collaboration agreements that we may enter from time to time.

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 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. Non-employee costs associated with our manufacturing facility including depreciation, amortization and facility costs are appropriately allocated to development programs based on the percentage of time spent per program.

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 as 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 our 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 maintain, expand, protect and defend 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 could 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.

#### ***Selling, general and administrative expenses***

Selling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate, commercial and business development and administrative functions. Selling, general and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, pre-commercial planning, 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 selling, general and administrative expenses will continue to increase in the future as we increase our selling, general and administrative headcount to support our continued research and development and pre-launch activities to prepare for 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 10% 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 debt obligations*

Interest expense on debt obligations consists of the amortization of debt discount and cash paid for interest under the loan agreement with Hercules.

##### *Interest expense on finance lease liability*

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

##### *Other income (expense), net*

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

## Income taxes

During the three months ended June 30, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses incurred in the United Kingdom in each period due to its uncertainty of realizing a benefit from those items. During the three months ended June 30, 2023, the Company recorded a tax expense of \$0.2 million primarily related to the Company's interest income in the United States, partially offset by discrete share-based compensation items.

The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate ("AETR"), adjusted for the effect of discrete items arising in that quarter. The impact of such inclusions could result in a higher or lower effective tax rate during a particular quarter, based upon the mix and timing of actual earnings or losses versus annual projections. In each quarter, the Company updates its estimate of the annual effective tax rate, and if the estimated annual tax rate changes, a cumulative adjustment is made in that quarter. For the three months ended June 30, 2023 and 2022, the Company excluded the United Kingdom from the calculation of the AETR as the Company anticipates an ordinary loss in this jurisdiction for which no tax benefit can be recognized.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets both in the United States and United Kingdom, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of June 30, 2023 and March 31, 2023, the Company has recorded a full valuation allowance against its net deferred tax assets.

## Results of operations

### Comparison of the three months ended June 30, 2023 and 2022

The following chart summarizes our results of operations for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		
	2023	2022	Change
(Amounts in thousands)			
Operating expenses:			
Research and development	\$ 40,437	\$ 29,478	\$ 10,959
Selling, general and administrative	15,211	11,398	3,813
Total operating expenses	55,648	40,876	14,772
Loss from operations	(55,648)	(40,876)	(14,772)
Other income (expense):			
Research and development incentives	393	851	(458)
Investment income	6,186	343	5,843
Interest expense on finance lease liability	(544)	(552)	8
Interest expense on debt obligations	(1,115)	—	(1,115)
Other income (expense)	1,374	(2,019)	3,393
Total other income (expense), net	6,294	(1,377)	7,671
Loss before income taxes	\$ (49,354)	\$ (42,253)	\$ (7,101)
Income tax provision	\$ 201	\$ —	\$ 201
Net loss	\$ (49,555)	\$ (42,253)	\$ (7,302)

### Research and development expenses

Research and development expenses for the three months ended June 30, 2023 were \$40.4 million, compared to \$29.5 million for the three months ended June 30, 2022. The following table summarizes our research and development expenses for the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30,		
	2023	2022	Change
Direct research and development expenses by program:			
RP1	12,296	5,962	6,334
RP2	1,286	1,868	(582)
RP3	3,940	5,008	(1,068)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	18,026	12,505	5,521
Other	4,889	4,135	754
Total research and development expenses	<u>\$ 40,437</u>	<u>\$ 29,478</u>	<u>\$ 10,959</u>

The increase in RP1 is primarily the result of an increase in our number of clinical trial sites and patient enrollment as compared to the prior year, and a reduction of \$1.1 million of costs sharing in the CERPASS trial from Regeneron during the current period as discussed in Note 12 to the consolidated financial statements appearing elsewhere in this Quarterly Report. Additionally, during the quarter, the Company focused on RP1 drug substance batches and saw increased clinical development expenses, including primarily data management costs, CRO costs and investigator costs, related to preparation of primary data release and a potential BLA filing.

In addition, the changes in our direct research and development expenses between our product candidates is primarily associated with process development, qualification and comparability of our in-house manufactured materials compared to our third-party manufactured materials in readiness for utilizing our product candidates made at our in-house manufacturing facility in our clinical development programs and preparation for potential commercial manufacture, if approved.

The increase of \$6.3 million in our unallocated expenses was due to a \$5.5 million increase in personnel-related costs and \$0.8 million increase in other expenses. The increase in personnel-related costs included a \$4.8 million increase in payroll and fringe benefits and a stock-based compensation increase of \$0.7 million. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions as we continue to expand the development plan in multiple indications. Personnel related costs for the three months ended June 30, 2023 and 2022 included stock-based compensation expense of \$3.3 million and \$2.6 million, respectively. Furthermore, the change in other expenses is primarily driven by an increase of approximately \$0.3 million in consulting costs across our platform and a \$0.3 million increase in medical affairs costs.

#### *Selling, general and administrative expenses*

Selling, general and administrative expenses were \$15.2 million for the three months ended June 30, 2023, compared to \$11.4 million for the three months ended June 30, 2022. The increase of \$3.8 million is primarily the result of an increase of \$2.8 million in personnel related costs, including a stock-based compensation increase of \$1.0 million, and an increase of \$1.8 million in payroll and fringe benefits. The increase in personnel related costs was driven by the continued hiring of additional personnel in our selling, general and administrative functions, focusing on additional pre-launch planning and initial build of the Company's commercial infrastructure. Additionally, there is an increase of \$1.3 million in other variable costs which is driven by approximately \$0.9 million in external spend increases in building and preparation for sales and marketing programs, and market research.

#### *Total other income (expense), net*

Other net income was \$6.3 million for the three months ended June 30, 2023, compared to a net expense of \$1.4 million for the three months ended June 30, 2022. The net change of \$7.7 million is primarily attributable to an increase in investment income of \$5.8 million as a result of higher interest rates during the quarter, as well as a decrease in expense of \$3.4 million in the current year compared to the prior year due to exchange rate fluctuations related to the changes in foreign exchange rates of the British Pound Sterling to the United States Dollar, specifically on intercompany and other non-functional currency transactions. This income is partially offset by an increase in interest expense of approximately \$1.1 million on debt obligations related to the Hercules Loan Agreement which we did not incur in the prior year.

#### *Income tax provision*



Income tax provision for the three months ended June 30, 2023 was \$0.2 million compared to \$0.0 million for the three months ended June 30, 2022. The income tax provision is primarily attributable to related to the Company's interest income in the United States, partially offset by discrete share-based compensation items.

### 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 borrowing under a secured loan facility. Through June 30, 2023, we had received net proceeds of \$935.9 million through the sale of shares of common stock and warrants exercisable for common stock in public offerings and at-the-market offerings, as well as net \$27.8 million from our incurrence of debt under the term loan agreement with Hercules. As of June 30, 2023, we had cash and cash equivalents and short-term investments of \$539.1 million.

#### Cash flows

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

	Three Months Ended June 30, 2023	
	2023	2022
	(Amounts in thousands)	
Net cash used in operating activities	\$ (48,588)	\$ (33,455)
Net cash used in investing activities	7,361	5,315
Net cash provided by financing activities	1,105	32,522
Effect of exchange rate changes on cash and cash equivalents	13	1,915
Net decrease in cash and cash equivalents	\$ (40,109)	\$ 6,297

#### Operating activities

During the three months ended June 30, 2023, net cash used in operating activities was \$48.6 million, primarily resulting from our net loss of \$49.6 million, partially offset by non-cash charges of \$4.3 million, which primarily consist of stock-based compensation expense of \$8.8 million, and a decrease in cash of \$3.4 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the three months ended June 30, 2023 consisted primarily of a \$1.2 million decrease in accrued expenses and other current liabilities, a \$1.6 million decrease in prepaid expenses and other current assets, a net \$0.6 million change in operating and financing right-of-use assets and lease liabilities, a \$0.8 million decrease in accounts payable, and a \$0.4 million decrease in research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures.

During the three months ended June 30, 2022, net cash used in operating activities was \$33.5 million, primarily resulting from our net loss of \$42.3 million, partially offset by non-cash charges of \$8.1 million, primarily consisting of stock-based compensation expense of \$7.2 million, and an increase in cash of \$0.7 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the three months ended June 30, 2022 consisted primarily of a \$1.1 million decrease in accrued expenses and other current liabilities, a \$0.9 million increase in accounts payable, a \$0.9 million decrease in research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures, a net \$0.6 million change in operating and financing right-of-use assets and lease liabilities, and as well as a \$1.2 million increase in prepaid expenses and other current assets.

#### Investing activities

During the three months ended June 30, 2023, net cash provided by investing activities was \$7.4 million, consisting of \$177.1 million in proceeds from sales and maturities of short-term investments, partially offset by \$169.3 million in purchases of available for sale securities, and \$0.4 million in purchases of property, plant and equipment.

During the Three Months Ended June 30, 2022, net cash provided by investing activities was \$5.3 million, consisting of \$67.0 million in proceeds from sales and maturities of short-term investments, partially offset by \$60.6 million in purchases of available for sale securities and \$1.1 million in purchases of property, plant and equipment.

#### *Financing Activities*

During the three months ended June 30, 2023, net cash provided by financing activities was \$1.1 million, consisting primarily of \$1.2 million in proceeds from the exercise of stock options.

During the Three Months Ended June 30, 2022, net cash provided by financing activities was \$32.5 million, consisting of primarily \$31.0 million from the issuance of common stock through ATM sales, as well as approximately \$1.6 million in proceeds from the exercise of stock options.

#### **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 RPx platform;
- operate, qualify and maintain our in-house manufacturing facility and qualify and maintain our product candidates made therein for use in our clinical trials;
- 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, protect and defend our intellectual property portfolio;
- hire and retain additional clinical, quality control, scientific and general and administration personnel;
- acquire or in-license other drugs, technologies or third-party intellectual property; 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 June 30, 2023, we had cash and cash equivalents and short-term investments of \$539.1 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of June 30, 2023, will enable us to fund operations into the second half of 2025. 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 three months ended June 30, 2023, 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, 2023, which was filed with the SEC on May 18, 2023.

### **Collaborations**

#### *BMS*

In February 2018, we entered into a Clinical Trial Collaboration and Supply Agreement with 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 (x) in the event of an uncured material breach by the other party, (y) in the event the other party is insolvent or in bankruptcy proceedings or (z) 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.

In April 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*

In May 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with 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, agreed in June 2018, 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 an agreed study plan will be split equally. In July 2022, Regeneron informed the Company that the costs of the study have reached the initial budget for the initial study plan of June 2018 and that Regeneron's reimbursement of CERPASS study costs to the Company have completed in the period ending June 30, 2022 in relation to the initial study budget. As a result of this notice from, and the ongoing communications with, Regeneron, we have not recorded any cost-sharing reimbursements from Regeneron in prepaid expenses and other current assets in the consolidated balance sheet or as an offset to research and development expense within the consolidated statement of operations since Regeneron informed us that Regeneron's reimbursement of CERPASS study costs have completed. The Company does not expect any further reimbursements from Regeneron related to the initial study plan of June 2018. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain time-based 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.

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 and 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 (ii) in the event of a material breach.

#### *Roche*

In December 2022, we announced entering into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to our RP2 and RP3 programs in colorectal cancer, or CRC, and hepatocellular carcinoma, or HCC. Under the agreement, the companies will collaborate in 30 patient cohort signal finding studies in third-line, or 3L, CRC and in first- and second-line, or 1L and 2L, respectively, HCC. Under the terms of the agreement, the companies will share costs and Roche will supply its currently approved drugs, atezolizumab and bevacizumab for 2L HCC and 3L CRC combined with RP3. Roche will also supply atezolizumab and bevacizumab for 1L HCC combined with RP3, and for 3L CRC combined with RP2. We have retained the responsibility of operating the clinical trials as well as retaining all the rights to the development and commercialization of our product candidates. The agreement may be terminated by either party upon sixty (60) days prior written notice to the other party.

#### *Incyte*

In July 2023, we entered into a Clinical Trial Collaboration and Supply Agreement with Incyte Corporation, or Incyte. Under the agreement, the companies will collaborate in a signal finding study in which Incyte will initiate and sponsor a clinical trial of INCB99280 (oral PD-L1 inhibitor) and RP1 in approximately 40 patients with unresectable, high risk CSCC in the neoadjuvant setting. Under the terms of the agreement, Replimune will supply Incyte with RP1 for the study and share costs of the study equally with Incyte. The agreement may be terminated by either party upon (i) a material breach not reasonably cured within thirty (30) days; (ii) by Replimune upon the inappropriate or unsafe use of the RP1 product candidate; (iii) the discontinuation of development of its clinical drug candidate; (iv) the unethical or illegal business practices of the other party; or (v) if the parties have not agreed on the protocol or budget within ninety (90) days of the effective date of the agreement.

### **Critical accounting policies 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 issue stock-based awards to employees, directors, consultants and non-employees in the form of stock options and restricted stock units. We measure such stock-based awards in accordance with ASC 718, Compensation — Stock Compensation, which requires all stock-based awards to be recognized in the consolidated statements of operations and comprehensive loss based on their fair value on the date of the grant and the related compensation expense for those awards is recognized 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 10 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.

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.

### **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. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2023. Based on this evaluation, our Chief Executive Officer and Chief Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2023.

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.

#### **Changes in internal control over financial reporting**

There have been no changes in our internal control over financial reporting for the three months ended June 30, 2023 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 product candidates;
- our ability to develop and advance any future product candidates based on our novel proprietary RPx 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 or the market acceptance of our product candidates if approved for commercial use;
- our ability to compete with other biopharmaceutical companies, 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 including clinical or commercial developments that may be attributed to our product candidates;
- 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 or alleged violation of any third-party intellectual property rights;
- our ability to successfully complete transfer of our product manufacturing to our in-house manufacturing facility from our contract manufacturers including comparability analysis and to qualify, obtain approval for, and maintain successful operation, approval and qualification of our in-house manufacturing operations;
- our ability to obtain and maintain sufficient quantities of raw material supplies to build or maintain our product candidate supplies or otherwise operate our in-house manufacturing facility;

- our ability to obtain and maintain sufficient quantities of materials and supplies to conduct our clinical trials, such as comparative, control and/or standard of care therapies including chemotherapeutic agents that are currently in short supply in the industry;
- the costs of operating our in-house manufacturing facility and our reliance on third-party collaborators and clinical trial service providers, which may be single or of limited source;
- 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, including potential material supplies and supply chain disruptions, hiring and retaining talent, and global or national economic impacts such as inflation; and
- the ongoing military conflict between Russia and Ukraine and the impact on the global economy and related governmental imposed sanctions and potential material supplies and supply chain disruptions and global or national economic impacts such as inflation.

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

***We 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 in manufacturing facilities or the manufacturing process for our product candidates may impact how our product candidates perform in clinical trials;
- 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, especially in light of the upcoming reauthorization of the Prescription Drug User Fee Act;
- 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 or we may not be able to obtain them on favorable terms due to reasons such as international trade policies and supply chain disruptions;
- 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. By example, the FDA may determine that larger trials, Phase 3 trials, randomized and controlled clinical trials, or clinical trials designed to replicate results found in our registrational or pivotal trials are required before we may file a BLA or before the FDA will approve a marketing application;

- 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, testing, comparability or quality processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates, including our registration directed or registration intended trials, 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 may decide that our intended pathways, including accelerated approval, are not appropriate for our product candidates, requiring that we conduct additional studies. By example, in recent years the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, depending on the results of our studies, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed. Even if accelerated approval is granted, payors, including governmental payors, may be less willing to provide sufficient reimbursement for products approved via accelerated approval;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates or necessary inspections before an approval can be issued may be delayed;
- 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.

***Topline data may not accurately reflect the complete results of a particular study or trial.***

We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data which are based on preliminary analysis of key efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or drug and our company in general. In addition, the information we may publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from a future analysis of results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be 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 ongoing IGRYTE Phase 1/2 trials with RP1, our Phase 1/2 clinical trial with RP2 and our Phase 1 and Phase 2 clinical trials with RP3 where we decide to use nivolumab. 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 using cemiplimab in the CERPASS trial, our first planned clinical trial under the Regeneron agreement. 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 our 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-PD(L)-1 therapies, and may develop RP1 or our other product candidates for use with other therapies. Although we intend our IGNYTE anti-PD-1 failed melanoma cohort and our CERPASS trial to be registration directed, 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, interrupted or halted. In the event we are unable to source a supply of an acceptable 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.

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

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our RPx platform. Our ability to generate any revenues from the sale of our product candidates will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates using our RPx platform. Since all of the product candidates in our current pipeline are based on our proprietary RPx platform, if any of our product candidates fail in development as a result of any underlying problem with our proprietary RPx 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.

***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. For example, in February 2023, we received a response from the FDA following submission of our draft statistical analysis plan in September 2022, which raised a number of points and recommendations requiring further discussion. As previously reported, we met with the FDA in the first quarter of 2023 and discussed the rationale for the changes to the study design we made in 2020 reducing the study size from 240 to 180 patients and adding CR as a dual independent primary endpoint (the study subsequently over enrolled with 211 patients randomized, as reported in November 2022). While no changes were made to the protocol as a result of the meeting, the FDA reiterated that the data would need to demonstrate an overall clinically meaningful benefit based on the totality of the data. 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, facilities, equipment 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.

***We conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We currently conduct clinical trials outside the United States. The acceptance by the FDA or comparable foreign regulatory authority of study data from clinical trials conducted outside the United States or another jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

***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, with the full departure of the United Kingdom from the European Union in January 2021, commonly referred to as Brexit, there is continuing regulatory uncertainty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, and the degree to which the United Kingdom and European Union regulatory regimes align or diverge could materially impact the execution of our clinical trials or 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;
- 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 or alleged violation of any third-party intellectual property rights;
- 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, other third-party payors coverage decisions or third-party intellectual property rights that another may allege are violated by our product candidates.

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;
- third-party intellectual property rights that another may allege are violated by our product candidates;
- 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 proprietary RPx 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 manufacturing operations and 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 successful commercialization of our product candidates, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.***

Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly-approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business and reduce our revenue.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. For example, the Inflation Reduction Act of 2022, or IRA, includes several measures intended to lower the cost of prescription drugs and related healthcare reforms, including limits on price increases and subjecting an escalating number of drugs to annual price negotiations with CMS. We cannot be sure whether additional legislation related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

If future reimbursement for approved product candidates, if any, is substantially less than we project, or rebate obligations associated with them are substantially greater than we expect, our future net revenue and profitability could be materially diminished.

***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 proprietary RPx platform, including our lead product candidate, RP1, and our other product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable and have incurred losses in each period since our inception. For the three months ended June 30, 2023 and 2022, we reported a net loss of \$49.6 million and \$42.3 million, respectively. At June 30, 2023, we had an accumulated deficit of \$535.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek 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 or our other product candidates, 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.

***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. At June 30, 2023, our cash and cash equivalents and short-term investments were \$539.1 million. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain 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 current operating plan, we expect that our existing cash and cash equivalents and short-term investments, as of June 30, 2023 will enable us to fund operations into the second half of calendar 2025. 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.

***We maintain our cash at financial institutions, often in balances that exceed federally insured limits.***

Our cash, cash equivalents and short-term investments are held in accounts with banking institutions. The balances of some of these accounts have in the past, and may in the future, exceed the Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. In March 2023, the FDIC took control of Silicon Valley Bank (“SVB”), where we previously held a portion of our cash. The Federal Reserve subsequently announced that account holders would be made whole and we were able to access all of our cash held at SVB. However, the FDIC may not make all account holders whole in the event of future bank failures. In addition, even if account holders are ultimately made whole with respect to a future bank failure, account holders’ access to their accounts and assets held in their accounts may be substantially delayed. Any material loss that we may experience in the future or inability for a material time period to access our cash, short-term investments and cash equivalents could have an adverse effect on our ability to pay our operational expenses, fund our operations or make other payments, which could adversely affect our business.

#### **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, proprietary RPx platform, including our lead product candidate, 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 have been and 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. In addition, defending against challenges in respect of the inventorship, scope, validity or enforceability of our patents may be expensive, time consuming, difficult and in some cases may not be possible. 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 or other administrative procedures 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. For example, we are aware of U.S. Patent 10,034,938 (the '938 Patent) held by Amgen Inc., which includes claims purported to cover methods and kits for treating stage IIIb to IV melanoma by the administration of (i) an effective amount of an anti-PD-1 antibody or anti-CTLA-4 antibody; and (ii) a herpes simplex virus, wherein the herpes simplex virus lacks a functional ICP34.5 encoding gene and a functional ICP47 encoding gene, and comprises a gene encoding human GM-CSF. We believe the USPTO erred in its issuance of the '938 Patent for at least the reason that the invention covered by the claims of the '938 Patent was in the public domain prior to the filing date of the '938 Patent, and accordingly on November 2, 2022, we filed a petition for inter partes review with the Patent Trial and Appeal Board (PTAB) of the USPTO, seeking to invalidate certain claims of United States Patent 10,034,938 (the '938 Patent).

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. At times we may attempt to initiate litigation or other administrative procedures to invalidate or otherwise limit the scope of a third party's intellectual property and these attempts may not be successful. 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, unenforceable or otherwise not infringed, 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 litigation 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, RP2 and RP3 for where nivolumab or cemiplimab, respectively, are intended to be used for these clinical programs. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our ongoing IGINYTE Phase 1/2 trials with RP1, our Phase 1/2 clinical trial with RP2 and our Phase 1 and Phase 2 clinical trials with RP3 where we intend to use nivolumab and may potentially do so for other clinical trials in the future; Regeneron is providing cemiplimab, its anti-PD-1 therapy, for use in our ongoing CERPASS 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, similar to our agreement with Roche. The outcome of these clinical trials is dependent, in part, 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. Additionally, we are subject to specific risks associated with our collaboration partners, including possible discrepancies as to the timing, nature and the extent of development plans, contract interpretations, and the costs and allocation of costs related to the conduct of our clinical trials. If we and any collaboration partner are unable to agree or fail to perform our respective obligations or effectively manage our relationship, our clinical trials performed under such collaboration could incur additional costs, be delayed or could result in costly or time-consuming legal proceedings that could have an adverse effect on a collaboration or on our business.

***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 de-emphasize 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 raw materials or process consumables 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 raw materials and clinical trial product supplies until our in-house manufactured clinical trial product supplies are qualified for use in our clinical trials. As a result, there can be no assurance that our clinical development or commercial supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices.

We currently have only one in-house manufacturing site approved for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of raw materials or 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 of raw materials or our product candidates, 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 raw materials or product candidates that meet the necessary quality standards may delay our development or commercialization.

If our manufacturers of raw materials, equipment or process consumables 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 Framingham manufacturing site cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or maintain regulatory approval for our 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 raw materials, products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization.

We are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, but, other than through our contractual arrangements, we have limited control over our raw materials or process consumables 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 clinical or commercial supply, including our own manufacturing facility.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against 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 manufacturing failures 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. We have completed the process of transferring the manufacturing of RP1, RP2 and RP3 from our third-party contract manufacturer. Comparability analysis of RP1, RP2 and RP3 produced at our in-house Framingham facility with the contract manufacturer material used in our clinical studies is complete. The FDA and some European regulatory agencies have approved the use of material produced at our Framingham facility in ongoing and future clinical trials. The Framingham 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 inspections. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we are not able to comply with the applicable regulatory requirements or produce product that meets our requirements and specifications, we will be subject to the same risks that we would be subject to should third party manufacturers be unable to comply with the applicable regulatory requirements or produce product meeting our requirements or specifications, as described above. 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. Further, should corrective or preventative actions be required, we will be fully responsible for these. 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, product candidate supplies and, if approved, our commercial product supplies. 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 and costs which may negatively affect our product development schedule and our ability to provide clinical trial supplies to patients in our clinical trials, and if approved, our commercial product supplies.

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 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.

***We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, numerous federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including personal data privacy laws, health information privacy laws, data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additionally, the California Consumer Privacy Act, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA also allows for statutory fines for noncompliance (up to \$7,500 per violation) and includes a private right of action for certain data breaches. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential

liability. In addition, it is anticipated that the California Privacy Rights Act, or CPRA, which became operative on January 1, 2023, will expand the CCPA, including by expanding consumers' rights with respect to certain sensitive personal data. The CPRA also creates the new California Privacy Protection Agency to implement and enforce the CCPA and the CPRA, which could increase compliance costs. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines up to the greater of €20 million or 4% of annual global revenue. Further, individuals may initiate litigation related to processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other jurisdictions outside of the United States). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. The SCCs, though approved by the European Commission as a suitable alternative, have faced challenges in European courts, and may be further challenged, suspended or invalidated. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Other countries in Europe, such as the UK, similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

## **Risks related to our operations**

***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.

***Our future success depends on our ability to retain our key employees and consultants, and to attract and motivate highly qualified personnel.***

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 executive leadership team, as well as our other scientific, manufacturing, quality and medical personnel. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, without our inability to find suitable replacements, could result in delays in product development and harm our business.

Changes in our management team resulting from the hiring or departure of executives and key employees from time to time could disrupt our business. For example, in May 2023, we announced Jean Franchi, our Chief Financial Officer notified us of her resignation from the Company effective June 2, 2023. These changes and any future significant leadership changes or senior management transitions involve inherent risk. Any failure to find a timely and suitable replacement and ensure an effective transition within executive leadership or senior management, including the effective onboarding, assimilation, and retention of our management team and key employees, could hinder our strategic planning, business execution and future performance. In addition, executive leadership transition periods can be disruptive and may result in a loss of personnel with deep institutional or technical knowledge, or result in changes to business strategy or objectives, and may negatively impact our operations and relationships with employees and third-parties due to increased or unanticipated expenses, operational inefficiencies, uncertainty regarding changes in strategy, decreased employee morale and productivity, and increased turnover.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option and restricted stock unit 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.

***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 business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack or unauthorized access and use by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. There can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Our internal computer systems and those of our contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics (including COVID-19), terrorism, war (including the ongoing conflict in Ukraine), and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre-clinical trial data or data from clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur notification obligations to affected individuals and government agencies, liability, including potential lawsuits from patients, collaborators, employees, stockholders or other third parties and liability under foreign, federal and state laws that protect the privacy and security of personal information, and the development and potential commercialization of our product candidates could be delayed. or additional information, see the Risk Factor captioned “*We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.*”

### **Risks related to our common stock and general risk factors**

#### ***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 including, but not limited to, the ongoing military conflict between Russia and Ukraine, acts of terrorism, governmental restrictions and sanctions, inflation, global supply chain disruptions, 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 engage clinical trial sites in the U.S. and in foreign territories, obtain the approval for conducting our clinical trials in foreign territories from their regulatory authorities, as well as our ability to enroll the number of patients necessary in our 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, including, but not limited to, those resulting from the ongoing military conflict between Russia and Ukraine, acts of terrorism, governmental restrictions and sanctions, inflation, global supply chain disruptions, 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.

***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 and restricted stock units, 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, including our ESPP if activated. 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 \$93.3 million of shares of our common stock in "at-the-market" offerings pursuant to a Sales Agreement entered into on June 23, 2022 with SVB Leerink LLC, or the 2022 Sales Agreement. The sale of a substantial number of shares of our common stock pursuant to the 2022 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 2022 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 one-time 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 have reduced and may continue to reduce our ability or willingness 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also adversely impact our clinical trials, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. A weak or declining economy or political disruption, including any international trade disputes, could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Although we do not currently operate in Russia or Ukraine, if the conflict broadens it may impact countries or territories in which we do operate or intend to operate, which could have a negative impact on our ability to achieve our objectives or timelines.

***The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.***

There has been increasing public focus by investors, customers, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure achievement of those goals, which could have a materially adverse impact on our business and financial condition. In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

**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
10.1	<a href="#">First Amendment to Loan and Security Agreement, dated as of June 28, 2023, by and among Replimune Group Inc., Replimune Inc., Replimune Limited and Hercules Capital, Inc.</a>			
10.2†	<a href="#">Separation Agreement and Release, dated as of May 18, 2023 by and between Jean Franchi and Replimune, Inc.</a>			
10.3†	<a href="#">Consulting Agreement, dated as of May 18, 2023 by and between Jean Franchi and Replimune, Inc.</a>			
31.1*	<a href="#">Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).</a>			
31.2*	<a href="#">Certification of the Chief Accounting Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).</a>			
32.1*	<a href="#">Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).</a>			
32.2*	<a href="#">Certification of the Chief Accounting Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).</a>			
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.			
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).			

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

† Indicates management contract or compensatory plan.

\*‡ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

**SIGNATURES**

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

**REPLIMUNE GROUP, INC.**

Dated: August 3, 2023

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

Dated: August 3, 2023

By: /s/ Andrew Schwendenman  
Name: Andrew Schwendenman  
Title: Chief Accounting Officer  
(Principal Accounting Officer)

**FIRST AMENDMENT  
TO  
LOAN AND SECURITY AGREEMENT**

This **First Amendment to Loan and Security Agreement** (this “**Amendment**”) is dated as of June 28, 2023 and is entered into by and among Replimune Group, Inc., a Delaware corporation, and each of its Subsidiaries (other than Excluded Subsidiaries and the MSC Subsidiary) party to the Loan Agreement as borrower (individually and collectively referred to as “**Borrower**”), the several banks and other financial institutions or entities from time to time parties to the Loan Agreement (collectively referred to as “**Lenders**”) and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lenders (in such capacity, “**Agent**”). *Capitalized terms used herein without definition shall have the same meanings given them in the Loan Agreement (as defined below).*

**Recitals**

**A.** Borrower, Agent and Lenders have entered into that certain Loan and Security Agreement dated as of October 6, 2022, among Borrower, Agent and Lenders (as amended, restated, amended and restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”), pursuant to which Lenders have agreed to extend and make available to Borrower certain advances of money.

**B.** In accordance with Section 11.3 of the Loan Agreement, Borrower has requested that Agent and Lenders agree to amend certain provisions of the Loan Agreement.

**C.** Agent and Lenders have agreed to so amend the Loan Agreement upon the terms and conditions more fully set forth herein.

**Agreement**

NOW, THEREFORE, in consideration of the foregoing Recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

**1. Amendments.**

Effective as of the First Amendment Closing Date:

**1.1** Section 2.2(a) of the Loan Agreement is hereby amended and restated to read as follows:

“(a) Tranche 1 Advance. Subject to the terms and conditions of this Agreement, on the Closing Date, the Lenders shall severally (and not jointly) make, and Borrower agrees to draw, an initial Term Loan Advance in an aggregate principal amount not less than Thirty Million Dollars (\$30,000,000); provided, that the aggregate amount of Term Loan Advances made under this Section 2.2(a) shall not exceed \$30,000,000 (such Term Loan Advance, a “Tranche 1 Advance”).”

**1.2** Section 2.2(b) of the Loan Agreement is hereby amended and restated to read as follows:

“(b) Tranche 2 Advance. Subject to the terms and conditions of this Agreement and the achievement of the Clinical Milestone, beginning upon the earlier of (i) the drawing of 100% of the Term Commitment in respect of the Tranche 1 Advances or (ii) September 30, 2023, Borrower may request, and the Lenders shall severally (and not jointly) make, in each case on or prior to December 31, 2023, additional Term Loan Advances in an aggregate principal amount up to Forty Five Million Dollars (\$45,000,000), in minimum draws of at least Twenty Million Dollars (\$20,000,000) (or if

less than Twenty Million Dollars (\$20,000,000), the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.2(b)) (each, a “Tranche 2 Advance”); provided that Borrower shall not be permitted to request more than two (2) Tranche 2 Advances in total.”

**1.3** Section 7.1(e) of the Loan Agreement is hereby amended and restated as follows:

“(e) as soon as practicable (and in any event within 30 days) after the end of each month, a report showing agings of accounts receivable and accounts payable;”.

**1.4** Schedule 1.1 of the Loan Agreement is hereby amended and restated in its entirety in the form set forth in **Annex A** of this Agreement.

**1.5** Exhibit D of the Loan Agreement is hereby amended and restated in its entirety in the form set forth in **Annex B** of this Agreement.

**1.6** Each reference in the Loan Agreement to “this Agreement” and the words “hereof,” “herein,” “hereunder,” or words of like import, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

**2. Borrower’s Representations And Warranties.** Borrower represents and warrants that:

**2.1** Immediately upon giving effect to this Amendment, (i) the representations and warranties contained in the Loan Documents are true and correct in all material respects except to the extent such representations and warranties expressly relate to an earlier date, in which case they are true and correct in all material respects as of such date and (ii) no default or Event of Default has occurred and is continuing with respect to which Borrower has not been notified in writing by Agent or Lenders.

**2.2** Borrower has the corporate power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment.

**2.3** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized by all necessary corporate action on the part of Borrower.

**2.4** This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors’ rights.

**2.5** As of the date hereof, it has no defenses against the obligations to pay any amounts under the Secured Obligations. Borrower acknowledges that each of Agent and Lenders has, as of the date hereof, acted in good faith and has conducted in a commercially reasonable manner its relationships with Borrower in connection with this Amendment and in connection with the Loan Documents.

Borrower understands and acknowledges that each of Agent and Lenders is entering into this Amendment in reliance upon, and in partial consideration for, the above representations and warranties, and agrees that such reliance is reasonable and appropriate.

**3. Limitation.** The amendments set forth in this Amendment shall be limited precisely as written and shall not be deemed (a) to be a waiver or modification of any other term or condition of the Loan Agreement or of any other instrument or agreement referred to therein or to prejudice any right or

remedy which Agent and/or Lenders may now have or may have in the future under or in connection with the Loan Agreement (as amended hereby) or any instrument or agreement referred to therein; or (b) to be a consent to any future amendment or modification or waiver to any instrument or agreement the execution and delivery of which is consented to hereby. Except as expressly amended hereby, the Loan Agreement shall continue in full force and effect.

**4. Effectiveness.** This Amendment shall become effective upon the satisfaction of all of the following conditions precedent (such date of satisfaction of such condition precedents, the “**First Amendment Closing Date**”):

**1.1 Amendment.** Borrower, Agent and Lenders shall have duly executed and delivered this Amendment to Lenders.

**1.2 Payment of Lender Expenses.** Borrower shall have paid all reasonable Lender expenses (including all reasonable attorneys' fees and reasonable expenses) incurred through the date of this Amendment for the documentation and negotiation of this Amendment, in each case, to the extent invoiced on or prior to the First Amendment Closing Date.

**5. POST-CLOSING DELIVERABLES.** By no later than ten (10) Business Day after the First Amendment Closing Date (or such later date to which the Agent may agree in its sole discretion), Borrower shall have delivered to Agent a duly executed Account Control Agreement, in form and substance reasonably satisfactory to Agent, in respect of the Borrower's Deposit Account at Citibank, N.A. with account number 54187798.

**6. RELEASE.** In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby to the extent possible under applicable law fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lender and all such other persons being hereinafter referred to collectively as the “Releasees” and individually as a “Releasee”), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time prior to the execution of this Amendment, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction existing prior to the execution of this Amendment which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

**7. Counterparts.** This Amendment may be signed in any number of counterparts, and by different parties hereto in separate counterparts, with the same effect as if the signatures to each such counterpart were upon a single instrument. All counterparts shall be deemed an original of this Amendment. This Amendment may be executed by facsimile, portable document format (.pdf) or similar technology signature, and such signature shall constitute an original for all purposes.

**8. Incorporation By Reference.** The provisions of Section 11 of the Loan Agreement shall be deemed incorporated herein by reference, *mutatis mutandis*.

**9. Reaffirmation.** By executing and delivering a counterpart hereof, (i) Borrower hereby agrees that all Advances incurred by Borrower shall be secured by the Collateral pursuant to the



applicable Loan Documents in accordance with the terms and provisions thereof and (ii) Borrower hereby (A) agrees that, notwithstanding the effectiveness of this Amendment, after giving effect to this Amendment, the Loan Documents continue to be in full force and effect, (B) agrees that all of the Liens and security interests created and arising under the Loan Documents remain in full force and effect on a continuous basis, and the perfected status and priority of each such Lien and security interest continues in full force and effect on a continuous basis, unimpaired, uninterrupted and undischarged, as collateral security for its obligations, liabilities and indebtedness under the Loan Agreement to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Amendment) and (C) affirms and confirms all of its obligations, liabilities and indebtedness under the Loan Agreement and each other Loan Document, in each case after giving effect to this Amendment, including the pledge of and/or grant of a security interest in its assets as Collateral pursuant to the Loan Documents to secure such Secured Obligations, all as provided in the Loan Documents, and acknowledges and agrees that such obligations, liabilities, guarantee, pledge and grant continue in full force and effect in respect of, and to secure, such Secured Obligations under the Loan Agreement and the other Loan Documents, in each case, to the extent provided in, and subject to the limitations and qualifications set forth in, such Loan Documents (as amended by this Amendment).

*[Signature Page Follows]*

**In Witness Whereof**, the parties have duly authorized and caused this Amendment to be executed as of the date first written above.

**BORROWER:**

REPLIMUNE GROUP, INC.

Signature: \_\_\_\_\_

Print Name: Philip Astley-Sparke

Title: Director

REPLIMUNE, INC.

Signature: \_\_\_\_\_

Print Name: Philip Astley-Sparke

Title: CEO

REPLIMUNE LIMITED

Signature: \_\_\_\_\_

Print Name: Philip Astley-Sparke

Title: Director

[Signature Page – First Amendment to LSA (Replimune)]

Accepted in Palo Alto, California:

**AGENT:**

HERCULES CAPITAL, INC.

Signature: \_\_\_\_\_

Print Name: Seth Meyer

Title: CFO

**LENDERS:**

HERCULES CAPITAL, INC.

Signature: \_\_\_\_\_

Print Name: Seth Meyer

Title: CFO

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: \_\_\_\_\_

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE FUND ONE LLC

By: Hercules Adviser LLC, its Investment Adviser

Signature: \_\_\_\_\_

Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules Adviser LLC, its Investment Adviser

[Signature Page – First Amendment to LSA (Replimune)]

Signature: \_\_\_\_\_

Name: Seth Meyer

Title: Authorized Signatory

[Signature Page – First Amendment to LSA (Replimune)]

ny-2580624

Annex A

**SCHEDULE 1.1**

**COMMITMENTS**

<b>LENDERS</b>	<b>TRANCHE 1</b>	<b>TRANCHE 2</b>	<b>TRANCHE 3</b>	<b>TRANCHE 4</b>	<b>TRANCHE 5</b>	<b>TRANCHE 6*</b>	<b>TOTAL COMMITMENTS</b>
Hercules Capital, Inc.	\$20,700,000.00	\$31,050,000.00	\$17,250,000.00	\$24,150,000.00	\$27,600,000.00	\$25,000,000.00*	\$145,750,000.00
Hercules Private Fund One LLC	\$5,400,000.00	--	--	--	--	--	\$5,400,000.00
Hercules Private Credit Fund 1 L.P.	--	\$8,100,000.00	\$4,500,000.00	\$6,300,000.00	\$7,200,000.00	--	\$26,100,000.00
Hercules Private Global Venture Growth Fund I L.P.	\$3,900,000.00	\$5,850,000.00	\$3,250,000.00	\$4,550,000.00	\$5,200,000.00	--	\$22,750,000.00
	\$30,000,000.00	\$45,000,000.00	\$25,000,000.00	\$35,000,000.00	\$40,000,000.00	\$25,000,000.00*	\$200,000,000.00

\*Funding of Tranche 6 is conditioned on approval by Lender's investment committee in its sole and unfettered discretion.

<b>LENDERS</b>	<b>Treaty Passport scheme reference number and jurisdiction of tax residence (if applicable)</b>
Hercules Capital, Inc.	13/H/376642/DTTP USA
Hercules Private Global Venture Growth Fund I L.P.	13/H/391494/DTTP
Hercules Private Fund One LLC	----
Hercules Private Credit Fund 1 L.P.	----

[Signature Page – First Amendment to LSA (Replimune)]

ny-2580624

Annex B

**EXHIBIT D**

Deposit Accounts

<u>Bank Name</u>	<u>Account Number</u>	<u>Branch Address</u>	<u>Company/ Subsidiary</u>	<u>Purpose of Account</u>
<b>Silicon Valley Bank</b>	3301390025	3005 Tasman Dr, Santa Clara, CA 95054	Replimune, Inc. (US)	SVB US Operating Account - 0025
<b>Silicon Valley Bank</b>	3302437787	3005 Tasman Dr, Santa Clara, CA 95054	Replimune, Inc. (US)	Collateral Account for King Street - 7787
<b>Silicon Valley Bank</b>	3302288720	3005 Tasman Dr, Santa Clara, CA 95054	Replimune Group, Inc. (US)	Analysis Checking
<b>Silicon Valley Bank</b>	3302727016	3005 Tasman Dr, Santa Clara, CA 95054	Replimune, Inc. (US)	Collateral Account for Unicorn Park - 7016
<b>Silicon Valley Bank</b>	20126468	Alphabeta, 14-18 Finsbury Square London, GB EC2A 1BR	Replimune Limited (UK)	USD DEPOSIT - 6468
<b>Silicon Valley Bank</b>	20126441	Alphabeta, 14-18 Finsbury Square London, GB EC2A 1BR	Replimune Limited (UK)	GBP DEPOSIT - 6441
<b>Silicon Valley Bank</b>	20126417	Alphabeta, 14-18 Finsbury Square London, GB EC2A 1BR	Replimune Limited (UK)	GBP OPERATING - 6417
<b>Citizens Bank, N.A.</b>	1404939064	1 Citizens Plaza, Providence, RI 02903	Replimune, Inc. (US)	Operating Account
<b>Citibank, N.A.</b>	54187798	1 Post Office Square Boston, MA 02109	Replimune, Inc. (US)	Operating Account

Accounts Holding Investment Property

<u>Account</u>	<u>Identifier</u>	<u>Description</u>	<u>Company/Subsidiary</u>
<b>Capital Advisors Group</b>	CAG4855	Investments	Replimune Securities Corporation

# Replimune Inc

500 Unicorn Park Dr.  
Woburn, MA 01801

PERSONAL & CONFIDENTIAL

May 18, 2023

Jean Franchi  
205 Pleasant Street  
Norwell, MA 02061

## RE: Separation Agreement and Release

Dear Jean:

This letter of agreement and general release (“Agreement”) confirms our mutual agreement regarding the terms and conditions of your separation from employment with Replimune, Inc. (the “Company”) without Cause (as defined in the Employment Agreement with the Company dated November 27, 2019 (the “Employment Agreement”). This Agreement provides for all payments to which you may be entitled from the Company, including under the Employment Agreement. You and the Company (the “Parties” and each, a “Party”) agree as follows:

1. Separation Date and Transition Period. Your last day of employment with the Company will be June 2, 2023 (the “Last Day of Employment”) and you shall be eligible for the benefits set forth in Section 2 below. Effective as of the date hereof, you shall continue to be available to the Company to complete certain projects and transition your duties, as requested by the Chief Executive Officer of the Company (the “CEO”). You will continue to receive your current base salary and benefits through the Last Day of Employment. Additionally, you will receive your salary and other amounts earned, accrued and owing but not yet paid through your Last Day of Employment, including any vested benefits accrued and due under any applicable benefit plans and programs of the Company, pursuant to the Employment Agreement, regardless of whether you execute or revoke this Agreement. You will also receive payment for approved expenses within 30 days after receipt of the expense report. Your employment and your participation in and eligibility for the Company’s employee benefit plans and programs will terminate on your Last Day of Employment. Except for consulting services, in accordance with the Consulting Agreement described below, effective as of the Last Day of Employment, you will automatically be deemed to resign from all Company-related positions, including as an officer and director of the Company and its parents, subsidiaries and affiliates, as applicable, and shall execute all documentation necessary to effectuate such resignation(s).
2. Consideration in Exchange for Release.
  - (a) Provided you timely execute and do not revoke this Agreement and that you comply with your obligations under the Employment Agreement, attached hereto as Exhibit A, and effectively transition your responsibilities prior to your Last Day of Employment: (i) you will be eligible to receive the severance payments and benefits set forth in Section 2(b) below and (ii) the Company will enter into the consulting agreement attached here as Exhibit B (the “Consulting Agreement”) with you, to be effective on June 3, 2023, and the Company will provide the compensation described therein upon performance of the services described therein.



- (b) Provided you have timely executed and not revoked this Agreement and provided you timely execute and do not revoke the release attached as Exhibit C (which must be executed on, but not before, the Last Day of Employment) and otherwise comply with their terms, you shall receive the following additional benefits:
- (i) An amount equal to \$483,080, which is 12 months of your current base salary, shall be paid to you in accordance with the following: (A) base salary amounts that would have been paid to you prior to March 15, 2024 if you had been employed by the Company during such time shall be paid in installments in accordance with the Company's normal payroll practices, commencing within 60 days following the Last Day of Employment, provided that, any installments not paid between the Last Day of Employment and the date of the first payment will be paid with the first payment, and (B) base salary amounts that would have been paid to you between March 15, 2024 and June 2, 2024 if you had been employed by the Company during such time shall be paid to you in a lump sum on March 15, 2024.
  - (ii) Provided that the fiscal year 2023 year-end audit is completed and that you assist with transitional duties requested by the CEO, including transitioning your duties and responsibilities to a successor, a prorated Annual Bonus (as defined in the Employment Agreement) for the year in which the Last Day of Employment occurs (the "Prorated Annual Bonus") shall be paid to you. The Prorated Annual Bonus will be an amount in cash equal to your target Annual Bonus for the year in which the Last Day of Employment occurs, multiplied by a fraction, the numerator of which is the number of days that you were employed by the Company during the fiscal year of termination and the denominator of which is 365. The Prorated Annual Bonus, if any, will be paid within 60 days following the Last Day of Employment.
  - (iii) During the period beginning on the Last Day of Employment and ending on the earliest of (i) the date on which you first become covered by any other "group health plan" as described in Section 4980B(g)(2) of the Internal Revenue Code of 1986, as amended (the "Code"), (ii) May 18, 2024, or (iii) the date you cease to be eligible for continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") for any reason, including your ceasing to pay the applicable COBRA premiums (such period, the "Coverage Period"), if you timely elect to receive continued health coverage under the Company's health plan pursuant to COBRA at a level of coverage at your level of coverage in effect on the Last Day of Employment, the Company will reimburse you on a monthly basis for the COBRA premiums you pay for yourself and your eligible dependents. You agree to promptly notify the Company of your coverage under an alternative health plan upon becoming covered by such alternative plan, or your other ineligibility for continued coverage under COBRA upon becoming ineligible. The COBRA health care continuation coverage period under Section 4980B of the Code shall run concurrently with the Coverage Period.

3. Release.

- (a) In consideration of the compensation and benefits set forth in Section 2(a) hereof, to the fullest extent permitted by law you waive, release, and forever discharge the Company and each of its past and current parents, subsidiaries, affiliates, and each of its and their respective past and current directors, officers, members, trustees, employees, representatives, agents, attorneys, employee benefit plans and such plans' administrators, fiduciaries, trustees, recordkeepers and service providers, and each of its and their respective successors and assigns, each and all of them in their personal and representative capacities (collectively the "Company Releasees") from any and all claims legally capable of being waived, agreements, causes of action, attorneys' fees, costs, damages, or any right to any monetary recovery or any other personal relief, whether known or unknown, in law or in equity, by contract, tort, law of trust or pursuant to federal, state or local statute, regulation, ordinance or common law, which you now have, ever have had, or may hereafter have, whether known or unknown to you, arising at any time up to the date of your execution of this Agreement, arising out of or relating in any way to your employment with the Company or the termination thereof.

Without limiting the generality of the foregoing, this waiver, release, and discharge includes any claim or right, to the extent legally capable of being waived, based upon or arising under any federal, state or local fair employment practices or equal opportunity laws, including, but not limited to, the Age Discrimination in Employment Act ("ADEA") (29 U.S.C. Section 621, et seq.), 42 U.S.C. Section 1981, Title VII of the Civil Rights Act of 1964, the Equal Pay Act, the Employee Retirement Income Security Act ("ERISA") (including, but not limited to, claims for breach of fiduciary duty under ERISA), the Americans With Disabilities Act, the Family and Medical Leave Act of 1993, the Massachusetts Fair Employment Practices Act, the Massachusetts Civil Rights Act, the Massachusetts Equal Rights Act, the Massachusetts Parental Leave Act, the Massachusetts Labor and Industries Act, the Massachusetts right of privacy law, the Massachusetts Wage Act (as further explained below), the Massachusetts Earned Sick Time law, the Massachusetts Equal Pay Act, the Massachusetts Minimum Fair Wage Law, as well as any claim or right under your Employment Agreement unless provided herein.

**Massachusetts Wage Act Waiver.** By signing this Agreement, you acknowledge that this waiver includes any claims against the Company Releasees under Mass. Gen. Laws ch. 149, § 148 et seq.,—the Massachusetts Wage Act. These claims include, but are not limited to, claims for failure to pay earned wages, failure to pay overtime, failure to pay earned commissions, failure to timely pay wages, failure to pay accrued vacation or holiday pay, failure to furnish appropriate pay stubs, improper wage deductions, and failure to provide proper check-cashing facilities.

- (b) You acknowledge that you have not made any claims or allegations related to discrimination, harassment, sexual abuse or retaliation, and none of the payments set forth as consideration in this Agreement or the release attached hereto as Exhibit C, are related to discrimination, harassment, sexual abuse or retaliation.

In addition, nothing in this Agreement precludes you from discussing or disclosing information about unlawful acts in the workplace, such as harassment, discrimination, sexual assault or any other conduct that you have reason to believe is unlawful, including the amount or fact of any settlement relating to such acts.

- (c) Notwithstanding the generality of the foregoing, nothing herein constitutes a release or waiver by you of, or prevents you from making or asserting: (i) any claim or right you may have under COBRA; (ii) any claim or right you may have for unemployment insurance or workers' compensation benefits (other than for retaliation under workers' compensation laws); (iii) any claim to vested benefits under the written terms of a qualified employee pension benefit plan; (iv) any claim for indemnity pursuant to Section 25 of your Employment Agreement, which is incorporated herein by reference; (v) any medical claim incurred during your employment that is payable under applicable medical plans or an employer-insured liability plan; (vi) any claim or right that may arise after the execution of this Agreement; (vii) any claim or right you may have under this Agreement; or (viii) any claim that is not otherwise able to be waived under applicable law.
  - (d) In addition, nothing herein shall prevent you from filing a charge or complaint with the Equal Employment Opportunity Commission ("EEOC") or similar federal or state fair employment practices agency or interfere with your ability to participate in any investigation or proceeding conducted by such agency; provided, however, that pursuant to Section 3(a) above, you are waiving any right to recover monetary damages or any other form of personal relief from the Company Releasees to the extent any such charge, complaint, investigation or proceeding asserts a claim subject to the release in Section 3(a) above. To the extent you receive any such personal or monetary relief in connection with any such charge, complaint, investigation or proceeding, the Company will be entitled to an offset for the payments made pursuant to Section 2(b) of this Agreement.
4. No Additional Entitlements. You agree and represent that other than as provided for in this Agreement, you have received all entitlements due from the Company relating to your employment with the Company or under your Employment Agreement, including but not limited to, all wages earned, including without limitation all commissions and bonuses, sick pay, vacation pay, overtime pay, and any paid and unpaid personal leave for which you were eligible and entitled, and that no other entitlements are due to you other than as set forth in this Agreement. Additionally, the Company agrees not to contest any claim for unemployment benefits you may file; provided, however, that the Company may respond to any inquiry from the unemployment compensation board to the extent you make any allegations of wrongdoing by the Company. Except as expressly provided for herein, your Employment Agreement with the Company is hereby terminated.
5. Protection of Confidential Information. Except as expressly permitted in Sections 3(b) and 7 of this Agreement or if otherwise required by law, you agree that you will not at any time, directly or indirectly, use or disclose any trade secret, confidential or proprietary information you have learned by reason of your employment with the Company and will continue to abide by your confidentiality obligations pursuant to Section 15(d) of your Employment Agreement.

6. Non-Disparagement. Except as expressly permitted in Sections 3(b) and 7 of this Agreement, you agree that you shall not at any time make any written or oral comments or statements of a defamatory or disparaging nature regarding the Company and/or the Company Releasees and you shall not take any action that would cause or contribute to their being held in disrepute. The Company agrees to direct its directors and officers not to at any time make any written or oral comments or statements of a defamatory or disparaging nature regarding you or take any action that would cause or contribute to you being held in disrepute. You and the Company agree to prepare a mutually acceptable internal communication to employees and third parties regarding your separation.
7. Reports to Government Entities. Nothing in this Agreement restricts or prohibits you from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency, from making other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation, or engaging in the conduct set forth in Section 3(b) of this Agreement. You do not need the prior authorization of the Company to engage in conduct protected by this Section, and you do not need to notify the Company that you have engaged in such conduct. Please take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.
8. Non-Admission. It is understood and agreed that neither the execution of this Agreement nor the terms of this Agreement constitute an admission of liability to you by the Company or the Company Releasees, and such liability is expressly denied. It is further understood and agreed that no person shall use this Agreement, or the consideration paid pursuant thereto, as evidence of an admission of liability, in as much as such liability is expressly denied.
9. Cooperation. You agree that upon the Company's reasonable notice to you, and a reasonable request, you shall cooperate with the Company and its counsel (including, if necessary, preparation for and appearance at depositions, hearings, trials or other proceedings) with regard to matters that relate to or arise out of matters you have knowledge about or have been involved with during your employment with the Company. In the event that such cooperation is required, you will be reimbursed for any reasonable travel expenses incurred in connection therewith.
10. Confidentiality of the Agreement. Except as permitted in Sections 3(b) and 7 of this Agreement, as may be required pursuant to the Securities Exchange Act of 1934, as amended, and the rules and regulations thereof, to enforce the terms of this Agreement or if otherwise required by law, the parties, including the Company, shall not disclose the terms of this Agreement, or the circumstances giving rise to this Agreement, to any person other than their respective attorneys, immediate family members, accountants,

financial advisors or corporate employees who have a business need to know such terms in order to approve or implement such terms.

11. Restrictive Covenant Obligations.

- (a) Subject to Section 7 of this Agreement, you reaffirm and agree that you remain bound by Sections 15(b) through (f), 16, and 17 of your Employment Agreement, which are incorporated herein by reference.
- (b) *Non-Competition.* You agree that during the one-year period following the Last Day of Employment, you will not, without the express written consent of the Company's Board of Directors, engage (directly or indirectly) in any Competitive Business in the Restricted Area. The term "Competitive Business" means any activities or services conducted by any third party with respect to the research, development, marketing, manufacturing or sale of oncolytic immunotherapies that are similar to the activities or services you have performed (or gained Proprietary Information (as defined in the Employment Agreement) about) at any time during the last two years of your employment with the Company. The term "Restricted Area" means the United States of America, Canada and countries within Europe, in respect of which the Company or any of its Affiliates has material business operations as of the date on which your employment terminates and in which you have provided services or had a material presence or influence at any time during the last two years of your employment with the Company or its Affiliates. You agree that the benefits set forth in Section 2 of this Agreement are fair and reasonable consideration for your compliance with this Section 11(b). You understand and agree that, given the nature of the business of the Company and its Affiliates and your position with the Company, the foregoing Restricted Area is reasonable and appropriate and that more limited geographical limitations on this non-competition covenant are therefore not appropriate. For purposes of this Agreement, the term "Affiliate" means the Company's sole shareholder, any subsidiary of the Company or other entity under common control with the Company. Unless otherwise specified herein, terms defined in the Employment Agreement, as they are used in this Section 11(b), shall have the meanings set forth in the Employment Agreement.

12. Return of Company Property. By no later than the last day on which you provide consulting services under the Consulting Agreement, you must (i) send to Camilo Garcia by overnight FedEx all originals and copies of all documents and property of the Company or an affiliate that is in your possession or under your control or to which you may have access, (ii) deliver to Camilo Garcia all Company property, including keys, key cards, access cards, identification cards, security devices, employer credit cards, network access devices, computers, cell phones, smartphones, PDAs, pagers, fax machines, equipment, manuals, reports, files, books, compilations, work product, e-mail messages, recordings, disks, thumb drives or other removable information storage devices, hard drives, and data, and (iii) to the extent that you made use of your personal electronics (e.g., laptop, iPad, telephone, thumb drives, etc.) during your employment with the Company, permit the Company to delete all Company property and information from such personal devices.

13. Acknowledgments. You hereby acknowledge that:

- (a) The Company advises you to consult with an attorney before signing this Agreement (including all Exhibits thereto);
  - (b) You have obtained independent legal advice from an attorney of your own choice with respect to this Agreement (including all Exhibits thereto), or you have knowingly and voluntarily chosen not to do so;
  - (c) You freely, voluntarily and knowingly entered into this Agreement and all Exhibits thereto after due consideration;
  - (d) You have had a minimum of twenty-one (21) days to review and consider this Agreement (including all Exhibits thereto) (the “Consideration Period”);
  - (e) You and the Company agree that changes to the Company’s offer contained in this Agreement, whether material or immaterial, will not restart the Consideration Period provided for in Section 13(d) above;
  - (f) You have a right to revoke this Agreement, by notifying the undersigned representative in writing, via hand delivery, facsimile or electronic mail, within seven (7) business days of your execution of this Agreement;
  - (g) In exchange for your waivers, releases and commitments set forth herein, including your waiver and release of all claims arising under the ADEA, the payments, benefits and other considerations that you are receiving pursuant to this Agreement exceed any payment, benefit or other thing of value to which you would otherwise be entitled, and are just and sufficient consideration for the waivers, releases and commitments set forth herein; and
  - (h) No promise or inducement has been offered to you, except as expressly set forth herein, and you are not relying upon any such promise or inducement in entering into this Agreement.
14. Medicare Disclaimer. You acknowledge that you are not a Medicare Beneficiary as of the time you enter into this Agreement. To the extent that you are a Medicare Beneficiary, you agree to contact a Company Human Resources Representative for further instruction.
15. Miscellaneous.
- (a) Entire Agreement. This Agreement (including the release attached hereto as Exhibit C), together with the expressly incorporated provisions of your Employment Agreement and the Consulting Agreement, sets forth the entire agreement between you and the Company and replaces any other oral or written agreement between you and the Company relating to the subject matter of this Agreement, including, without limitation, any prior offer letters and/or employment agreements, but not including the Replimune Group, Inc. 2018 Omnibus Incentive Compensation Plan, which remains in full force and effect.
  - (b) Governing Law. This Agreement shall be construed, performed, enforced and in all respects governed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of law thereof. Additionally, all disputes arising from or related to this Agreement shall be

brought in a state or federal court situated in the Commonwealth of Massachusetts, Suffolk County, and the parties hereby expressly consent to the jurisdiction of such courts for all purposes related to resolving such disputes.

- (c) Severability. Should any provision of this Agreement be held to be void or unenforceable, the remaining provisions shall remain in full force and effect, to be read and construed as if the void or unenforceable provisions were originally deleted.
- (d) Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state, and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. You shall bear all expense of, and be solely responsible for, the employee portion of all federal, state, and local taxes due with respect to any payment received under this Agreement.
- (e) Section 409A. This Agreement is intended to comply with Section 409A of the Code, and its corresponding regulations, or an exemption thereto, and payments may only be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Severance benefits under this Agreement are intended to be exempt from Section 409A of the Code under the “short-term deferral” exception, to the maximum extent applicable, and then under the “separation pay” exception, to the maximum extent applicable. All payments to be made upon a termination of employment under this Agreement may only be made upon a “separation from service” to the extent required under Section 409A of the Code. For purposes of Section 409A of the Code, each payment hereunder shall be treated as a separate payment, and the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may you, directly or indirectly, designate the calendar year of a payment. Notwithstanding any provision of this Agreement to the contrary, in no event shall the timing of your execution of this Agreement or Exhibit C, directly or indirectly, result in your designating the calendar year of payment of any amounts of deferred compensation subject to Section 409A of the Code. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A of the Code. The Parties agree that this Agreement may be amended, as reasonably requested by either Party and as may be necessary to comply with Section 409A of the Code and all related rules and regulations as mutually agreed-upon by the Parties. The Parties intend that any such amendment will preserve the payments and benefits provided hereunder without additional cost to either Party, to the extent practicable.

- (f) Amendments. This Agreement may not be modified or amended, except upon the express written consent of both you and the Company.
- (g) Breach. You acknowledge that if you breach your commitments to the Company agreed upon in Sections 5, 6, 8, 9, 10, 11, or 12 you will forfeit the severance benefits set forth in Section 2 (and may be required by the Company to repay all severance amounts previously paid) and be subject to suit by the Company for damages and equitable relief relating to such breach and your Consulting Agreement will terminate immediately. You further acknowledge that any breach by you of Sections 5, 6, 8, 9, 10, 11, or 12 will cause irreparable damage to the Company and that in the event of such breach the Company shall have, in addition to any and all remedies at law, the right to an injunction, specific performance or other equitable relief from a court of competent jurisdiction to prevent and/or restrain such breach, without the necessity of posting a bond or undertaking.
- (h) Waiver. A waiver by either Party hereto of a breach of any term or provision of the Agreement shall not be construed as a waiver of any subsequent breach.
- (i) Counterparts. This Agreement may be executed in one or more counterparts, and be transmitted by facsimile or pdf, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.
- (j) Assignment. In the event of a change of control, the Company will assign any surviving obligations in this Agreement to the appropriate entity to the extent permitted by law. This Agreement shall inure to the benefit of the Company and permitted successors and assigns. However, you may not assign this Agreement or any part hereof. Any purported assignment by you shall be null and void from the initial date of purported assignment.
- (k) Effective Date. This Agreement will become effective and enforceable upon the expiration of the seven (7) business day revocation period provided for in Section 13(f) above (the “Effective Date”). If you fail to return an executed original before the expiration of the Consideration Period (or otherwise revoke this Agreement pursuant to Section 13(f) above), this Agreement, including but not limited to the obligation of the Company to provide the compensation and benefits provided in Section 2 above, shall be deemed automatically null and void.

***[Signature Page Follows]***



If the above accurately states our agreement, including the separation, waiver and release, kindly sign below and return the original Agreement to me.

Sincerely,

Replimune Inc.

By: /s/ Philip Astley-Sparke

Date: May 18, 2023

**UNDERSTOOD, AGREED TO AND ACCEPTED WITH THE INTENTION TO BE LEGALLY BOUND:**

/s/ Jean Franchi

Jean Franchi

Date: May 18, 2023

*Signature Page to Separation and Release Agreement*

**EXHIBIT A**  
**EMPLOYMENT AGREEMENT**

THIS EMPLOYMENT AGREEMENT (this "Agreement") is entered into by and between Replimune, Inc. (the "Company") and Jean Franchi (the "Executive") as of November 27, 2019.

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

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

1. Employment.

(a) Term. The initial term of this Agreement shall begin on December 9, 2019 (the "Effective Date") and shall continue for two years, unless the Executive's employment is sooner terminated in accordance with Sections 6, 7, 8, 9, 10, or 11. Unless earlier terminated, the term of this Agreement shall automatically renew for periods of one year unless either party gives the other party written notice at least 90 days prior to the end of the then existing term that the term of this Agreement shall not be further extended. The period commencing on the Effective Date and ending on the date on which the term of this Agreement terminates is referred to herein as the "Term."

(b) Duties. During the Term, the Executive shall serve as the Chief Financial Officer, Treasurer, Secretary and Compliance Officer of the Company, with duties, responsibilities, and authority commensurate therewith, and shall report to the Executive Chairman of the Company (the "Chairman"); provided that the Executive may be required to report to the Chief Executive Officer of the Company (the "CEO"), as determined by the Company in its sole discretion. The Executive shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to the Executive by the Chairman or the CEO, as applicable. The Executive represents to the Company that the Executive is not subject to or a party to any employment agreement, noncompetition covenant, or other agreement that would be breached by, or prohibit the Executive from, executing this Agreement and performing fully the Executive's duties and responsibilities hereunder.

(c) Best Efforts. During the Term, the Executive shall devote her best efforts and full time and attention to promote the business and affairs of the Company and its affiliated entities, and may be engaged in other business activities only to the extent the Executive has received the prior written consent of the Board of Directors of the Company (the "Board") and such activities do not materially interfere or conflict with the Executive's obligations to the Company hereunder, including, without limitation, obligations pursuant to Section 15 below. The foregoing shall not be construed as preventing the Executive from (1) serving on civic, educational, philanthropic or charitable boards or committees and (2) managing personal investments, so long as such activities are permitted under the Company's code of conduct and employment policies and do not violate the provisions of Section 15 below. As of the Effective Date, the Executive is engaged in the business activities set forth on Exhibit A, which have been approved by the Board.

(d) Principal Place of Employment. The Executive understands and agrees that her principal place of employment will be in the Company's offices located in the Boston, MA

metropolitan area and that the Executive will be required to travel for business in the course of performing her duties for the Company.

2. Compensation.

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

(b) Annual Bonus. The Executive shall be eligible to be awarded an annual discretionary bonus for each fiscal year during the Term, based on the establishment and attainment of individual and corporate performance goals and targets established by the Compensation Committee ("Annual Bonus") in its sole discretion. The target amount of the Executive's Annual Bonus for any fiscal year during the Term is 40% of the Executive's annual Base Salary. Any Annual Bonus awarded shall be paid after the end of the fiscal year to which it relates, at the same time and under the same terms and conditions as the bonuses for other executives of the Company; provided that the Executive must be employed in good standing on the date that Executive's Annual Bonus is paid. The Annual Bonus shall be subject to the terms of the annual bonus plan that is applicable to other executives of the Company, including the requirement as to continued employment in good standing, subject to the provisions of Section 7 below.

(c) Sign-On Bonus. As an inducement for the Executive to join the Company in the role of Chief Financial Officer, Treasurer, Secretary and Compliance Officer, the Company shall pay the Executive a sign-on bonus in the aggregate amount of \$50,000 (the "Sign-On Bonus"). The Sign-On Bonus will be paid in one lump sum within 30 days following the Effective Date, provided that the Executive is employed on the payment date. The Sign-On Bonus shall not be for services rendered, but is an incentive payment to encourage the Executive to commence employment with the Company. As such, the Executive will be required to repay the a prorated amount of the Sign-On Bonus paid to her if, prior to the first anniversary of the Effective Date, the Executive's employment terminates either (1) by the Company for Cause (as defined below), or (2) by the Executive for any reason other than Good Reason (as defined below). The prorated amount shall be determined by multiplying the Sign-On Bonus by a fraction, the numerator of which is the days between the Effective Date and the termination date and the denominator of which is 365.

(d) Stock Option. Subject to the approval of the Compensation Committee, which has already been obtained contingent on the Executive's commencement of employment, the Executive will be granted a Nonqualified Stock Option (as defined in the Replimune Group, Inc. 2018 Omnibus Incentive Compensation Plan (the "Plan")) to purchase 180,000 shares (the "Option"), pursuant to the terms of the Company's Plan and subject to the standard form of Nonqualified Stock Option Award Agreement under the Plan. Vesting and exercisability of the Option will be over four years from the date of grant with 25% vesting and becoming exercisable on the first anniversary of the date of grant, and the remainder vesting and becoming exercisable monthly for three years thereafter.

3. Retirement and Welfare Benefits. During the Term, the Executive shall be eligible to participate in the Company's health, life insurance, long-term disability, retirement and welfare benefit plans, and programs available to similarly-situated employees of the Company, pursuant to their respective terms and conditions. Nothing in this Agreement shall preclude the

Company or any Affiliate (as defined below) of the Company from terminating or amending any employee benefit plan or program from time to time after the Effective Date.

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

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

6. Termination Without Cause; Resignation for Good Reason. The Company may terminate the Executive's employment at any time without Cause upon 30 days' advance written notice. The Executive may initiate a termination of employment by resigning without Cause or for Good Reason as described below. Upon termination by the Company without Cause or resignation by the Executive for Good Reason before or after the Change of Control Protection Period (as defined below), if the Executive executes and does not revoke a written Release (as defined below), the Executive shall be entitled to receive, in lieu of any payments under any severance plan or program for employees or executives, the following:

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

(b) The Company shall make a lump-sum payment within 60 days following the termination date equal to the COBRA premiums that the Executive would pay if she elected continued health coverage under the Company's health plan for the Executive and her dependents for the 12-month period following the termination date, based on the COBRA rates in effect at the termination date.

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

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

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

(b) The Company shall make a lump-sum payment within 60 days following the termination date equal to the COBRA premiums that the Executive would pay if she elected continued health coverage under the Company's health plan for the Executive and her dependents for the 12-month period following the termination date, based on the COBRA rates in effect at the termination date.

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

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

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

10. Disability. If the Executive incurs a Disability during the Term, in accordance with applicable law, the Company may terminate the Executive's employment on or after the date of Disability. If the Executive's employment terminates on account of Disability, the Executive shall be entitled to receive any Accrued Obligations. For purposes of this Agreement, the term "Disability," shall mean the Executive is eligible to receive long-term disability benefits under the Company's long-term disability plan.

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

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

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

(a) "Cause" shall mean a determination by the Board that the Executive (1) has breached this Agreement or any confidentiality, nonsolicitation, noncompetition or inventions assignment agreement or obligations with the Company; (2) committed an act of dishonesty, fraud, embezzlement or theft; (3) engaged in conduct that causes, or is likely to cause, material damage to the property or reputation of the Company; (4) failed to perform satisfactorily the material duties of the Executive's position (other than by reason of Disability) after receipt of a written warning from the Board; (5) committed a felony or any crime of moral turpitude; or (6) materially failed to comply with the Company's code of conduct or employment policies.

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

- (1) A material diminution by the Company of the Executive's authority, duties or responsibilities;
- (2) A material and permanent change in the geographic location at which the Executive must perform services under this Agreement (which, for purposes of this Agreement, means relocation of the offices of the Company at which the Executive is principally employed to a location that increases the Executive's commute to work by more than 50 miles);
- (3) A material diminution in the Executive's Base Salary, other than a general reduction in Base Salary that affects all similarly-situated executives in substantially the same proportions;
- (4) Any action or inaction that constitutes a material breach by the Company of this Agreement; or
- (5) The Company elects not to renew the Term of this Agreement pursuant to Section 1(a) above for any reason other than Cause or Disability and does not offer the Executive continued employment on substantially similar terms as set forth in this Agreement.

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

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

#### 14. Section 409A.

(a) This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and its corresponding regulations, or an exemption thereto, and payments may only be made under this Agreement upon an event and in a manner permitted by section 409A of the Code, to the extent applicable. Severance benefits under this Agreement are intended to be exempt from section 409A of the Code under the "short-term deferral" exception, to the maximum extent applicable, and then under the "separation pay" exception, to the maximum extent applicable. Notwithstanding anything in this Agreement to the contrary, if required by section 409A of the Code, if the Executive is considered a "specified employee" for purposes of section 409A of the Code and if payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to section 409A of the Code, payment of such amounts shall be delayed as required by section 409A of the Code, and the accumulated amounts shall be paid in a lump-sum payment within 10 days after the end of the six-month period. If the Executive dies during the postponement period prior to the payment of benefits, the amounts withheld on account of section 409A of the Code shall be paid to the personal representative of the Executive's estate within 60 days after the date of the Executive's death.

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

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

15. Restrictive Covenants.

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

(b) Nonsolicitation of Company Personnel. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, hire or attempt to hire any employee, consultant or independent contractor of the Company or its Affiliates, or solicit or attempt to solicit any such person to change or terminate his or her relationship with the

Company or an Affiliate or otherwise to become an employee, consultant or independent contractor to, for or of any other person or business entity, unless more than 12 months shall have elapsed between the last day of such person's employment or service with the Company or Affiliate and the first day of such solicitation or hiring or attempt to solicit or hire. If any employee, consultant or independent contractor is hired or solicited by any entity that has hired or agreed to hire the Executive, such hiring or solicitation shall be conclusively presumed to be a violation of this subsection (b).

(c) Nonsolicitation of Business Partners. The Executive agrees that during the Restriction Period, the Executive will not, either directly or through others, solicit, divert or appropriate, or attempt to solicit, divert or appropriate for the benefit of a Competitive Business, any (1) business partner or (2) prospective business partner of the Company or an Affiliate who is or was identified through leads developed during the course of the Executive's employment or service with the Company, in each case, with whom the Executive was involved as part of the Executive's job responsibilities during the Executive's employment or service with the Company, or regarding whom the Executive learned Proprietary Information (as defined below) during the Executive's employment or service with the Company.

(d) Proprietary Information. At all times, the Executive will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Proprietary Information (defined below) of the Company or an Affiliate, except as such disclosure, use or publication may be required in connection with the Executive's work for the Company or as described in Section 15(e) below, or unless the Company expressly authorizes such disclosure in writing. "Proprietary Information" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company and its Affiliates and shareholders, including but not limited to information relating to financial matters, investments, budgets, business plans, marketing plans, personnel matters, business contacts, products, processes, know-how, designs, methods, improvements, discoveries, inventions, ideas, data, programs, and other works of authorship. Proprietary Information does not include information which (1) was disclosed in response to a valid order by a court or other governmental body, where the Executive provided the Company with prior written notice of such disclosure, (2) was or becomes generally available to the public other than as a result of disclosure by the Executive or any of the Executive's agents, advisors or representatives, (3) was within the Executive's possession prior to its being furnished to the Executive by or on behalf of the Company, provided that the source of the information was not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to Executive by a contractual, legal or fiduciary obligation, or (4) was or becomes available to the Executive on a non-confidential basis from a source other than the Company or its representatives, provided that such source is not bound by a confidentiality agreement with the Company or otherwise prohibited from transmitting the information to the Executive by a contractual, legal or fiduciary obligation.

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



who disclose trade secrets to their attorneys, courts, or government officials in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

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

(g) Return of Company Property. Upon termination of the Executive's employment with the Company for any reason, and at any earlier time the Company requests, the Executive will (1) deliver to the person designated by the Company all originals and copies of all documents and property of the Company or an Affiliate that is in the Executive's possession or under the Executive's control or to which the Executive may have access, (2) deliver to the person designated by the Company all Company property, including keys, key cards, access cards, identification cards, security devices, employer credit cards, network access devices, computers, cell phones, smartphones, PDAs, pagers, fax machines, equipment, manuals, reports, files, books, compilations, work product, e-mail messages, recordings, disks, thumb drives or other removable information storage devices, hard drives, and data, and (3) to the extent that the Executive made use of the Executive's personal electronics (e.g., laptop, iPad, telephone, thumb drives, etc.) during employment with the Company, permit the Company to delete all Company property and information from such personal devices. The Executive will not reproduce or appropriate for the Executive's own use, or for the use of others, any property, Proprietary Information or Work Product.

16. Legal and Equitable Remedies.

(a) Because the Executive's services are personal and unique and the Executive has had and will continue to have access to and has become and will continue to become acquainted with the Proprietary Information of the Company and its Affiliates, and because any breach by the Executive of any of the restrictive covenants contained in Section 15 would result in irreparable

injury and damage for which money damages would not provide an adequate remedy, the Company shall have the right to enforce Section 15 and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach, or threatened breach, of the restrictive covenants set forth in Section 15. The Executive agrees that in any action in which the Company seeks injunction, specific performance or other equitable relief, the Executive will not assert or contend that any of the provisions of Section 15 are unreasonable or otherwise unenforceable.

(b) The Executive irrevocably and unconditionally (1) agrees that any legal proceeding arising out of this Agreement shall be brought solely in the United States District Court for the District of Massachusetts, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the State of Massachusetts, (2) consents to the exclusive jurisdiction of such court in any such proceeding, and (3) waives any objection to the laying of venue of any such proceeding in any such court. The Executive also irrevocably and unconditionally consents to the service of any process, pleadings, notices or other papers.

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

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

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

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

(a) The "Reduced Amount" shall be an amount expressed in present value which maximizes the aggregate present value of Payments under this Agreement without causing any

Payment under this Agreement to be subject to the Excise Tax (defined below), determined in accordance with section 280G(d)(4) of the Code. The term “Excise Tax” means the excise tax imposed under section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

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

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

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

If to the Company, to:

Replimune Inc.

18 Commerce Way

Woburn, MA 01801

Attn: Executive Chairman

with a copy to:

Morgan, Lewis & Bockius LLP  
One Federal Street

Boston, MA 02110

Attn: Gitte Blanchet

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

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

solely responsible for, all federal, state, and local taxes due with respect to any payment received under this Agreement.

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

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

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

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

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

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

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

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

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

***(Signature Page Follows)***

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

REPLIMUNE, INC.

/s/ Philip Astley-Sparke

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Name: Philip Astley-Sparke

Title: Executive Chairman

Date: November 27, 2019

EXECUTIVE

/s/ Jean Franchi

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Name: Jean Franchi

Date: November 27, 2019

Exhibit A

Biophytis SA (member of the Board of Directors)

Visionary Technologies (member of the Board of Directors)

Merrimack Pharmaceuticals (consultant pursuant to a Consulting Agreement dated June 25, 2019)

**EXHIBIT C**  
**AGREEMENT AND RELEASE**

In consideration of the payments, benefits and other compensation and benefits provided by Replimune, Inc. (the “Company”) as set forth in the Separation Agreement and Release dated May 18, 2023 (the “Separation Agreement”), which you acknowledge and agree is just and sufficient consideration for the waivers, releases and commitments set forth herein, by executing this Agreement and Release (“Release”) you hereby IRREVOCABLY AND UNCONDITIONALLY agree to WAIVE, RELEASE AND FOREVER DISCHARGE the Company Releasees (as defined in Section 3 of the Separation Agreement) from any and all claims legally capable of being waived, agreements, causes of action, attorneys’ fees, costs, damages, or any right to any monetary recovery or any other personal relief, whether known or unknown, in law or in equity, by contract, tort, law of trust or pursuant to federal, state or local statute, regulation, ordinance or common law, which you now have, ever have had, or may hereafter have, whether known or unknown to you, arising at any time up to the date of your execution of this Release, arising out of or relating in any way to your employment with the Company or the termination thereof.

Without limiting the generality of the foregoing, this waiver, release, and discharge includes any claim or right, to the extent legally capable of being waived, based upon or arising under any federal, state or local fair employment practices or equal opportunity laws, including, but not limited to, the Age Discrimination in Employment Act (“ADEA”) (29 U.S.C. Section 621, et seq.), 42 U.S.C. Section 1981, Title VII of the Civil Rights Act of 1964, the Equal Pay Act, the Employee Retirement Income Security Act (“ERISA”) (including, but not limited to, claims for breach of fiduciary duty under ERISA), the Americans With Disabilities Act, the Family and Medical Leave Act of 1993, the Massachusetts Fair Employment Practices Act, the Massachusetts Civil Rights Act, the Massachusetts Equal Rights Act, the Massachusetts Parental Leave Act, the Massachusetts Labor and Industries Act, the Massachusetts right of privacy law, the Massachusetts Wage Act (as further explained below), the Massachusetts Earned Sick Time law, the Massachusetts Equal Pay Act, the Massachusetts Minimum Fair Wage Law, as well as any claim or right under your Employment Agreement unless as provided herein.

**Massachusetts Wage Act Waiver.** By signing this Release, you acknowledge that this waiver includes any claims against the Company Releasees under Mass. Gen. Laws ch. 149, § 148 et seq.,—the Massachusetts Wage Act. These claims include, but are not limited to, claims for failure to pay earned wages, failure to pay overtime, failure to pay earned commissions, failure to timely pay wages, failure to pay accrued vacation or holiday pay, failure to furnish appropriate pay stubs, improper wage deductions, and failure to provide proper check-cashing facilities.

Notwithstanding the generality of the foregoing, nothing herein constitutes a release or waiver by you of, or prevents you from making or asserting: (i) any claim or right you may have under COBRA; (ii) any claim or right you may have for unemployment insurance or workers’ compensation benefits (other than for retaliation under workers’ compensation laws); (iii) any claim to vested benefits under the written terms of a qualified employee pension benefit plan; (iv) any claim for indemnity pursuant to Section 25 of your Employment Agreement, which is incorporated herein by reference; (v) any medical claim incurred during your employment that is payable under applicable medical plans or an employer-insured liability plan; (vi) any claim or right that may arise after the execution of this Release; (vii) any claim or right you may have under this Release; (viii) any claim that is not otherwise able to be waived under applicable law;



(ix) any claim or right that may arise after your execution of this Exhibit C; or (x) any claim or right you may have under this Exhibit C. In addition, nothing in this Exhibit C shall prevent you from filing a charge or complaint with the Equal Employment Opportunity Commission (“EEOC”) or similar federal or state fair employment practices agency or interfere with your ability to participate in any investigation or proceeding conducted by such agency; provided, however, that you understand and agree that, pursuant to the Separation Agreement (i) you are waiving any right to recover monetary damages or any other form of personal relief in connection with any such charge, action, investigation or proceeding; and (ii) to the extent you receive any such personal or monetary relief in connection with any such charge, complaint, investigation or proceeding, the Company will be entitled to an offset for the payments made pursuant to Section 2(b) of the Separation Agreement to the fullest extent permitted by law.

By signing this Exhibit C, you understand and acknowledge that you were advised of and afforded the opportunity to take advantage of each of the protections set forth in Section 13 of the Separation Agreement, including, but not limited to: (i) consultation with an attorney before signing this Exhibit C; (ii) at least twenty-one (21) calendar days in which to consider Exhibit C; and (iii) at least seven (7) calendar days in which to revoke Exhibit C after signature. You further acknowledge that you freely, voluntarily and knowingly entered into this Exhibit C after due consideration.

This Exhibit C incorporates by reference, as if set forth fully herein, all terms and conditions of the Separation Agreement between the Company and you, including the recitation of consideration provided by the Company. By signing this Exhibit C, you waive, release and forever discharge any and all claims that may have arisen through the date of your execution of this Exhibit C. It is not your intention to otherwise change, alter or amend any of the terms and conditions of the Separation Agreement, for which you received adequate consideration, and which Separation Agreement remains in full force and effect. You acknowledge and agree that you continue to be bound by the terms and conditions of the Separation Agreement.

This Exhibit C shall become effective upon the expiration of the seven (7) day revocation period described above, provided you have not exercised your right to revoke. You understand and agree that, should you fail to timely execute this Exhibit C, or if you timely execute but then revoke this Exhibit C, you shall not be eligible for and you shall not receive the severance benefits set forth in Section 2(b) of your Separation Agreement.

I UNDERSTAND AND ACKNOWLEDGE THAT I SHALL EXECUTE THIS EXHIBIT C ON, BUT NOT BEFORE, MY SEPARATION DATE WITH THE COMPANY.

UNDERSTOOD, AGREED TO

AND ACCEPTED WITH THE

INTENTION TO BE LEGALLY BOUND:

Date: June 7, 2023 \_\_\_\_\_ /s/ Jean Franchi \_\_\_\_\_  
Jean Franchi

**EXHIBIT B**  
**REPLIMUNE, INC.**

**CONSULTING AGREEMENT**

This CONSULTING AGREEMENT (this "Agreement") is dated as of May 18, 2023, by and between Replimune, Inc. (the "Company") and Jean Franchi (the "Consultant," together with the Company, the "Parties" and each, a "Party"). This Agreement will be effective on June 3, 2023. For the avoidance of doubt, if the Consultant does not execute or revokes the Separation Agreement and Release, dated of May 18, 2023, between the Company and the Consultant (the "Separation Agreement"), this Agreement shall not become effective, the Term (as defined in Section 3(a) below) of this Agreement shall not commence and this Agreement shall automatically terminate and become null and void ab initio.

1. Consulting Services.

(a) Subject to and upon the terms and conditions set forth in this Agreement, effective on June 3, 2023 (the "Start Date"), the Company hereby retains the Consultant, and the Consultant hereby agrees to be retained by the Company, to provide consulting services including transition support, completion of year-end and quarter-end requirements, completion of special projects and such other services as shall be determined and reasonably requested from time to time by the Chief Executive Officer, Executive Chairman, or Chief Financial Officer of the Company (the "Services").

(b) The amount of time that Consultant shall devote to the performance of the Services pursuant to this Agreement shall be: (i) with respect to the period beginning on the Start Date and ending on June 30, 2023, three days per week; (ii) with respect to the period beginning on July 1, 2023 and ending on September 30, 2023, two days per week; and (iii) with respect to the period beginning on October 1, 2023, and ending on December 31, 2023, one day per week.

(c) The Consultant shall provide the Services under this Agreement at such times and locations as are mutually agreed upon by the Consultant and the Company. In rendering the Services under this Agreement, the Consultant shall act solely as an independent contractor, the Consultant will not be eligible for any employee benefit plans or programs maintained by the Company, and this Agreement shall not be construed to create any employee/employer relationship between the Consultant and the Company.

(d) During the Term of this Agreement, and except to the extent otherwise agreed upon in writing by the Consultant and the Company, the Consultant will keep separate and not co-mingle (i) her Services for the Company, and (ii) any contact information obtained during her consulting relationship with the Company, with those provided, or pursuant to, any other consulting arrangements.

(e) It is understood and agreed that, subject to Section 11 of that certain Separation Agreement, the Consultant may be involved in any capacity in other businesses, endeavors and undertakings. The Consultant agrees that her continuing obligations under Section 11 of the Separation Agreement shall remain in full force and effect during the Term of this Agreement and are hereby incorporated by reference, provided, that, solely for purposes of this Section 1(e), the terms of the Separation Agreement are hereby modified such that reference therein to the term of the Consultant's employment with the Company and termination thereof shall include reference to the Consultant's consultancy pursuant to this Agreement and the termination thereof such that, for example, the non-solicitation covenants set forth in the Employment Agreement

and incorporated into the Separation Agreement and the non-competition covenants set forth in the Separation Agreement shall continue during the Term of this Agreement and for the one-year period thereafter. As consideration for the payments and continued vesting of the Options and RSUs (as each defined in Section 2(c) below), if applicable, the Consultant agrees to continue to abide by the terms of the Separation Agreement as modified pursuant to the foregoing provisions of this Section 1(e).

2. Compensation and Equity Awards.

(a) Consulting Fees.

- (i) Subject to, and in accordance with, the terms and conditions set forth in this Agreement, during the Term, the Consultant will be eligible for a consulting fee in an amount equal to \$1,950 for each day the Consultant has set aside for the performance of services as required by Section 1(b) above. For the avoidance of doubt, nothing in this Agreement shall entitle the Consultant to the consulting fee after the end of the Term.
- (ii) Consulting fees shall be paid in monthly installments within 30 days following the Consultant's submission to the Company of a monthly invoice. The Company will not withhold any income or other employment taxes from the payments due to the Consultant under this Agreement. The Consultant hereby agrees that she will timely pay all taxes and fees upon the income paid by the Company hereunder, and will indemnify and hold the Company harmless against the claims of any governmental taxing authority made in connection with the revenue derived by the Consultant under this Agreement.

(b) The Company shall reimburse the Consultant for any actual out-of-pocket expenses incurred by the Consultant while rendering Services under this Agreement so long as such expenses are reasonable and necessary, and appropriately documented and approved per the Company's standard practices. Without limiting the generality of the foregoing, any out-of-pocket travel expenses as well as any out-of-pocket expenses that, individually or in the aggregate, exceed \$500.00, shall be reimbursed by the Company only if approved by the Company in advance of such out-of-pocket expenses being incurred by the Consultant.

(c) All of the Consultant's stock options to purchase shares of Replimune Group, Inc.'s common stock ("Options") and restricted stock units on Replimune Group, Inc.'s common stock ("RSUs") that are unvested as of the Last Day of Employment (as defined in the Separation Agreement) will continue to vest in accordance with the terms of the governing plan and award agreements ("Award Agreements"), until the end of the Term (as defined in Section 3(b) below). The Parties to this Agreement expressly agree that, if there is a Change of Control (as defined in the Replimune Group, Inc. 2018 Omnibus Incentive Compensation Plan (the "Plan")) before the end of the Term of this Agreement, the Options and RSUs will be treated in accordance with the terms of the Plan and the Award Agreements.

(d) Except for the consulting fees described in Section 2(a), any expense reimbursement made in accordance with Section 2(b) hereof, and any Option and RSU vesting arrangement set forth in Section 2(c), the Company shall have no obligation to provide any compensation or benefits to the Consultant with respect to any Services rendered by the Consultant to the Company pursuant to this Agreement. The compensation and benefits set forth

in this Section 2 are separate and apart from the severance benefits provided under the Separation Agreement.

3. Term; Termination.

(a) This Agreement shall take effect as of the Start Date and shall continue thereafter in full force and effect until December 31, 2023, unless terminated earlier in accordance with the provisions of Section 3(b) hereof (the "Term"). The Consultant shall begin providing the Services to the Company on the Start Date.

(b) Upon a determination by the Company that the Consultant has breached this Agreement or the Separation Agreement or otherwise engaged in any willful misconduct that has the effect, or potential effect, of causing harm to the Company (monetarily, reputationally or otherwise), the Company may terminate this Agreement, upon 30 days' prior written notice to the Consultant and the provision to the Consultant of an opportunity to cure within such 30-day period. Upon a determination that the Company has breached this Agreement or the Separation Agreement or otherwise engaged in willful misconduct that has the effect, or potential effect, of causing harm to the Consultant (monetarily, reputationally or otherwise), the Consultant may terminate this Agreement upon 30 days' prior written notice to the Company and the provision to the Company of an opportunity to cure within such 30-day period. The Parties may also terminate this Agreement by mutual agreement. This Agreement and the Services provided by the Consultant hereunder shall terminate immediately upon the Consultant's death. Upon termination of this Agreement and the Services for any reason, the Company is only obligated to pay the Consultant any amounts owed for the Services performed through the date of termination. The provisions of Sections 1(e), 3(c), 4, 5, 6 and 7 of this Agreement and the entirety of the Separation Agreement, with Section 11 of that Agreement modified by the provisions of Section 1(e) herein, shall survive the termination of this Agreement.

(c) Upon expiration or termination of this Agreement, the Consultant agrees that she will not represent herself to third parties as continuing to have ongoing obligations to and with the Company, and will not hold herself out as having a role with the Company, nor have any authority to speak or act for or on behalf of the Company.

4. No Conflicting Obligation. The Consultant hereby represents that she is free to enter into this Agreement and that her performance of all of the terms of this Agreement and of all of her duties as a consultant to the Company do not and will not breach (i) any agreement to keep in confidence information acquired by the Consultant in confidence or in trust, (ii) any agreement to assign to any third party inventions made by the Consultant, or (iii) any agreement not to compete against the business of any third party. Consultant further represents that she has not made and will not make any agreements in conflict with this Agreement.

5. No Use of Name, Etc.

(a) Without the prior written consent of the Company, the Consultant shall not at any time use, for herself or on behalf of any other person, any name that is identical or similar to or likely to be confused with the name of the Company or any of Affiliate of the Company (as defined in Section 7(c) below) or any product or service produced or provided by the Company or any Affiliate of the Company.

(b) The Consultant shall not hold herself out as currently representing the Company without the prior written consent of the Company, unless it is within the scope of the Services

being provided for the Company. Matters and inquiries outside the scope of the Services and relating to the Company should be directed to the Chief Executive Officer of the Company.

(c) Nothing in this Agreement restricts or prohibits the Consultant from initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency, or from making other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation. The Consultant does not need the prior authorization of the Company to engage in conduct protected by this Section, and the Consultant does not need to notify the Company that she has engaged in such conduct. The Consultant should take notice that federal law provides criminal and civil immunity to federal and state claims for trade secret misappropriation to individuals who disclose a trade secret to their attorney, a court, or a government official in certain, confidential circumstances that are set forth at 18 U.S.C. §§ 1833(b)(1) and 1833(b)(2), related to the reporting or investigation of a suspected violation of the law, or in connection with a lawsuit for retaliation for reporting a suspected violation of the law.

6. Return of Property. The Consultant agrees to promptly return to the Company after the end of the Term or sooner if requested by Company all of its property, including, but not limited to, computers, files, and documents, including any correspondence or other materials containing trade secrets of the Company, identification cards, credit cards, keys, equipment, software and data, however stored other than as required to perform the consultancy services, as agreed with the Company. To the extent the Consultant has any Company information or material stored on any PDA, personal computer, personal email, hard drive, thumb drive, cloud or other electronic storage device, the Consultant agrees to cooperate with the Company in permanently deleting such information from such devices, subject to any Company litigation preservation directive then in effect.

7. Miscellaneous.

(a) This Agreement represents the entire Agreement of the parties with respect to the arrangements contemplated hereby. No prior agreement, whether written or oral, shall be construed to change, amend, alter, repeal or invalidate this Agreement. This Agreement may be amended only by a written instrument executed in one or more counterparts by the parties.

(b) No consent to or waiver of any breach or default in the performance of any obligations hereunder shall be deemed or construed to be a consent to or waiver of any other breach or default in the performance of any of the same or any other obligations hereunder. Failure on the part of either party to complain of any act or failure to act of the other party or to declare the other party in default, irrespective of the duration of such failure, shall not constitute a waiver of rights hereunder and no waiver hereunder shall be effective unless it is in writing, executed by the party waiving the breach or default hereunder.

(c) This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. This Agreement may be assigned by the Company to any Affiliate of the Company (as long as the Company remains secondarily liable for any payments or obligations hereunder) and to a successor of its business to which this Agreement relates (whether by purchase or otherwise). "Affiliate of the Company," means any person or entity which, directly or indirectly, controls or is controlled by or is under common control with the Company and, for the purposes of this definition, "control" (including the terms "controlled by" and "under common control with") shall mean the possession, directly or

indirectly, of the power to direct or cause the direction of the management and policies of another whether through the ownership of voting securities or holding of office in another, by contract or otherwise. The Consultant may not assign or transfer any or all of her rights or obligations under this Agreement; provided, that, any amounts due under this Agreement upon or following the Consultant's death shall be paid to Consultant's estate or beneficiaries, as applicable.

(d) Unless otherwise provided herein, any notice, report, payment or document to be given by one Party to the other shall be in writing and shall be deemed given when delivered personally or mailed by certified or registered mail, postage prepaid (such mailed notice to be effective on the date which is three (3) business days after the date of mailing), or sent by nationally recognized overnight courier (such notice sent by courier to be effective one business day after it is deposited with such courier), or sent by email (such notice sent by email to be effective when sent, if confirmed by certified or registered mail or overnight courier as aforesaid), or sent by telefax (such notice sent by telefax to be effective when sent, if confirmed by certified or registered mail or overnight courier as aforesaid) addressed to the Party at the address set forth on the signature page to this Agreement or to such other place as any Party may designate as to itself by written notice to the other Party. Either Party may change its address for notices by means of a notice delivered in accordance with this Section 7(d). Notwithstanding the foregoing, all such notices, reports, payments or documents provided by the Company to the Consultant shall be sent by email (in addition to any other form of delivery chosen by the Company) to the Consultant at his personal email address on file with the Company.

(e) This Agreement shall be governed by and construed in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to any choice or conflict of laws rule or provision that would result in the application of the substantive law of any other jurisdiction. Section headings of this Agreement are for reference only and shall not affect its interpretation. In the event that any provision of this Agreement should be held unenforceable by a court of competent jurisdiction, such court is hereby authorized to amend such provision so as to be enforceable to the fullest extent permitted by law, and all remaining provisions shall continue in full force without being impaired or invalidated in any way.

(f) The parties agree that any breach or threatened breach of Sections 1(e), 4, 5, 6 or 7 of this Agreement by the Consultant may cause irreparable harm to the Company; and that money damages will not provide an adequate remedy. In the event of a breach or threatened breach of Sections 1(e), 4, 5, 6 or 7 of this Agreement by the Consultant, the Company shall, in addition to any other rights and remedies it may have, be entitled to seek an injunction, without the need to post bond.

(g) This Agreement may be executed in counterparts, all of which together shall for all purposes constitute one agreement binding on each of the parties hereto notwithstanding that each such Party shall not have signed the same counterpart.

*[Signature Page Follows]*

IN WITNESS WHEREOF, the parties have signed this Agreement as of the date first above written, intending it to take effect as a sealed instrument.

**REPLIMUNE, INC.**

By: /s/ Philip Astley-Sparke  
Name: Philip Astley-Sparke  
Title: CEO  
Address: 500 Unicorn Park, Woburn MA 01801  
Email:

**CONSULTANT**

By: /s/ Jean Franchi  
Jean Franchi

Address:

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Email: \_\_\_\_\_

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

I, Philip Astley-Sparke, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Replimune Group, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.



Date: August 3, 2023

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, Andrew Schwendenman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Replimune Group, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2023

By: /s/ Andrew Schwendenman  
Andrew Schwendenman  
Chief Accounting Officer  
(Principal Accounting 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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Philip Astley-Sparke, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 3, 2023

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 June 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Andrew Schwendenman, Chief Accounting Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 3, 2023

By: /s/ Andrew Schwendenman  
*Andrew Schwendenman*  
*Chief Accounting Officer*  
*(Principal Accounting Officer)*