

**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, 2026

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

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

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

The number of shares of the registrant's Common Stock, par value \$0.001 per share, outstanding as of August 11, 2026 was 94,219,634.



## REPLIMUNE GROUP, INC.

## FORM 10-Q

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# PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements.

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

|                                                                                                                                                                                                                     | June 30, 2026     | March 31, 2026    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|
| <b>Assets</b>                                                                                                                                                                                                       |                   |                   |
| Current assets:                                                                                                                                                                                                     |                   |                   |
| Cash and cash equivalents                                                                                                                                                                                           | \$ 185,359        | \$ 209,024        |
| Short-term investments                                                                                                                                                                                              | 9,969             | 59,865            |
| Research and development incentives receivable                                                                                                                                                                      | —                 | 1,619             |
| Prepaid expenses and other current assets                                                                                                                                                                           | 5,479             | 8,611             |
| Total current assets                                                                                                                                                                                                | 200,807           | 279,119           |
| Property, plant and equipment, net                                                                                                                                                                                  | 11,858            | 12,974            |
| Restricted cash                                                                                                                                                                                                     | 1,703             | 1,703             |
| Other non-current assets                                                                                                                                                                                            | 3,238             | 2,942             |
| Right-of-use asset - operating leases                                                                                                                                                                               | 3,068             | 3,270             |
| Right-of-use asset - finance leases                                                                                                                                                                                 | 31,773            | 32,380            |
| Total assets                                                                                                                                                                                                        | <u>\$ 252,447</u> | <u>\$ 332,388</u> |
| <b>Liabilities and Stockholders' Equity</b>                                                                                                                                                                         |                   |                   |
| Current liabilities:                                                                                                                                                                                                |                   |                   |
| Accounts payable                                                                                                                                                                                                    | \$ 4,261          | \$ 6,671          |
| Accrued expenses and other current liabilities                                                                                                                                                                      | 30,111            | 47,516            |
| Operating lease liabilities, current                                                                                                                                                                                | 1,136             | 1,158             |
| Finance lease liabilities, current                                                                                                                                                                                  | 2,904             | 2,883             |
| Total current liabilities                                                                                                                                                                                           | 38,412            | 58,228            |
| Operating lease liabilities, non-current                                                                                                                                                                            | 2,136             | 2,328             |
| Finance lease liabilities, non-current                                                                                                                                                                              | 21,685            | 21,909            |
| Long term debt, net of discount                                                                                                                                                                                     | 84,114            | 83,308            |
| Other liabilities, non-current                                                                                                                                                                                      | 455               | 455               |
| Total liabilities                                                                                                                                                                                                   | 146,802           | 166,228           |
| Commitments and contingencies (Note 14)                                                                                                                                                                             |                   |                   |
| Stockholders' equity                                                                                                                                                                                                |                   |                   |
| Common stock, \$0.001 par value; 150,000,000 shares authorized as of June 30, 2026 and March 31, 2026; 83,979,366 and 82,716,923 shares issued and outstanding as of June 30, 2026 and March 31, 2026, respectively | 84                | 82                |
| Additional paid-in capital                                                                                                                                                                                          | 1,431,870         | 1,423,194         |
| Accumulated deficit                                                                                                                                                                                                 | (1,332,285)       | (1,262,519)       |
| Accumulated other comprehensive income                                                                                                                                                                              | 5,976             | 5,403             |
| Total stockholders' equity                                                                                                                                                                                          | <u>\$ 105,645</u> | <u>\$ 166,160</u> |
| Total liabilities and stockholders' equity                                                                                                                                                                          | <u>\$ 252,447</u> | <u>\$ 332,388</u> |

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

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

|                                                               | Three Months Ended June 30, |             |
|---------------------------------------------------------------|-----------------------------|-------------|
|                                                               | 2026                        | 2025        |
| Operating expenses:                                           |                             |             |
| Research and development                                      | \$ 49,277                   | \$ 57,843   |
| Selling, general and administrative                           | 18,970                      | 32,579      |
| Total operating expenses                                      | 68,247                      | 90,422      |
| Loss from operations                                          | (68,247)                    | (90,422)    |
| Other income (expense):                                       |                             |             |
| Research and development incentives                           | 296                         | 420         |
| Investment income                                             | 1,960                       | 4,714       |
| Interest expense on finance lease liability                   | (506)                       | (521)       |
| Interest expense on debt obligations                          | (2,581)                     | (1,475)     |
| Other (expense) income, net                                   | (688)                       | 591         |
| Total other (expense) income, net                             | (1,519)                     | 3,729       |
| Net loss                                                      | \$ (69,766)                 | \$ (86,693) |
| Net loss per common share, basic and diluted                  | \$ (0.72)                   | \$ (0.95)   |
| Weighted average common shares outstanding, basic and diluted | 96,864,452                  | 91,516,199  |

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>2026</b>                        | <b>2025</b>        |
| Net loss                                      | \$ (69,766)                        | \$ (86,693)        |
| Other comprehensive gain (loss):              |                                    |                    |
| Foreign currency translation gain (loss)      | 582                                | (938)              |
| Net unrealized loss on short-term investments | (9)                                | (269)              |
| Comprehensive loss                            | <u>\$ (69,193)</u>                 | <u>\$ (87,900)</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<br>paid-in<br>capital | Accumulated<br>deficit | Accumulated<br>other<br>comprehensive<br>income | Total<br>stockholders'<br>equity |
|-------------------------------------------|--------------|--------|----------------------------------|------------------------|-------------------------------------------------|----------------------------------|
|                                           | Shares       | Amount |                                  |                        |                                                 |                                  |
| <b>Balances as of March 31, 2026</b>      | 82,716,923   | \$ 82  | \$ 1,423,194                     | \$ (1,262,519)         | \$ 5,403                                        | \$ 166,160                       |
| Foreign currency translation adjustment   | —            | —      | —                                | —                      | 582                                             | 582                              |
| Unrealized loss on short-term investments | —            | —      | —                                | —                      | (9)                                             | (9)                              |
| Exercise of stock options                 | 118,075      | 1      | 1,003                            | —                      | —                                               | 1,004                            |
| Vesting of RSUs                           | 1,144,368    | 1      | (1)                              | —                      | —                                               | —                                |
| Stock-based compensation expense          | —            | —      | 7,674                            | —                      | —                                               | 7,674                            |
| Net loss                                  | —            | —      | —                                | (69,766)               | —                                               | (69,766)                         |
| <b>Balances as of June 30, 2026</b>       | 83,979,366   | 84     | 1,431,870                        | (1,332,285)            | 5,976                                           | 105,645                          |
| <b>Balances as of March 31, 2025</b>      | 77,085,024   | \$ 77  | \$ 1,358,897                     | \$ (948,579)           | \$ 5,448                                        | \$ 415,843                       |
| Foreign currency translation adjustment   | —            | —      | —                                | —                      | (938)                                           | (938)                            |
| Unrealized loss on short-term investments | —            | —      | —                                | —                      | (269)                                           | (269)                            |
| Exercise of stock options                 | 966          | —      | 8                                | —                      | —                                               | 8                                |
| Vesting of RSUs                           | 721,184      | 1      | 1                                | —                      | —                                               | 2                                |
| Stock-based compensation expense          | —            | —      | 8,762                            | —                      | —                                               | 8,762                            |
| Net loss                                  | —            | —      | —                                | (86,693)               | —                                               | (86,693)                         |
| <b>Balances as of June 30, 2025</b>       | 77,807,174   | 78     | 1,367,668                        | (1,035,272)            | 4,241                                           | 336,715                          |

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>2026</b>                        | <b>2025</b> |
| <b>Cash flows from operating activities:</b>                                          |                                    |             |
| Net loss                                                                              | \$ (69,766)                        | \$ (86,693) |
| Adjustments to reconcile net loss to net cash used in operating activities:           |                                    |             |
| Stock-based compensation expense                                                      | 7,674                              | 8,762       |
| Depreciation and amortization                                                         | 937                                | 873         |
| Operating lease, right-of-use-asset amortization                                      | 206                                | 185         |
| Finance lease, right-of-use-asset amortization                                        | 607                                | 607         |
| Net amortization of premiums and discounts on short-term investments                  | (112)                              | (1,339)     |
| Impairment on property, plant and equipment                                           | 108                                | —           |
| Noncash interest expense                                                              | 806                                | 415         |
| Unrealized foreign currency transaction (gains) losses                                | (688)                              | 591         |
| Changes in operating assets and liabilities:                                          |                                    |             |
| Research and development incentives receivable                                        | 1,347                              | 1,631       |
| Prepaid expenses and other current assets                                             | 3,129                              | 234         |
| Accounts payable                                                                      | (2,334)                            | 3,765       |
| Accrued expenses and other current liabilities                                        | (17,424)                           | (5,536)     |
| Operating lease liabilities                                                           | (218)                              | (195)       |
| Other non-current liabilities                                                         | —                                  | (316)       |
| Net cash used in operating activities                                                 | (75,728)                           | (77,016)    |
| <b>Cash flows from investing activities:</b>                                          |                                    |             |
| Purchases of property, plant and equipment and software capitalization                | (6)                                | (2,740)     |
| Purchase of short-term investments                                                    | (9,884)                            | (37,581)    |
| Proceeds from sales and maturities of short-term investments                          | 59,883                             | 105,369     |
| Net cash provided by investing activities                                             | 49,993                             | 65,048      |
| <b>Cash flows from financing activities:</b>                                          |                                    |             |
| Principal payment of finance lease obligation                                         | (203)                              | (166)       |
| Proceeds from exercise of stock options                                               | 1,003                              | 8           |
| Net cash provided by (used in) financing activities                                   | \$ 800                             | \$ (158)    |
| <b>Effect of exchange rate changes on cash, cash equivalents and restricted cash</b>  | 1,270                              | (1,616)     |
| <b>Net decrease in cash, cash equivalents and restricted cash</b>                     | (23,665)                           | (13,742)    |
| Cash, cash equivalents and restricted cash at beginning of period                     | 210,727                            | 112,822     |
| Cash, cash equivalents and restricted cash at end of period                           | \$ 187,062                         | \$ 99,080   |
| <b>Supplemental disclosure of cash flow information:</b>                              |                                    |             |
| Cash paid during the period for interest                                              | 1,775                              | 1,059       |
| Cash paid for income taxes, net                                                       | 33                                 | —           |
| <b>Supplemental disclosure of non-cash investing and financing activities:</b>        |                                    |             |
| Purchases of property and equipment included in accounts payable and accrued expenses | 3                                  | 645         |

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 commercial-stage biotechnology company with the mission to transform cancer treatment by pioneering the development of a novel portfolio of oncolytic immunotherapies. The Company's proprietary oncolytic immunotherapy product and 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 companies in the biotechnology industry, including, but not limited to, those related to the development and commercialization of our product and product candidates, our ability to successfully complete one or more confirmatory trials of TUDRIQEV (vusolimogene oderparepvec-wtpg), previously referred to as RP1, our expectations about our cash runway, the design and advancement of our clinical trials, the requirements and views of regulators, the 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 review and 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 revenue from product sales.

The Company's proprietary RPx platform is based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with added payloads that are intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. In addition to TUDRIQEV, the Company currently has two further RPx product candidates, RP2 and RP3. We have been conducting a number of clinical trials of TUDRIQEV, both as a monotherapy and in combination with anti-PD-1 therapy with the goal of establishing a major skin cancer treatment franchise.

### **Basis of presentation**

The accompanying condensed 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 \$69.8 million and \$86.7 million for the three months ended June 30, 2026 and 2025, respectively. In addition, as of June 30, 2026, the Company had an accumulated deficit of \$1,332.3 million.

The Company expects to continue to generate operating losses for the foreseeable future and will need to finance its future cash needs through any or a combination of equity offerings, debt financings, collaborations, strategic partnerships and alliances or licensing arrangements. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate some or all of its research and development programs, preclinical and clinical testing or commercialization efforts, which could adversely affect its business prospects. As described in the Company's Annual Report on Form 10-K for the year ended March 31, 2026, substantial doubt existed about the Company's ability to continue as a going concern. The conditions that raised substantial doubt have been subsequently alleviated, as the Company raised approximately \$141.0 million in net proceeds from an equity offering in August 2026. The Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operations for greater than twelve months from the issuance of these condensed consolidated financial statements, which includes the commercialization of TUDRIQEV in advanced melanoma and for working capital and general corporate purposes. These estimates are based on assumptions that may prove to be wrong and the Company could utilize its available capital resources sooner than expected.

## **2. Summary of significant accounting policies**

### ***Principles of consolidation***

The accompanying condensed 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed 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 condensed consolidated balance sheet as of June 30, 2026, the condensed consolidated statements of operations, condensed consolidated statements of comprehensive loss and consolidated statements of stockholders' equity for the three months ended June 30, 2026 and 2025 and the condensed consolidated statements of cash flows for the three months ended June 30, 2026 and 2025 are unaudited. The unaudited interim condensed 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 statement of the Company's financial position as of June 30, 2026 and the results of its operations for the three months ended June 30, 2026 and 2025 and its cash flows for the three months ended June 30, 2026 and 2025. The financial data and other information disclosed in these consolidated notes related to the three months ended June 30, 2026 and 2025 are unaudited. The results for the three months ended June 30, 2026 are not necessarily indicative of results to be expected for the year ending March 31, 2027, 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, 2026, which was filed with the U.S. Securities and Exchange Commission, or the SEC, on June 29, 2026 (the "Annual Report").

During the three months ended June 30, 2026, there have been no changes to the Company's significant accounting policies as described in the Annual Report.

### *Recently Issued Accounting Pronouncements*

In November 2024, the FASB issued ASU-2024-03, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Topic 220): Disaggregation of Income Statement Expenses. The ASU requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, "Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40) Targeted Improvements to the Accounting for Internal-Use Software (ASU 2025-06)", which is intended to simplify the capitalization guidance for internal-use software by removing references to project stages and clarifying when the capitalizing of eligible costs is required. The new guidance is effective for annual periods beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted. ASU 2025-06 may be applied retrospectively or prospectively. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements and related disclosures.

### **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<br>June 30, 2026 Using:  |         |            |         |            |
|--------------------------------------------------------|---------|------------|---------|------------|
|                                                        | Level 1 | Level 2    | Level 3 | Total      |
| Cash equivalents                                       |         |            |         |            |
| Money market funds                                     | \$ —    | \$ 37,513  | \$ —    | \$ 37,513  |
| US Government Agency bonds                             | —       | 4,984      | —       | 4,984      |
| US Treasury bonds                                      | —       | 39,939     | —       | 39,939     |
| Short-term investments                                 |         |            |         |            |
| US Government Agency bonds                             | —       | 9,969      | —       | 9,969      |
|                                                        | —       | 92,405     | —       | 92,405     |
| Fair Value Measurements as of<br>March 31, 2026 Using: |         |            |         |            |
|                                                        | Level 1 | Level 2    | Level 3 | Total      |
| Cash equivalents                                       |         |            |         |            |
| Money market funds                                     | \$ —    | \$ 104,275 | \$ —    | \$ 104,275 |
| US Government Agency bonds                             | —       | 15,998     | —       | 15,998     |
| Short-term investments                                 |         |            |         |            |
| US Government Agency bonds                             | —       | 3,984      | —       | 3,984      |
| US Treasury bonds                                      | —       | 55,881     | —       | 55,881     |
|                                                        | —       | 180,138    | —       | 180,138    |

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

During the three months ended June 30, 2026 and 2025, 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.

#### 4. Short-term investments

As of June 30, 2026 and March 31, 2026, the Company's available-for-sale investments by type consisted of the following:

| June 30, 2026              |                |                        |                         |               |            |
|----------------------------|----------------|------------------------|-------------------------|---------------|------------|
|                            | Amortized cost | Gross unrealized gains | Gross unrealized losses | Credit Losses | Fair value |
| US Government agency bonds | \$ 9,970       | \$ —                   | \$ (1)                  | \$ —          | \$ 9,969   |
| Total                      | \$ 9,970       | \$ —                   | \$ (1)                  | \$ —          | \$ 9,969   |
| March 31, 2026             |                |                        |                         |               |            |
|                            | Amortized cost | Gross unrealized gains | Gross unrealized losses | Credit Losses | Fair value |
| US Government agency bonds | \$ 3,985       | \$ —                   | \$ (1)                  | \$ —          | \$ 3,984   |
| US Treasury bonds          | 55,872         | 9                      | —                       | —             | 55,881     |
| Total                      | \$ 59,857      | \$ 9                   | \$ (1)                  | \$ —          | \$ 59,865  |

As of June 30, 2026 and March 31, 2026, available-for-sale securities consisted of investments that mature within one year.

## 5. Property, plant and equipment, net

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

|                                               | June 30, 2026 | March 31, 2026 |
|-----------------------------------------------|---------------|----------------|
| Office equipment                              | \$ 1,897      | \$ 1,897       |
| Computer equipment                            | 2,516         | 2,441          |
| Plant, manufacturing and laboratory equipment | 12,727        | 12,325         |
| Leasehold improvements                        | 2,504         | 2,504          |
| Capitalized software                          | 9,736         | 9,736          |
| Construction in progress                      | 146           | 802            |
| Total property, plant and equipment           | 29,526        | 29,705         |
| Less: Accumulated depreciation                | (17,668)      | (16,731)       |
| Property, plant and equipment, net            | \$ 11,858     | \$ 12,974      |

Depreciation and amortization expense, including amortization on capitalized software, was \$0.9 million for the three months ended June 30, 2026 and \$0.9 million for the three months ended June 30, 2025. Amortization on capitalized software for the three months ended June 30, 2026 and 2025 was \$0.3 million and \$0.3 million, respectively. Depreciation and amortization 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:

|                                                      | June 30, 2026 | March 31, 2026 |
|------------------------------------------------------|---------------|----------------|
| Accrued research and development costs               | \$ 21,716     | \$ 26,740      |
| Accrued compensation and benefits costs              | 5,127         | 17,483         |
| Accrued professional fees                            | 1,230         | 537            |
| Other                                                | 2,038         | 2,756          |
| Total accrued expenses and other current liabilities | \$ 30,111     | \$ 47,516      |

## 7 Debt

On October 6, 2022, the Company and certain of its subsidiaries 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 have drawn, but did not draw down, an additional \$30.0 million on or prior to September 30, 2023. The Company can also draw 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 pursuant to which the Company agreed 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 reflects a decrease of \$30.0 million from the \$60.0 million in the original Loan Agreement for tranche 1. The total amount of the Loan Agreement, as well as the outstanding balance of the loan, was unchanged, but the option to borrow additional funds were redistributed from tranche 1 to tranche 2.

A second amendment was made to the Loan Agreement (the "Second Amendment") on December 22, 2023 pursuant to which the Company agreed to draw a term loan advance in an aggregate principal amount not less than \$15.0 million, provided that the aggregate amount of the term loan advances made under tranche 2 do not exceed \$15.0 million on or prior to December 31, 2023. The Second Amendment re-allocated the total future consideration of the Loan Agreement to the future

tranches extending through September 2026, subject to the terms and conditions of the Loan Agreement. The Second Amendment did not change the total aggregate maximum principal amount to be drawn under the Loan Agreement, which remained up to \$200.0 million. Upon closing of the Second Amendment on December 22, 2023, the Company drew down the tranche 2 amount of \$15.0 million.

A third amendment was made to the Loan Agreement (the "Third Amendment") on January 29, 2026 (the "Third Amendment Closing Date") pursuant to which the Company drew down the tranche 3 loan advance amount of \$35.0 million. The Third Amendment maintains a \$200.0 million maximum principal amount and re-allocates the future tranches extending through December 2027, subject to the terms and conditions of the Loan Agreement. In addition, the Third Amendment extended the amortization date, with a balloon payment, inclusive of accrued interest and principal due on the maturity date of October 1, 2027 with the caveat that if the Company receives FDA approval prior to October 1, 2027, the amortization and maturity date shall be extended to October 1, 2029. As a result of the Company's receipt of approval from the FDA, the maturity date has been extended to October 1, 2029. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through September 2029, with the outstanding principal balance of the Term Loan Facility bearing interest payable in cash at a floating rate per annum equal to the greater of (i) 8.50% and (ii) the Prime Rate plus 1.75%.

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.

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 Third Amendment Closing Date, 2.0% after 12 months following the Third Amendment 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 the Company 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 which commenced on January 1, 2024. In addition, the Loan Agreement, as amended, also contains a financial covenant that beginning on the later of (i) July 1, 2026 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. The amount accrued for the final payment is \$2.1 million as of June 30, 2026 and \$1.7 million as of March 31, 2026.

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 of \$0.4 million and \$0.5 million were recorded in other assets as of June 30, 2026 and March 31, 2026, respectively. Interest expense for the three months ended June 30, 2026 was \$2.6 million and \$1.5 million for the three months ended June 30, 2025.

The summary of obligations under the term loan as of June 30, 2026 and March 31, 2026 consisted of the following (in thousands):

|                                   | June 30, 2026    | March 31, 2026   |
|-----------------------------------|------------------|------------------|
| Principal loan balance            | \$ 82,564        | \$ 82,252        |
| Facility charge and diligence fee | (96)             | (120)            |
| Unamortized issuance costs        | (430)            | (536)            |
| Accumulated end of term fee       | 2,076            | 1,712            |
| Long term debt, net of discount   | <u>\$ 84,114</u> | <u>\$ 83,308</u> |

The annual principal payments due under the Loan Agreement as of fiscal June 30, 2026 and March 31, 2026 were as follows:

|       | June 30, 2026 | March 31, 2026 |
|-------|---------------|----------------|
| 2027  | \$ —          | \$ —           |
| 2028  | 84,150        | 84,150         |
| Total | \$ 84,150     | \$ 84,150      |

The table of future payments of long-term debt excludes the end of term charge of \$4.0 million, which is due upon the maturity of the loan.

## 8 Stockholders' equity

### *Common stock*

As of June 30, 2026 and March 31, 2026, 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 stock 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:

|                                                           | June 30, 2026 | March 31, 2026 |
|-----------------------------------------------------------|---------------|----------------|
| Stock options, issued and outstanding                     | 12,492,872    | 11,711,111     |
| Restricted and performance stock units                    | 4,825,591     | 5,500,000      |
| Stock options and restricted stock units, future issuance | 3,696,006     | 1,500,000      |
| Employee stock purchase plan, available for future grants | 4,799,623     | 4,100,000      |
| Pre-funded warrants                                       | 14,058,153    | 14,000,000     |
| Total shares of common stock reserved for future issuance | 39,872,245    | 37,000,000     |

### *Undesignated preferred stock*

As of June 30, 2026, 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, 2026.

### *ATM program*

On August 3, 2023, the Company and Leerink Partners LLC (the "Agent") entered into a sales agreement, which was subsequently amended on May 16, 2024, November 25, 2024 and May 22, 2025 (as so amended, the "2023 Sales Agreement"). Under the 2023 Sales Agreement, the Company may sell, from time to time, at its option, up to an aggregate of \$100.0 million of shares of the Company's common stock, \$0.001 par value shares (the "Shares"), through the Agent, as the Company's sales agent.

Any Shares to be offered and sold under the 2023 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 SEC on November 6, 2025, which became effective in accordance with the provisions of Section 8(a) of the Securities Act of 1933, as may be amended from time to time, for an offering 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 2023 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 year ended March 31, 2026, pursuant to the 2023 Sales Agreement, the Company issued and sold an aggregate of 4,019,975 shares of its common stock, resulting in net proceeds of \$31.1 million, with \$67.9 million left to sell under the Agreement.

During the three months ended June 30, 2026 and 2025, the Company did not issue or sell any shares under the 2023 Sales Agreement. The Company cannot provide any assurances that it will issue any Shares pursuant to the 2023 Sales Agreement.

### ***Equity offerings***

On June 14, 2024, the Company completed a private placement transaction (the "Private Placement") pursuant to which the Company sold (a) 5,668,937 shares of the Company's common stock, at an offering price of \$8.82, and (b) in lieu of common stock to certain investors, pre-funded warrants to purchase 5,669,578 shares of the Company's common stock at an offering price of \$8.819 per pre-funded warrant (the "June 2024 Pre-funded Warrants"). The Company received aggregate net proceeds in the Private Placement of approximately \$96.7 million after deducting placement agent fees and other offering expenses payable by the Company of approximately \$3.3 million.

On November 25, 2024, the Company completed a public offering of (a) 8,538,377 shares of the Company's common stock, inclusive of the underwriters fully exercised 30-day option to purchase up to 1,615,377 additional shares of the Company's common stock at a public offering price of \$13.00 per share, and (b) pre-funded warrants to purchase 3,846,184 shares of the Company's common stock at a public offering price of \$12.9999 per pre-funded warrant (the "December 2024 Pre-Funded Warrants"). The company received aggregate net proceeds of approximately \$156.0 million after deducting fees and expenses of approximately \$5.0 million.

## **9 Pre-funded Warrants**

The Company's pre-funded warrants are exercisable at any time after the date of their issuance. As of June 30, 2026, unless otherwise modified by a holder of a pre-funded warrant, no holder may exercise a pre-funded warrant (i) if such holder, together with its affiliates, would beneficially own more than 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise, or (ii) if the combined voting power of our securities beneficially owned by such holder, together with its affiliates, would exceed 9.99% (or, in the case of the December 2024 Pre-Funded Warrants, 4.99%) of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise of such pre-funded warrants, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. A holder of the June 2024 Pre-funded Warrants may increase or decrease this percentage to any other percentage not in excess of 9.99%, whereas a holder of the Company's other Pre-funded Warrants, may increase or decrease this percentage up to 19.99%, in all cases, by providing at least 61 days' prior notice to the Company.

The 14,058,153 shares of the Company's common stock underlying the pre-funded warrants issued by the Company are not included in the number of issued and outstanding shares of the Company's common stock as reported on the consolidated balance sheet, though they are included in the Company's annual pool increase calculation as described in Note 10, as well as the weighted average outstanding common stock in the calculation of basic and diluted net loss per share, as described below in Note 11.

## **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<br/>June 30,</b> |                 |
|-------------------------------------|----------------------------------------|-----------------|
|                                     | <b>2026</b>                            | <b>2025</b>     |
| Research and development            | \$ 3,615                               | \$ 4,689        |
| Selling, general and administrative | 4,059                                  | 4,073           |
|                                     | <u>\$ 7,674</u>                        | <u>\$ 8,762</u> |

The following table summarizes stock-based compensation expense by award type for the three months ended June 30, 2026 and 2025:

|                                        | Three Months Ended<br>June 30, |                 |
|----------------------------------------|--------------------------------|-----------------|
|                                        | 2026                           | 2025            |
| Stock options                          | \$ 3,460                       | \$ 4,137        |
| Restricted and performance stock units | 4,214                          | 4,625           |
|                                        | <u>\$ 7,674</u>                | <u>\$ 8,762</u> |

### ***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 14,058,153 shares issuable upon exercise of those pre-funded warrants as of March 31, 2026, as described in Note 9 to these condensed consolidated financial statements, or such lesser amount as determined by the Board. On April 1, 2026, the number of shares reserved for issuance under the 2018 Plan automatically increased by 3,871,003 shares pursuant to the terms of the 2018 Plan and based on total number of shares of common stock outstanding on March 31, 2026. As of June 30, 2026, 3,696,006 shares remained available for future grants under the 2018 Plan.

The 2018 Plan is 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 plan is 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.

In 2024, the Company's board of directors approved the award of performance stock units ("PSUs"), under the 2018 Plan in addition to the aforementioned stock option awards and RSUs available as part of the Company's equity incentive for employees, officers, advisors and consultants of the Company, subject to non-market performance and service conditions. The grant date fair value for the PSUs is determined based on the market price of the Company's common stock on the grant date and expense is recognized over the requisite service period if and when the achievement of such performance condition is determined to be probable by the Company. On June 30, 2026, the compensation committee of the board of directors agreed to extend the performance period with respect to the "Target" performance level set forth in the PSU Award Agreement to end on December 24, 2026. Accordingly, the PSUs will vest at 100% given the approval of the Company's first Biologics License Application ("BLA") for TUDRIQEV by the Food and Drug Administration ("FDA"). The timing of recognition of this stock-based compensation expense is subject to our judgment as to when the performance conditions are considered probable of being

achieved. The Company did not grant any PSUs under the 2018 Plan during the three months ended June 30, 2026 or 2025. The Company reassesses the probability of achieving the performance condition at each reporting period. As of June 30, 2026, the Company has not recognized any expense related to PSUs.

### ***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 14,058,153 shares issuable upon exercise of those pre-funded warrants described in Note 9 to these condensed 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, 2026, the number of shares reserved for issuance under the ESPP automatically increased by 697,224, for a total of 4,799,623 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***

From time to time, the Company grants equity awards to newly hired employees and executives as a material inducement to enter into employment with the Company. The grants constitute "employment inducement grants" in accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules and have been issued outside of the 2018 Plan and each of the other stock incentive plans described above. The inducement grants typically include nonqualified stock options to purchase shares of the Company's common stock, as well as restricted stock unit grants representing 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 grants are included in the stock option and RSU award tables below. The Company did not grant any out-of-plan inducement grants during the three months ended June 30, 2026. During the three months ended June 30, 2025, the Company granted 156,895 nonqualified stock options to purchase shares of the Company's common stock, and 240,960 restricted stock units under employment inducement grants.

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

The fair value of stock option grants is estimated 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 determined by reference to the U.S Treasury yield curve in effect at the time of grant of the award for a period that approximates the expected term of the option, and our expected dividend yield. The expected term of stock options granted to non-employees is equal to the contractual term of the option 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. 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.

Forfeitures are accounted for as they occur.

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:

|                          | <b>Three Months Ended<br/>June 30,</b> |             |
|--------------------------|----------------------------------------|-------------|
|                          | <b>2026</b>                            | <b>2025</b> |
| Risk-free interest rate  | 4.06 %                                 | 3.97 %      |
| Expected term (in years) | 6.0                                    | 6.0         |
| Expected volatility      | 106.7 %                                | 76.3 %      |
| Expected dividend yield  | 0 %                                    | 0 %         |

### Stock options

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

|                                                         | Number of<br>Shares | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Contractual<br>Term (Years) | Aggregate<br>Intrinsic<br>Value |
|---------------------------------------------------------|---------------------|------------------------------------------|----------------------------------------------------|---------------------------------|
| Outstanding as of March 31, 2026                        | 11,785,458          | \$ 14.12                                 | 5.63                                               | \$ 4,323                        |
| Granted                                                 | 2,167,083           | 7.63                                     |                                                    |                                 |
| Exercised                                               | (118,075)           | 8.49                                     |                                                    |                                 |
| Cancelled                                               | (1,341,594)         | 14.53                                    |                                                    |                                 |
| Outstanding as of June 30, 2026                         | 12,492,872          | 13.00                                    | 5.71                                               | 25,470                          |
| Options exercisable as of June 30, 2026                 | 8,594,036           | 14.99                                    | 4.23                                               | 14,195                          |
| Options vested and expected to vest as of June 30, 2026 | 12,492,872          | \$ 13.00                                 | 5.71                                               | \$ 25,470                       |

As of June 30, 2026, there was \$23.4 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, 2026 and 2025 was \$6.33 and \$5.80, respectively. The aggregate intrinsic value of stock options exercised during the three months ended June 30, 2026 was \$0.2 million and the aggregate intrinsic value of stock options exercised during the three months ended June 30, 2025 was immaterial.

### Restricted and performance stock units

A summary of the changes in the Company's RSUs and PSUs during the three months ended June 30, 2026 is as follows:

|                                  | Number of<br>Restricted Shares | Weighted<br>Average<br>Grant Date Fair<br>Value |
|----------------------------------|--------------------------------|-------------------------------------------------|
| Outstanding as of March 31, 2026 | 5,508,882                      | \$ 9.69                                         |
| Granted                          | 2,510,630                      | 7.65                                            |
| Vested                           | (1,144,368)                    | 10.47                                           |
| Cancelled                        | (2,049,553)                    | 8.79                                            |
| Outstanding as of June 30, 2026  | 4,825,591                      | \$ 8.82                                         |

During the three months ended June 30, 2026 and 2025, the weighted average grant date fair value of awards granted is \$19.2 million and \$20.1 million, respectively. In addition, the total fair value of shares vested during the three months ended June 30, 2026 and 2025 is \$12.0 million and \$11.7 million, respectively. As of June 30, 2026, there was \$34.1 million of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.7 years. In addition, unrecognized compensation costs related to performance based awards tied to the achievement of a company milestone account for approximately \$3.2 million.

### 11 Net loss per share

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

|                                                               | Three Months Ended June 30, |             |
|---------------------------------------------------------------|-----------------------------|-------------|
|                                                               | 2026                        | 2025        |
| Numerator:                                                    |                             |             |
| Net loss                                                      | \$ (69,766)                 | \$ (86,693) |
| Denominator:                                                  |                             |             |
| Weighted average common shares outstanding, basic and diluted | 96,864,452                  | 91,516,199  |
| Net loss per share, basic and diluted                         | \$ (0.72)                   | \$ (0.95)   |

The 14,058,153 shares of the Company's common stock issuable upon exercise of pre-funded warrants described in Note 9 to these condensed 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, unvested restricted and performance stock units 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:

|                                                 | Three Months Ended June 30, |            |
|-------------------------------------------------|-----------------------------|------------|
|                                                 | 2026                        | 2025       |
| Options to purchase common stock                | 12,492,872                  | 12,273,997 |
| Unvested restricted and performance stock units | 4,825,591                   | 5,231,911  |
| Warrants to purchase common stock               | —                           | 497,344    |
|                                                 | 17,318,463                  | 18,003,252 |

## 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.

## 13 Collaboration and other arrangements

## Roche

In December 2022, the Company entered into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to the Company's RP2 and RP3 programs in colorectal cancer, or CRC, and hepatocellular carcinoma, or HCC. Under the agreement, the companies intended to 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. Following the Company's re-prioritization of its product development portfolio in December 2023, the Company agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has continued to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is not sharing costs following the Company's re-prioritization. Under the terms of the agreement the Company retained the responsibility of operating the clinical trials as well as retaining all the rights to the development and commercialization of its product candidates. The agreement may be terminated by either party upon sixty days prior written notice to the other party.

## Amgen

In August 2023 the Company entered into a Settlement Agreement with Amgen and mutually agreed to terminate the Company's challenges to Amgen's patents. In connection with the Settlement Agreement, the Company entered into a License and Covenant Agreement with Amgen in which the Company agreed to pay Amgen low single-digit royalty payments on net sales of its products that, but for the license, could be found to infringe a valid Amgen patent on a country-by-country and product-by-product basis.

## 14 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, 2026 and 2025:

|                                    | Three Months Ended June 30, |                 |
|------------------------------------|-----------------------------|-----------------|
|                                    | 2026                        | 2025            |
| Lease cost                         |                             |                 |
| Finance lease costs:               |                             |                 |
| Amortization of right-of-use asset | \$ 607                      | \$ 607          |
| Interest on lease liabilities      | 506                         | 521             |
| Operating lease costs              | 289                         | 288             |
| Total lease cost                   | <u>\$ 1,402</u>             | <u>\$ 1,416</u> |

The following table summarizes the classification of lease costs in the consolidated statement of operations for the three months ended June 30, 2026 and 2025 as follows:

|                                     | Three Months Ended June 30, |                 |
|-------------------------------------|-----------------------------|-----------------|
|                                     | 2026                        | 2025            |
| <b>Finance Lease Costs</b>          |                             |                 |
| Research and development            | \$ 607                      | \$ 607          |
| Other expenses                      | 506                         | 521             |
| <b>Operating Lease Costs</b>        |                             |                 |
| Research and development            | 215                         | 223             |
| Selling, general and administrative | 74                          | 65              |
| Total lease cost                    | <u>\$ 1,402</u>             | <u>\$ 1,416</u> |

The following table summarizes the maturity of the Company's lease liabilities on an undiscounted cash flow basis by fiscal year and a reconciliation to the operating and finance lease liabilities recognized on its balance sheet as of June 30, 2026:

|                              | June 30, 2026    |               |           |
|------------------------------|------------------|---------------|-----------|
|                              | Operating leases | Finance lease | Total     |
| 2027 (remaining nine months) | \$ 861           | \$ 2,175      | \$ 3,036  |
| 2028                         | 1,107            | 2,969         | 4,076     |
| 2029                         | 1,021            | 3,058         | 4,079     |
| 2030                         | 588              | 3,096         | 3,684     |
| 2031                         | 370              | 3,096         | 3,466     |
| Thereafter                   | —                | 25,802        | 25,802    |
| Total lease payments         | 3,947            | 40,196        | 44,143    |
| Less: interest               | 675              | 15,607        | 16,282    |
| Total lease liabilities      | \$ 3,272         | \$ 24,589     | \$ 27,861 |

The following table provides lease disclosure for the three months ended June 30, 2026 and 2025:

|                                                                         | Three Months Ended June 30, |        |       |        |
|-------------------------------------------------------------------------|-----------------------------|--------|-------|--------|
|                                                                         | 2026                        |        | 2025  |        |
| Other information                                                       |                             |        |       |        |
| Cash paid for amounts included in the measurement of lease liabilities: |                             |        |       |        |
| Operating cash flows from operating leases                              | \$                          | 302    | \$    | 299    |
| Operating cash flows from finance leases                                | \$                          | 506    | \$    | 521    |
| Financing cash flows from finance leases                                | \$                          | 203    | \$    | 166    |
| Weighted-average remaining lease term - operating leases                |                             | 3.6    | years | 4.5    |
| Weighted-average remaining lease term - finance leases                  |                             | 13.1   | years | 14.1   |
| Weighted-average discount rate - operating leases                       |                             | 10.4 % |       | 10.5 % |
| Weighted-average discount rate - finance leases                         |                             | 8.3 %  |       | 8.3 %  |

The variable lease costs and short-term lease costs were insignificant for the three months ended June 30, 2026 and 2025 respectively.

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

The Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of June 30, 2026 and March 31, 2026, the Company had committed to minimum payments under these arrangements totaling \$0.8 million and \$0.8 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 condensed consolidated financial statements as of June 30, 2026 or March 31, 2026.

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

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

On July 24, 2025, a class action complaint alleging violations of the federal securities laws was filed against the Company and its directors and certain officers in the United States District Court for the District of Massachusetts, or the District of Massachusetts. The complaint, captioned Jboor v. Replimune Group, Inc. et al., Case No. 1:25-cv-12085-JEK, was filed shortly after the Company announced it received a complete response letter from the FDA for its RP1 BLA for the treatment of advanced melanoma on July 22, 2025 and the subsequent decline in the trading price of the Company's common stock. The Court has appointed a lead plaintiff, or the Lead Plaintiff. On January 13, 2026, Lead Plaintiff filed an amended complaint. Following the second CRL issued by the FDA on April 10, 2026 for the Company's RP1 BLA for the treatment of advanced melanoma, the Lead Plaintiff filed a second amended complaint in the class action that addresses the second CRL. The Company's and the other defendants' response is now due on August 17, 2026. The Company and the other defendants deny any wrongdoing and continue to vigorously defend this action.

Following the class action complaint, three shareholders filed separate derivative actions on behalf of the Company in the District of Massachusetts captioned Chea v. Patel et al., Case No. 1:25-cv-12316-JEK, Wright v. Patel et al., Case No. 1:25-cv-12401-WGY, and Vochten v. Patel et al., Case No. 1:25-cv-12484-JEK. The plaintiffs allege substantially similar facts as the class action complaint and assert that the Company's directors and officers breached their fiduciary duties. The parties have consolidated the derivative actions and agreed to a stay pending further developments in the class action.

On September 10, 2025, the Company received a letter from a shareholder demanding that the Company's board of directors take action to address alleged wrongdoing by certain directors and officers. The demand letter alleged substantially similar facts as the class action and derivative action complaints. The board of directors determined to defer action on the demand pending further developments in the class action.

On September 29, 2025, the SEC informed the Company that it was conducting an investigation and requested that the Company produce certain documents and communications connected with the RP1 BLA. The investigation is reviewing essentially the same subject matter raised in the litigation following the CRL. On June 24, 2026, the SEC informed the Company that it has concluded its investigation of the Company and that it is not recommending an enforcement action be taken against the Company.

On August 6, 2026, a class action complaint alleging violations of the federal securities laws was filed against the Company and its directors and certain officers in the District of Massachusetts. The complaint, captioned Toor v. Replimune Group, Inc. et al., Case No. 1:26-cv-13612, alleges essentially the same facts and circumstances as the Lead Plaintiff's case. The Company and the other defendants deny any wrongdoing and continue to vigorously defend this action.

As the matters noted above are preliminary, the Company is unable to determine whether any loss will ultimately occur and cannot reasonably estimate the range of expected exposure. Therefore, the Company has not recorded any liability in the condensed consolidated financial statements as of and for the three months ended June 30, 2026.

## **15 Income taxes**

The Company did not record an income tax provision for the three months ended June 30, 2026 or 2025 as a result of forecasted United States and United Kingdom losses for the respective years.

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, future reversals of existing taxable temporary differences, 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.

## **16 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 table below:

|                | June 30, 2026    | March 31, 2026   |
|----------------|------------------|------------------|
| United States  | \$ 11,171        | \$ 12,174        |
| United Kingdom | 687              | 800              |
|                | <u>\$ 11,858</u> | <u>\$ 12,974</u> |

## 17 Segment information

The Company manages its operations as a single operating and reportable segment with a focus on developing and commercializing novel oncolytic immunotherapies in order to treat cancer. The Company defines its segments on the basis of the way in which internally reported financial information is regularly reviewed to analyze financial performance and make operating decisions. The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer. The CODM reviews consolidated operating results, and uses the Company's loss from operations and consolidated net income (loss), in order to monitor actual results as compared to the budget, and to determine how best to allocate the Company's operating and capital resources, specifically as it relates to the Company's development programs.

The following table presents selected financial information with respect to the Company's single operating segment, including significant segment expenses by program, for the three months ended June 30, 2026 and 2025:

|                                                              | Three Months Ended<br>June 30, |                        |
|--------------------------------------------------------------|--------------------------------|------------------------|
|                                                              | 2026                           | 2025                   |
|                                                              | (Amounts in thousands)         |                        |
| Operating expenses:                                          |                                |                        |
| Direct research and development expenses by program:         |                                |                        |
| RP1 program costs by study:                                  |                                |                        |
| IGNYTE                                                       | \$ 674                         | \$ 3,452               |
| ARTACUS                                                      | 484                            | 1,619                  |
| CERPASS                                                      | (270)                          | 1,208                  |
| IGNYTE-3                                                     | 7,950                          | 4,861                  |
| Other RP1 study costs                                        | 1,399                          | 4,422                  |
| RP2                                                          | 8,828                          | 3,875                  |
| RP3                                                          | 246                            | 857                    |
| Unallocated research and development expenses <sup>1</sup> : | 29,966                         | 37,549                 |
| Selling, general and administrative                          | 18,970                         | 32,579                 |
| Total operating expenses                                     | <u>68,247</u>                  | <u>90,422</u>          |
| Loss from operations                                         | <u>(68,247)</u>                | <u>(90,422)</u>        |
| Other (expense) income, net                                  | <u>(1,519)</u>                 | <u>\$ 3,729</u>        |
| Net loss                                                     | <u><u>(69,766)</u></u>         | <u><u>(86,693)</u></u> |

<sup>1</sup>Includes personnel-related costs and other costs

## 18 Subsequent Events

### *FDA approval of TUDRIQEV*

On August 6, 2026, the FDA granted accelerated approval for TUDRIQEV (vusolimogene oderparepvec-wtpg), previously referred to as RP1, in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression on an anti-PD-1 antibody-based regimen. This indication is approved under accelerated approval based on objective response rate and duration of response. This approval is a significant milestone for the Company, and the commercial launch of TUDRIQEV is in progress.

### *Equity offering*

On August 10, 2026, the Company completed an offering of (a) 9,701,490 shares of the Company's common stock at an offering price of \$12.06 per share and, (b) in lieu of common stock to certain investors, pre-funded warrants to purchase 2,736,340 shares of its common stock at an offering price of \$12.0599 per pre-funded warrant. The company received aggregate net proceeds of approximately \$141.0 million after deducting fees and expenses of approximately \$9.0 million.

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## 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 condensed 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, 2026, included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2026.*

*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 the SEC.*

*We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. Statements made herein are as of the date of the filing of this Quarterly Report with the 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 commercial-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 oncolytic immunotherapies. Our proprietary oncolytic immunotherapy product and product candidates are designed and intended to maximally activate the immune system against cancer.

Oncolytic immunotherapy is an emerging drug class. 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 and product candidates incorporate multiple mechanisms 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. 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 and product candidates, while also improving patient outcomes.

Our proprietary RPx platform is based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with payloads added that are intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is intended to have unique dual local and systemic activity 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. Our product and product candidates are 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. In addition to TUDRIQEV, we currently have two further RPx product candidates in our development pipeline, RP2 (sturlimgene erparepvec) and RP3. Although our fiscal year ends March 31st, our programs and program updates are reported on a calendar year basis.

We have been conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with the goal of establishing a major skin cancer treatment franchise.

Our leading clinical trial of RP1 is referred to as the IGNYTE trial, which is a multi-cohort clinical trial being conducted in 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.

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The leading tumor specific cohort in the IGNYTE trial is our registration directed Phase 2 expansion cohort in anti-PD-1 failed cutaneous melanoma. The anti-PD-1 failed melanoma cohort from the IGNYTE trial includes 140 patients who received RP1 in combination with nivolumab. On August 6, 2026, we announced the FDA granted accelerated approval to TUDRIQEV (vusolimogene oderparepvec-wtpg), previously referred to as RP1, in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression on an anti-PD-1 antibody-based regimen. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent on verification of clinical benefit in a confirmatory trial(s). The IGNYTE trial enrolled 140 patients with 91 patients with at least one non-injected lesion included in the efficacy-evaluable population. In this population, TUDRIQEV plus nivolumab achieved an objective response rate (ORR) of 24.2%, with a median duration of response of 14.1 months. Treatment was well tolerated with mostly mild-to-moderate adverse events. The patient population included patients with Stage 4 disease (80%), prior anti-PD-1 adjuvant treatment (13%), PD-L1 negative status (54%), lung (45%) and liver lesions (24%). TUDRIQEV in combination with nivolumab was generally well tolerated, with adverse events predominantly mild to moderate in severity. The most common (incidence  $\geq 10\%$ ) adverse reactions in patients treated with TUDRIQEV combined with nivolumab were nausea, diarrhea, vomiting, constipation, decreased appetite, abdominal pain, fatigue, pyrexia, chills, injection site reaction, influenza-like illness, infections, musculoskeletal pain, arthralgia, headache, dizziness, cough, dyspnea, rash, edema, pruritus and hemorrhage. Most treatment-related adverse reactions were grade 1 and 2 and transient. There were no grade 4 or 5 common adverse events. See additional Important Safety Information. The IGNYTE study data were published in the Journal of Clinical Oncology in July 2025.

In November 2024, we announced submission of our first Biologics License Application, or BLA, to the U.S. Food and Drug Administration, or the FDA, for TUDRIQEV in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD-1 containing regimen, and that the FDA had granted Breakthrough Therapy designation for TUDRIQEV in combination with nivolumab in the same setting. In July 2025, we received the first of two CRLs on our BLA for TUDRIQEV in combination with nivolumab for advanced melanoma patients, with the second CRL being issued by the FDA in April 2026. Ultimately, however, at a July 30, 2026 meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (the "Advisory Committee"), the Advisory Committee voted 10 to 3 on the question: "Are the efficacy results from IGNYTE evaluable and clinically meaningful?" Following this meeting, on August 6, 2026, the FDA granted accelerated approval of TUDRIQEV in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression on an anti-PD-1 antibody-based regimen.

In August 2024, we announced the dosing of the first patient in the IGNYTE-3 trial, or the I-3 trial, a 2-arm randomized Phase 3 clinical trial with physician's choice of treatment as a comparator arm in anti-PD-1 failed melanoma patients. Overall survival is the primary endpoint, and the trial is expected to randomize approximately 400 patients. We continue to enroll patients in the I-3 trial. The I-3 trial is an FDA postmarketing requirement and is intended to serve as the required accelerated approval confirmatory study. In addition to the I-3 trial, we must also complete a pediatric study of TUDRIQEV in combination with nivolumab in pediatric patients 12 years of age and older and are required to fulfill certain other postmarketing commitments set out in FDA's TUDRIQEV approval letter. We continue to enroll patients in the I-3 trial.

In addition to our development of TUDRIQEV for melanoma, we also are studying the product for other indications. In our non-melanoma skin cancer, or NMSC, cohort of the IGNYTE trial, we provided a data update in December 2023 from the first 30 patients with at least 6 months of follow up including patients with cutaneous squamous cell carcinoma, or CSCC, Merkel cell carcinoma, or MCC, basal cell carcinoma, or BCC, and angiosarcoma in this cohort. The data showed that treatment with TUDRIQEV in combination with nivolumab led to an ORR of 30% which is consistent with data from the anti-PD-1 failed melanoma cohort with approximately one-third of patients responding and 60% demonstrating clinical benefit. The combination of TUDRIQEV and nivolumab was well tolerated in this patient population with a safety profile consistent with the overall experience seen with this treatment regimen to date. We provided updated data from the NMSC cohort during our June 2025 Investor Day event and in October 2025 at the European Society for Medical Oncology, or ESMO, conference. Responses to TUDRIQEV plus nivolumab occurred across the NMSC tumor types enrolled, with confirmed responses seen in patients with both anti-PD-1 naïve and anti-PD-1 failed disease, as well as both in locally advanced and metastatic disease. The ORR by NMSC tumor type for anti-PD-1 naïve patients was 100.0% (n=4) in MCC, 33.3% (n=3) in BCC, 66.7% (n=6) in angiosarcoma, and 56.3% (n=16) in CSCC. The ORR by NMSC tumor type for anti-PD-1 failed patients was 26.3% (n=19) in MCC, 30.0% (n=10) in BCC, 37.5% (n=8) in angiosarcoma, and 15.2% (n=33) in CSCC. We closed enrollment in the NMSC tumor type cohorts in the fourth quarter of 2025.

We had been furthering development of TUDRIQEV through enrollment in a Phase 1b/2 clinical trial of single agent TUDRIQEV in solid organ transplant recipients with skin cancers, including CSCC, which we referred to as the ARTACUS trial. The ARTACUS trial enrolled 69 patients to assess the safety and efficacy of TUDRIQEV in liver, kidney, heart, lung, and hematopoietic cell transplant patients with skin cancers. Most recently, Dr. Michael R. Migden presented updated data from the ARTACUS trial at the Society for Melanoma Research 22nd International Congress in October 2025. This updated data showed anti-tumor activity in locally advanced CSCC with an ORR of 34.6% (CR rate of 23.1%) and 2-year duration of response of

61.0%. Furthermore, the data showed that TUDRIQEV monotherapy continued to be well tolerated and the safety profile continued to be similar to that observed in non-immunocompromised patients with advanced skin cancers, and, importantly, no implant rejections were attributed to the TUDRIQEV treatment. We have closed enrollment in the ARTACUS trial and are planning a publication of the data in 2026.

Our previous clinical trial of TUDRIQEV in patients with CSCC, which we referred to as the CERPASS trial, is fully closed and we are planning for a study report to be available in 2026.

We are also developing or are continuing to develop 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 TUDRIQEV, 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 continue the development of our product candidate RP2 with the goal of moving beyond skin cancers and aiming to treat the more prevalent tumor types commonly found in liver and lung metastasis and including those involving primary liver cancer. Notably, as previously reported, from our Phase 1 clinical trial of RP2 alone and in combination with nivolumab, we have seen durable responses from a monotherapy cohort in a variety of difficult to treat tumors as well as in combination with anti-PD-1 and in particular in patients with metastatic uveal melanoma, or mUM. In November 2023, we presented updated data from a cohort of mUM patients during a Plenary Session at the 20th Annual International Society for Melanoma Research Congress. The updated data showed RP2 led to an ORR of 29.4% (5 of 17 patients; one of the responding patients was treated with RP2 monotherapy and four of the responding patients were treated with RP2 combined with nivolumab), including responses in patients with liver, lung, and bone metastases. The median duration of response (DOR) at the data cutoff was 11.47 months (range of 2.78 to 21.22 with responses ongoing). Nearly all patients (15 of 17, 88.2%) in the study had progressed on or after immunotherapy with 12 of 17 patients (70.6%) having previously received both anti-PD-1 and anti-CTLA-4 therapies, including four of the responding patients. RP2 was generally well tolerated both as monotherapy and in combination with nivolumab with no additive adverse events observed. The most common grade 1 or 2 treatment related adverse events, or TRAEs, overall in both cohorts were pyrexia, chills, fatigue, hypotension and pruritis. Six patients had grade 3 TRAEs, including two cases of hypotension. There were no grade 4 or 5 TRAEs. In June 2024, we presented that the disease control rate for this cohort of mUM patients was 58.8%.

Leading the development of the RP2 product candidate is our REVEAL study. The REVEAL study is enrolling patients in a registration-directed study of RP2 in mUM patients who are immune checkpoint inhibitor-naïve. The REVEAL study is a randomized, Phase 2/3 open label study expected to enroll approximately 280 patients to investigate the efficacy and safety of RP2 in combination with nivolumab vs. ipilimumab in combination with nivolumab in immune checkpoint inhibitor naïve adult patients with metastatic uveal melanoma. The primary endpoints of the trial are overall survival and progression free survival, and key secondary endpoints are overall response rate and disease control rate. In January 2026 we announced the Phase 2/3 transition is expected to occur in the first quarter of 2027.

We continue our signal finding trial of RP2 in combination with atezolizumab and bevacizumab in the second-line (2L) setting of patients with hepatocellular carcinoma, or HCC, in collaboration with Roche. The protocol has been amended to include RP2 as monotherapy and we plan to release preliminary HCC data by the end of 2026. We have also opened a cohort in our RP2 study to investigate the potential to address biliary tract cancer, or BTC, through the dosing of RP2 in combination with durvalumab. We are currently evaluating these signal finding studies.

TUDRIQEV, RP2 and RP3 are administered by direct injection into solid tumors, guided either visually or by ultrasound, computerized tomography 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, proceeds from borrowing under secured loan facilities. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of TUDRIQEV and our other product candidates. As of June 30, 2026, 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 \$1,132.9 million in net proceeds to fund our operations, of which \$101.2 million was from our IPO, \$862.0 million was from four separate follow-on offerings, or the Public Offerings, that we closed in November 2019, June 2020, October 2020, December 2022, and November 2024, respectively, \$96.7 million was from our private investment in public equity offering in June 2024, and \$73.0 million was from at-the-market offerings.

Our net losses were \$69.8 million and \$86.7 million for the three months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of \$1,332.3 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 fluctuate from period to period depending upon the Company's development programs and priorities. We expect to continue to incur costs and expenses in the future and our expenses may increase if and as we:

- seek to successfully commence and achieve commercial sales of TUDRIQEV;
- seek to successfully complete one or more confirmatory trials of TUDRIQEV, including our ongoing IGNYTE-3 clinical trial;
- seek to obtain adequate coverage and reimbursement for TUDRIQEV
- continue to conduct our current and future clinical trials;
- further preclinical development of our platform;
- seek to manufacture and maintain sufficient commercial supply of TUDRIQEV, or clinical supply of our product candidates, from our in-house manufacturing facility;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product and product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, protect and defend our intellectual property portfolio;
- hire, train 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.

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As of June 30, 2026, we had cash and cash equivalents and short-term investments of \$195.3 million. Based on our current operating plan including the commercialization of TUDRIQEV in the near term, we believe that our existing cash and cash equivalents and short-term investments, including the \$141.0 million of net proceeds from the issuance of our common stock in August 2026, will be sufficient to fund operating expenses and capital expenditure requirements for greater than twelve months from the issuance of these condensed 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 previously did not have any approved products prior to the approval of TUDRIQEV in August 2026. We can not be certain we will generate any revenue from the sale of TUDRIQEV or other potential products in the future. If our development efforts for any of our 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 raw materials and supplies for our product and product candidates and their manufacturing, packaging and labeling;
- 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 and 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.

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Direct research and development costs, consisting of costs, such as fees paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical development activities, are tracked by study. Additional costs, consisting primarily of our initial manufacturing costs, including materials, supplies, depreciation and facility costs, are allocated at a program level, based upon manufacturing runs, as the drug product can be utilized across multiple studies for any particular program. Additional costs to label, package and distribute the drug product is then directly allocated to the specific studies when incurred, as that drug product has then been assigned to a particular study. In the event our additional future or ongoing study costs become meaningful to investors, we will present those costs by study.

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.

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 in, and the initiation of, additional clinical trials, as well as the continued discovery and development of additional product candidates. However, if we determine that the commercialization of TUDRIQEV is not viable, our outlook and plans may be uncertain and the impact on our research and development expenses will also be uncertain. At this time the ability to fund and successfully develop, and commercialize, if approved, 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 extent to which we are able to reach a mutually agreeable path forward with the FDA with respect to the scope, design, implementation and timing of an approval for our 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 and the timing of such approval;
  - 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 and the views and implementation of such regulation and guidance from the leadership of the applicable regulatory agencies.
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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 our selling, general and administrative expenses to continue to increase in the future as we increase our selling, general and administrative headcount to support our continued operations and pre-launch and launch activities for the commercialization of TUDRIQEV. 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. If we are unable to successfully commercialize TUDRIQEV, we expect that our selling, general and administrative expenses will decrease but to what extent we are uncertain.

***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 16.2% 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 (expense) income***

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

***Income taxes***

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.

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.

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## Results of operations

### Comparison of the three months ended June 30, 2026 and 2025

The following chart summarizes our results of operations for the three months ended June 30, 2026 and 2025:

|                                             | Three Months Ended<br>June 30, |             |            |
|---------------------------------------------|--------------------------------|-------------|------------|
|                                             | 2026                           | 2025        | Change     |
| (Amounts in thousands)                      |                                |             |            |
| Operating expenses:                         |                                |             |            |
| Research and development                    | \$ 49,277                      | \$ 57,843   | \$ (8,566) |
| Selling, general and administrative         | 18,970                         | 32,579      | (13,609)   |
| Total operating expenses                    | 68,247                         | 90,422      | (22,175)   |
| Loss from operations                        | (68,247)                       | (90,422)    | 22,175     |
| Other income (expense):                     |                                |             |            |
| Research and development incentives         | 296                            | 420         | (124)      |
| Investment income                           | 1,960                          | 4,714       | (2,754)    |
| Interest expense on finance lease liability | (506)                          | (521)       | 15         |
| Interest expense on debt obligations        | (2,581)                        | (1,475)     | (1,106)    |
| Other (expense) income, net                 | (688)                          | 591         | (1,279)    |
| Total other (expense) income, net           | (1,519)                        | 3,729       | (5,248)    |
| Net loss                                    | \$ (69,766)                    | \$ (86,693) | \$ 16,927  |

### Research and development expenses

Research and development expenses for the three months ended June 30, 2026 were \$49.3 million, compared to \$57.8 million for the three months ended June 30, 2025. The following table summarizes our research and development expenses for the three months ended June 30, 2026 and 2025:

|                                                        | Three Months Ended<br>June 30, |           |            |
|--------------------------------------------------------|--------------------------------|-----------|------------|
|                                                        | 2026                           | 2025      | Change     |
| Direct research and development expenses by program    |                                |           |            |
| RP1 program costs by study:                            |                                |           |            |
| IGNYTE                                                 | 674                            | 3,452     | (2,778)    |
| ARTACUS                                                | 484                            | 1,619     | (1,135)    |
| CERPASS                                                | (270)                          | 1,208     | (1,478)    |
| IGNYTE-3                                               | 7,950                          | 4,861     | 3,089      |
| Other RP1 study costs                                  | 1,399                          | 4,422     | (3,023)    |
| Total RP1 costs                                        | 10,237                         | 15,562    | (5,325)    |
| RP2                                                    | 8,828                          | 3,875     | 4,953      |
| RP3                                                    | 246                            | 857       | (611)      |
| Unallocated research and development expenses:         |                                |           |            |
| Personnel related (including stock-based compensation) | 23,533                         | 27,324    | (3,791)    |
| Other                                                  | 6,433                          | 10,225    | (3,792)    |
| Total research and development expenses                | \$ 49,277                      | \$ 57,843 | \$ (8,566) |

The overall decrease of \$8.6 million in total research and development expenses was driven by a decrease in unallocated expenses of approximately \$7.6 million, which included a decrease of \$3.8 million in personnel related costs and a decrease of \$3.8 million in other costs. Personnel related costs, including stock compensation, were down as a result of the

Company restructuring which was announced in April 2026. The decrease in other costs is driven by a decrease in consulting costs and medical affairs spending.

Direct research costs decreased by approximately \$1.0 million overall which was a result of a decrease of \$5.3 million in total TUDRIQEV costs relating to the IGNYTE, ARTACUS and CERPASS studies, specifically as a result of the completion of enrollment in the IGNYTE advanced melanoma cohort and declining enrollment and the wind down of the CERPASS and ARTACUS studies. These TUDRIQEV cost decreases were somewhat offset by an increase of \$3.1 million related to the IGNYTE-3 confirmatory study, which continued to progress in first quarter of fiscal 2027. In addition, RP2 direct spending increased by approximately \$5.0 million versus the same quarter of the prior year related to the REVEAL study, as the Company continued to ramp up enrollment and expanded this trial outside of the United States.

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

Selling, general and administrative expenses were \$19.0 million for the three months ended June 30, 2026, compared to \$32.6 million for the three months ended June 30, 2025. The decrease of \$13.6 million is primarily the result of a decrease of \$10.2 million in external sales and marketing costs and a decrease of \$3.4 million in personnel related costs in the sales and marketing and G&A functions. These decreases are the result of the Company restructuring which occurred during the first quarter of fiscal 2027, and included a reduction of workforce by approximately 55%, impacting the entirety of the Company's commercial team.

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

Other expense was \$1.5 million for the three months ended June 30, 2026, compared to income of \$3.7 million for the three months ended June 30, 2025. The net change of \$5.2 million is primarily attributable to a decrease in investment income of \$2.8 million as a result of a lower investment balance year over year. In addition, there was an increase in expense of \$1.3 million in the current quarter 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, as well as an increase in expense on debt of \$1.1 million as a result of a higher debt balance as compared to the same quarter in the prior year.

### **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. Until we are able to generate sufficient revenue from TUDRIQEV and our other product candidates that we develop, which may never occur, we anticipate that we will continue to incur significant operating losses and negative cash flows from our operations.

#### *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, 2026, we had received net proceeds of \$1,132.9 million through the sale of shares of common stock and pre-funded warrants exercisable for common stock in public offerings, a private placement transaction, and at-the-market offerings, as well as our incurrence of debt under the Hercules Loan Agreement. As of June 30, 2026, we had cash and cash equivalents and short-term investments of \$195.3 million.

#### *Cash flows*

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

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|                                                              | Three Months Ended June 30, |                    |
|--------------------------------------------------------------|-----------------------------|--------------------|
|                                                              | 2026                        | 2025               |
|                                                              | (Amounts in thousands)      |                    |
| Net cash used in operating activities                        | \$ (75,728)                 | \$ (77,016)        |
| Net cash provided by investing activities                    | 49,993                      | 65,048             |
| Net cash provided by (used in) financing activities          | 800                         | (158)              |
| Effect of exchange rate changes on cash and cash equivalents | 1,270                       | (1,616)            |
| Net decrease in cash and cash equivalents                    | <u>\$ (23,665)</u>          | <u>\$ (13,742)</u> |

#### *Operating activities*

During the three months ended June 30, 2026, net cash used in operating activities was \$75.7 million, primarily resulting from our net loss of \$69.8 million partially offset by non-cash charges of \$9.5 million, which primarily consist of stock-based compensation expense of \$7.7 million and depreciation and amortization of \$1.8 million, and a decrease in cash of \$15.5 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the three months ended June 30, 2026 consisted primarily of a \$2.3 million decrease in accounts payable, a \$17.4 million decrease in accrued expenses and other current liabilities, and a \$1.3 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, 2025, net cash used in operating activities was \$77.0 million, primarily resulting from our net loss of \$86.7 million partially offset by non-cash charges of \$10.1 million, which primarily consist of stock-based compensation expense of \$8.8 million and depreciation and amortization of \$1.7 million, somewhat offset by net amortization of premiums and discounts on short-term investments of \$1.3 million, and a decrease in cash of \$0.4 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the three months ended June 30, 2025 consisted primarily of a \$5.5 million decrease in accrued expenses and other current liabilities, offset by a \$3.8 million increase in accounts payable, and a \$1.6 million decrease in research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures.

#### *Investing activities*

During the three months ended June 30, 2026, net cash provided by investing activities was \$50.0 million, consisting of \$59.9 million in proceeds from sales and maturities of short-term investments, partially offset by \$9.9 million in purchases of available for sale securities.

During the three months ended June 30, 2025, net cash provided by investing activities was \$65.0 million, consisting of \$105.4 million in proceeds from sales and maturities of short-term investments, partially offset by \$37.6 million in purchases of available for sale securities and \$2.7 million in purchases of property, plant and equipment and capitalized software.

#### *Financing Activities*

During the three months ended June 30, 2026, net cash provided by financing activities was \$0.8 million, relating to approximately \$1.0 million in proceeds from the exercise of stock options, somewhat offset by principal payments of the Company's financing lease obligation.

During the three months ended June 30, 2025, net cash used in financing activities was \$0.2 million, relating to principal payments of the Company's financing lease obligation.

#### *Funding requirements*

Our plan of operation is to continue implementing our business strategy, commence and achieve commercial sales of TUDRIQEV, and continue research and development of our 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 commercialization of TUDRIQEV and the preclinical activities and clinical trials of our product candidates and if and as we:

- seek to successfully commence and achieve commercial sales of TUDRIQEV;

- seek to complete one or more confirmatory trials of TUDRIQEV, including our ongoing IGNYTE-3 clinical trial, as well as our other post marketing requirements and commitments;
- seek to obtain adequate coverage and reimbursement for TUDRIQEV
- conduct our current and future clinical trials with RP2 and RP3;
- further preclinical development of any of our product candidates from our RPx platform;
- operate, qualify and maintain our in-house manufacturing facility and qualify and maintain our product and 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;
- seek to manufacture and maintain sufficient commercial supply of TUDRIQEV, or clinical supply of our product candidates, from our in-house manufacturing facility;
- maintain, expand, protect and defend our intellectual property portfolio;
- hire, train 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, 2026, we had cash and cash equivalents and short-term investments of \$195.3 million. Based on its current operating plan, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operations for greater than twelve months from the issuance of these condensed consolidated financial statements, which includes the commercialization of TUDRIQEV in advanced melanoma and for working capital and general corporate purposes.

Because of the numerous risks and uncertainties associated with the commercialization of TUDRIQEV and the development of our 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 can not be certain will become commercially available. 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.

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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, 2026, 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, 2026, which was filed with the SEC on June 29, 2026.

### **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.

#### *Roche*

In December 2022, we entered 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 HCC. Under the agreement, the companies intended to 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. Following our re-prioritization of our product development portfolio in December 2023, we have agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has continued to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is not sharing costs following our re-prioritization. Under the terms of the initial agreement we 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 days prior written notice to the other party.

### **Critical accounting policies and estimates**

Our management’s discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our condensed 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 condensed 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

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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 condensed 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 condensed consolidated financial statements.

#### ***Accrued research and development expenses***

As part of the process of preparing our condensed 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 condensed 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 condensed 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.

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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 condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

#### **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, Chief Financial Officer and Chief Accounting Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2026. Based on this evaluation, our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer concluded that, as of June 30, 2026, our disclosure controls and procedures were effective at a reasonable assurance level.

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, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings.

On July 24, 2025, a class action complaint alleging violations of the federal securities laws was filed against the Company and its directors and certain officers in the United States District Court for the District of Massachusetts, or the District of Massachusetts. The complaint, captioned *Jboor v. Replimune Group, Inc. et al.*, Case No. 1:25-cv-12085-JEK, was filed shortly after the Company announced it received a complete response letter, or CRL, from the FDA for its RP1 BLA for the treatment of advanced melanoma on July 22, 2025 and the subsequent decline in the trading price of the Company's common stock. The Court has appointed a lead plaintiff, or the Lead Plaintiff. On January 13, 2026, Lead Plaintiff filed an amended complaint. Following the second CRL issued by the FDA on April 10, 2026 for the Company's RP1 BLA for the treatment of advanced melanoma, the Lead Plaintiff filed a second amended complaint in the class action that addresses the second CRL. The Company's and the other defendants' response is now due August 17, 2026. The Company and the other defendants deny any wrongdoing and will vigorously defend this action.

Following the class action complaint, three shareholders filed separate derivative actions on behalf of the Company in the District of Massachusetts captioned *Chea v. Patel et al.*, Case No. 1:25-cv-12316-JEK, *Wright v. Patel et al.*, Case No. 1:25-cv-12401-WGY, and *Vochten v. Patel et al.*, Case No. 1:25-cv-12484-JEK. The plaintiffs allege substantially similar facts as the class action complaint and assert that the Company's directors and officers breached their fiduciary duties. The parties have consolidated the derivative actions and agreed to a stay pending further developments in the class action.

On September 10, 2025, the Company received a letter from a shareholder demanding that the Company's board of directors take action to address alleged wrongdoing by certain directors and officers. The demand letter alleged substantially similar facts as the class action and derivative action complaints. The board of directors determined to defer action on the demand pending further developments in the class action.

On September 29, 2025, the SEC, informed the Company that it was conducting an investigation and requested that the Company produce certain documents and communications connected with the RP1 BLA. The investigation is reviewing essentially the same subject matter raised in the litigation following the CRL. On June 24, 2026, the SEC informed the Company that it has concluded its investigation of the Company and that it is not recommending an enforcement action be taken against the Company.

On August 6, 2026, a class action complaint alleging violations of the federal securities laws was filed against the Company and its directors and certain officers in the District of Massachusetts. The complaint, captioned *Toor v. Replimune Group, Inc. et al.*, Case No. 1:26-cv-13612, alleges essentially the same facts and circumstances as the Lead Plaintiff's case. The Company and the other defendants deny any wrongdoing and continue to vigorously defend this action.

### 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 condensed 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:

- our ability to successfully commence and achieve commercial sales of TUDRIQEV in the U.S. for its approved indication;
  - our ability to successfully complete one or more confirmatory trials of TUDRIQEV, including our ongoing IGNYTE-3 clinical trial, as well as our other post marketing requirements and commitments;
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- 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 and proprietary RPx platform and successfully complete clinical trials and prepare for and successfully complete inspections, submissions and reviews of licensing applications;
- 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 and 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/or 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 TUDRIQEV and our 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 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, train and retain additional qualified professionals;
- our competitive position, and developments and projections relating to our competitors and our industry;
- the potential increased costs associated with tariffs imposed or threatened by the current U.S. administration on pharmaceuticals and pharmaceutical ingredients where there is no available exception; and
- the ongoing trade and military conflicts between Russia-Ukraine and Israel-Hamas and U.S.-China, including imposed and threatened tariffs, and other international hostilities and conflicts, and their 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 commercialization**

***Our near-term prospects are wholly dependent on TUDRIQEV. We have no experience with the commercialization of TUDRIQEV, and if we are unable to successfully commercialize TUDRIQEV in the U.S. for its approved indication, our ability to generate meaningful revenue or achieve profitability will be materially and adversely affected.***

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In August 2026, we received FDA approval to commercialize TUDRIQEV in combination with nivolumab in the U.S. for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with an anti-PD-1 antibody-based regimen, and we are preparing to initiate a commercial launch of TUDRIQEV in the U.S. in that indication. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent on verification of clinical benefit in one or more confirmatory trials, including our ongoing IGNYTE-3 clinical trial. We are conducting our ongoing IGNYTE-3 clinical trial as a confirmatory study. Additionally, we are also required to conduct a pediatric study and fulfill certain other postmarketing commitments set out in FDA's TUDRIQEV approval letter.

TUDRIQEV is our only product approved for marketing by the FDA, and our ability to generate revenue from product sales and achieve profitability is wholly dependent on our ability to successfully commercialize TUDRIQEV in the U.S. for its approved indication. We may not be able to successfully commercialize TUDRIQEV for a number of reasons, including:

- we may not be able to establish or demonstrate in the medical community the safety and efficacy of TUDRIQEV and its potential advantages over and side effects compared to existing treatments;
  - physicians may be reluctant to prescribe TUDRIQEV until longer-term efficacy and safety data exists;
  - we have no prior experience in marketing, selling and distributing TUDRIQEV or any other product; following receipt of a second CRL in April 2026, we implemented significant cost-savings measures, including significant reductions in force in our in-house sales, marketing or commercialization teams; although we have begun to rebuild these capabilities in advance of commercializing TUDRIQEV, we may face challenges in rehiring former staff or hiring, training, and deploying new staff to meet our commercialization objectives;
  - we are dependent on the reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, insurance companies, health maintenance organizations and other plan administrators and may not be able to obtain adequate reimbursement and coverage for TUDRIQEV;
  - sales may be affected by the relative price of TUDRIQEV in combination with nivolumab as compared to alternative treatment options;
  - sales volumes will depend on the incidence and prevalence of patients in TUDRIQEV's approved indication, and our market and sales estimates may be incorrect;
  - future competitive or other market factors may adversely affect the commercial potential of TUDRIQEV;
  - we may not be able to obtain and maintain regulatory approvals for TUDRIQEV in any other jurisdictions or for any other indications;
  - changes could be required to the label for TUDRIQEV that further restrict how we market and sell TUDRIQEV, including as a result of adverse events observed following commercialization or in ongoing and future studies of TUDRIQEV;
  - we may be unable to timely or successfully complete one or more confirmatory trials that verify the clinical benefit of TUDRIQEV, including our ongoing IGNYTE-3 clinical trial, or may be unable to timely or successfully complete the required pediatric study and other postmarketing commitments;
  - we may encounter manufacturing challenges that may impact product supply or may need to conduct product recalls;
  - we might not be able to maintain compliance with the many legal and regulatory requirements for the manufacturing, marketing, promotion, sale, distribution and commercialization of TUDRIQEV and may face enforcement actions;
  - we may not be able to maintain adequate commercial supplies of TUDRIQEV, or there may not be adequate supplies of nivolumab to meet demand at an acceptable cost or at all; and
  - we may need additional financial or other resources to successfully commercialize TUDRIQEV.
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Moreover, successful commercialization of TUDRIQEV may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all. In any event, if we are unable to successfully commercialize TUDRIQEV in the U.S. for its approved indication, our ability to generate meaningful revenue from product sales and achieve profitability will be materially and adversely affected, which in turn could have a material adverse effect on our business and business prospects.

***To be commercially successful, TUDRIQEV must be accepted by the healthcare community, which can be slow to adopt or unreceptive to new technologies and products.***

TUDRIQEV may not achieve market acceptance in the U.S. for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with an anti-PD-1 antibody-based regimen or any other indication that might be approved by the FDA in the future, or achieve the potential international revenue we believe may be possible if TUDRIQEV is approved outside the U.S., since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize TUDRIQEV. The degree of market acceptance of TUDRIQEV depends on a number of factors, including:

- the clinical indications for which TUDRIQEV is or may in the future be approved, as well as any contraindications, risks, and warnings;
  - the establishment and demonstration to the medical community of the clinical efficacy and safety of TUDRIQEV;
  - the ability to demonstrate that TUDRIQEV is superior to alternatives on the market at the time, including with respect to efficacy, safety, cost or mode of administration;
  - the willingness of medical professionals to prescribe, and patients to use, TUDRIQEV in combination with nivolumab;
  - the publication of unfavorable safety or efficacy data concerning TUDRIQEV by third parties or us or the publication of favorable data concerning competitive products;
  - restrictions on use of TUDRIQEV alone or in combination with other products;
  - the label and promotional claims allowed by the FDA for TUDRIQEV, as well as such claims allowed by similar international regulatory authorities for TUDRIQEV, if any, including usage for only certain indications and any limitations or warnings about the prevalence or severity of any side effects;
  - the timing of market introduction of TUDRIQEV as well as competitive products, including sequencing of available products; the effectiveness of sales, marketing and distribution support for TUDRIQEV;
  - the ability of any third-party distributors or other service providers we may contract with to distribute TUDRIQEV and the processes required to order and administer TUDRIQEV in combination with nivolumab;
  - the extent to which TUDRIQEV is approved for inclusion on formularies or otherwise authorized for use in hospitals and other treatment centers;
  - the pricing of TUDRIQEV in combination with nivolumab, both in absolute terms and relative to alternative treatments;
  - the availability of nivolumab and TUDRIQEV;
  - the availability of healthcare professionals and treatment centers with the expertise, personnel and equipment necessary to administer TUDRIQEV by direct injection into tumors;
  - the availability of coverage and adequate reimbursement by government and third-party payors; and
  - the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including governmental authorities.
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Government payors, insurers and/or third-party payors may decide that any potential benefit that TUDRIQEV may provide to clinical outcomes in advanced melanoma is not adequate to justify the potential adverse effects or the costs of treatment with TUDRIQEV in combination with nivolumab. If the healthcare community does not accept TUDRIQEV for any of the foregoing reasons, or for any other reasons, our ability to commercialize TUDRIQEV in the U.S. for its approved indication or for any other indications for which TUDRIQEV may be approved may be negatively impacted or precluded altogether, which would seriously and adversely affect our business and business prospects.

***TUDRIQEV was approved under the accelerated approval pathway, and continued approval may be contingent upon verification of clinical benefit in one or more confirmatory trials, including our ongoing IGNYTE-3 clinical trial. If we fail to satisfy the requirements applicable to accelerated approval, the FDA may withdraw approval of TUDRIQEV.***

The FDA granted accelerated approval of TUDRIQEV in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with an anti-PD-1 antibody-based regimen. This indication was approved based on overall response rate and duration of response. Under the accelerated approval pathway, the FDA may approve a product for a serious or life-threatening disease or condition based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The FDA generally reserves the use of accelerated approvals for situations in which the product at issue provides a meaningful therapeutic benefit over existing treatments.

Products granted accelerated approval are subject to certain post-marketing requirements, which include a requirement to conduct one or more post-approval studies to confirm the clinical benefit of the product, which must be completed with due diligence. For instance, the continued approval of TUDRIQEV may be contingent upon verification of clinical benefit in one or more confirmatory trials, including our ongoing IGNYTE-3 clinical trial. The FDA also sets forth the conditions for post-marketing requirements and post-marketing commitments. The FDA may disagree with our clinical study designs for or our conduct of post-marketing confirmatory studies and may require study conditions that are unfavorable to us or impractical, which could delay completion of the study or lead to studies not demonstrating a clinical benefit. We also may not be able to complete or may not successfully complete the required post-marketing confirmatory studies. If we do not complete the required post-marketing confirmatory studies or if these do not confirm TUDRIQEV's clinical benefit, FDA could withdraw the product from the market using an expedited withdrawal process, we may choose to voluntarily withdraw the product from the market, or we may need to conduct further studies to determine whether the product has a clinical benefit. Failure to conduct the required confirmatory studies or to conduct such studies with due diligence, as well as failure to submit the required update reports can subject us to penalties.

In addition, sponsors of products approved under accelerated approval are required to provide reports to the FDA on the progress of the required confirmatory studies. FDA regulations further require that sponsors of products granted accelerated approval submit during the pre-approval review period copies of all promotional materials intended to be used within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the FDA, the sponsor must submit all promotional materials at least 30 days prior to use.

The accelerated approval pathway has come under scrutiny within the FDA, by Congress and by other stakeholders. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA previously convened an advisory committee to review cases where confirmatory studies have not been completed or where results did not confirm benefit.

As noted above, the FDA also has the authority to withdraw products approved under the accelerated approval pathway using expedited withdrawal procedures. Circumstances that may lead to such withdrawal include:

- the failure to conduct required post-approval study of TUDRIQEV with due diligence, including with respect to conditions specified by the FDA;
  - a study required to verify and describe the predicted clinical benefit of TUDRIQEV fails to verify and describe such benefit;
  - other evidence demonstrates that TUDRIQEV is not shown to be safe or effective under the conditions of use; or
  - our dissemination of false or misleading promotional materials relating to TUDRIQEV.
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If we fail to complete IGNYTE-3 or any other required post-approval study with due diligence, if any such study fails to verify and describe the predicted clinical benefit of TUDRIQEV or if other evidence demonstrates that TUDRIQEV is not shown to be safe or effective under the conditions of use, the FDA may withdraw approval of TUDRIQEV, which could have a material adverse effect on our business and business prospects.

#### **Risks related to product development and regulatory approval**

***Our product candidates are in various stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We cannot be certain that we will be able to successfully develop further product candidates or obtain regulatory approval for our product candidates. We have not yet generated any revenue from product sales and may never be profitable.***

Although we have recently received approval from the FDA for TUDRIQEV, in combination with nivolumab for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with an anti-PD-1 antibody-based regimen, all of our product candidates are in earlier stages of research or clinical development. We have not generated any revenue from the sale of any product to date. Our product candidates require extensive preclinical and/or clinical testing and regulatory review from the FDA prior to approval and commercial use. It is possible that the FDA will not approve an application that we may submit, or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence or continue clinical trials for our product candidates or ultimately commercialize them. Any delay or failure in obtaining required approvals could have a material adverse effect on our business and business prospects. For example, we received multiple CRLs from the FDA in connection with our BLA for TUDRIQEV in combination with nivolumab for the treatment of advanced melanoma.

The process from development to commercialization can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand, without any guarantee or assurance that we will be successful with regulatory approval, or commercial success, of such product candidate.

In addition, any of our other research and development efforts may not be successful. Furthermore, even if our clinical development efforts result in what we believe to be 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, the data is being reviewed or during the license application process.

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:

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- 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 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;
  - 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 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, including the imposition of tariffs;
  - 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. For 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 or maintain 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 or study data analysis that may 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;
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- 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 or may find that such data is not sufficiently representative;
- 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 and may delay approval, refuse to approve or rescind approval of a product candidate;
- 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. For 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. For instance, our confirmatory studies may not confirm a product's clinical benefit, in which case, the FDA could withdraw the product from the market, we may choose to voluntarily withdraw the product from the market, or we may need to conduct further studies to determine whether the product has a clinical benefit. Even if accelerated approval is granted, payors, including governmental payors, may be less willing to provide sufficient reimbursement for products approved via accelerated approval;
- we may not be able to obtain or maintain any special designations that our product candidates have received, including breakthrough designation. For instance, the FDA may find that, following designation, our product candidates no longer qualify for the designation due to changed circumstances or study results. This may result in the FDA rescinding a designation that we previously received. Any such designation also may not expedite or otherwise facilitate product development;
- 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;
- there may be events outside of our control, including, with respect to the budget, staffing, and funding of the U.S. Federal government, the FDA's ability to hire and retain key personnel, the FDA's ability to accept user fees, and other regulatory and policy changes. Disruptions at the FDA may slow the time to approval of a new drug or may otherwise impact our ability to obtain guidance from and interact with the agency. For instance, in recent years, the U.S. Federal government has experienced shutdowns. Should there be a prolonged government shutdown, it could significantly impact the ability of the FDA to review or slow the FDA in its review of any of our submissions or applications, which could have a materially adverse impact on our business;
- changes within the FDA, including its leadership may impede or delay our ability to develop and obtain approval for our product candidates, including due to changing priorities and policies. By example, over the last year, there have been a number of different leadership changes within the agency, which may continue; and
- 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.

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 will 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.

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

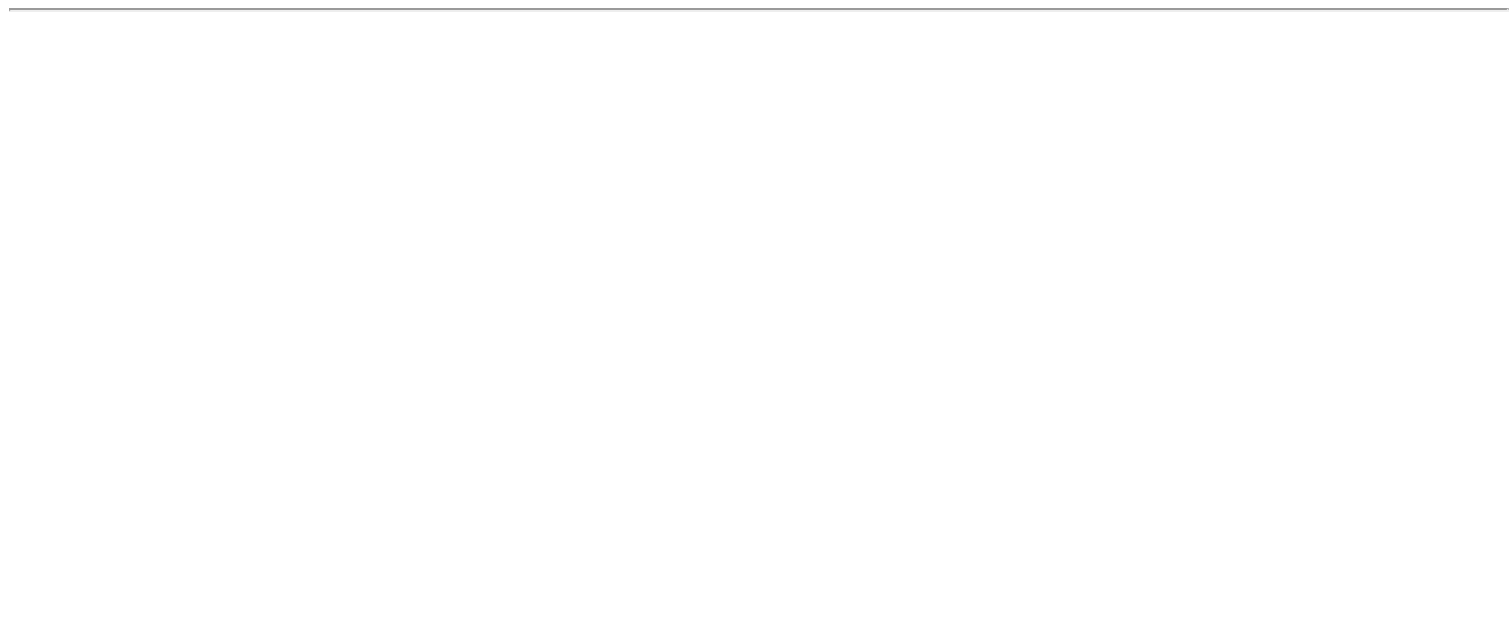
We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data. As topline or interim data, the results and related findings and conclusions are subject to change following a more comprehensive review of the data 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 and interim 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 and interim 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 and interim 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 IGNYTE 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. Additionally, our signal finding study in HCC is being developed in combination with atezolizumab and bevacizumab under a supply and clinical collaboration agreement with Roche. 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. Although we have entered into such collaboration and supply agreements, and may continue to do so, our partners may remain in control of the supply and other decisions relating to their products or product candidates and we rely on their adherence to the terms of such agreements for the proper execution of their obligations. Our ability to develop and ultimately commercialize our product candidates used in combination with nivolumab, cemiplimab, atezolizumab, bevacizumab 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 availability and 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 previously 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 for some of our trials to support registrational filings, 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 or the FDA may pull back a previously granted marketing license if a confirmational trial does not result in data supporting an earlier approval. 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. Developments related to the other product may further 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 or Roche 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 or Roche or any of our current or future collaborators or suppliers 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 RPx platform. If we were required to discontinue development of our product candidates that are based on our RPx platform, 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 from our RPx platform.

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

In addition to TUDRIQEV, we intend to continue to pursue clinical development of additional product candidates, including RP2 and, in the future potentially reinitiating development plans with 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 and 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 and 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 (remotely or in person) 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 and 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 and product candidates occur in any jurisdiction, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

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- 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 REMS or equivalent post-marketing measures to monitor the safety or efficacy of the products.

Following the issuance of two CRLs in respect of our BLA for TUDRIQEV, in August 2026, we received FDA approval to commercialize TUDRIQEV in combination with nivolumab in the U.S. for the treatment of adults with unresectable advanced cutaneous melanoma who experienced disease progression with an anti-PD-1 antibody-based regimen, and we are preparing to initiate a commercial launch of TUDRIQEV in the U.S. in that indication. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication is contingent on verification of clinical benefit in one or more confirmatory trials, including our ongoing IGYTE-3 clinical trial. There can be no assurance that we will be able to complete one or more confirmatory trials of TUDRIQEV.

The FDA could also require post-market commitments or requirements following an approval that are onerous, costly or may not be feasible in the time required by the FDA and that ultimately limit or inhibit the continued development or commercialization of TUDRIQEV.

***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, require additional or different analysis of clinical data or otherwise cause delays in the approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

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

***The FDA or a comparable foreign regulatory authority may determine that our product and 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 TUDRIQEV or our 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.

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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.

***Our product candidates may be subject to review by an FDA advisory committee, and an unfavorable recommendation could adversely affect our business.***

The FDA may convene an advisory committee to review and evaluate data relating to one or more of our product candidates, as was the case with TUDRIQEV. Advisory committees are comprised of independent experts who provide recommendations to the FDA regarding the approval, labeling, post-marketing requirements, and other regulatory matters associated with product candidates. Although the FDA is not bound by an advisory committee's recommendation, it generally gives significant weight to the committee's views when making regulatory decisions.

If an advisory committee reviewing one of our product candidates recommends against approval, expresses concerns regarding the safety, efficacy, manufacturing, labeling, or risk-benefit profile of the product candidate, or recommends additional clinical studies or other requirements, the FDA may delay, limit, or deny approval. Even if the advisory committee ultimately recommends approval, the FDA may impose significant restrictions on the approved indication, require post-marketing commitments, or otherwise limit the commercial opportunity for the product candidate.

The announcement of an advisory committee meeting, the committee's deliberations, the publication of briefing materials, or the committee's recommendation may create significant uncertainty regarding the regulatory prospects of our product candidates and could result in substantial volatility in the market price of our common stock. An unfavorable outcome could materially harm our business, financial condition, results of operations, 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, penalties, injunctions, or other enforcement actions, including criminal 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

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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 and comparable foreign regulatory authorities' 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 relevant regulatory authorities. 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 and non- or deferred prosecution agreements and could lead to 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 claims action, pay civil penalties, criminal fines or restitution, 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, supply obligations and 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

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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 or other comparable foreign regulatory authorities to monitor and ensure compliance with cGMPs and other 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 conducting a review into safety information, or 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 procurement and non-procurement programs, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, corporate integrity agreements, or non- or deferred prosecution agreements; or
- injunctions, the imposition of civil penalties, criminal fines, or 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

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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. Further, action in one country may lead to similar or different action in another. 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 as 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. Even if the foregoing is complied with, 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. By example, over the last year, new policies have been proposed to encourage companies to conduct clinical trials in the United States. 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 though the FDA granted marketing approval of TUDRIQEV, or if it grants approval for any of our other product candidates, 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.

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

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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.

***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. Further, depending on the specific competing product, earlier approval of a competitor's products could block us from receiving approval and could require that we change our development strategy. In addition, our ability to compete may be affected in many cases by insurers or 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, training 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 TUDRIQEV or any of our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.***

We intend to commercialize TUDRIQEV and our product candidates, if and when they receive marketing approval, 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 continue to build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We have incurred and we expect we will continue to 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. 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.

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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, managing, growing and operating a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop is, and will continue to be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We have and will continue 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 an effective marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere in an effective manner, 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, pricing 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.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we expand our internal manufacturing, marketing and sales capabilities, managing our future growth will impose significant added responsibilities on members of our management team and will be time consuming and costly. We must be able to manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; and improve managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure.

***TUDRIQEV and 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 our 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 connection with our product candidates, whether arising from our past work, or future work, will not cause significant delays or unanticipated costs, or that such development problems can be solved.

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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. Limited immunotherapies, particularly oncolytic immunotherapies, have 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 TUDRIQEV or 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. TUDRIQEV and our other product candidates, even if they are approved by the appropriate regulatory authorities for marketing and sale, may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If TUDRIQEV or any other product candidate 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.

Additionally, efforts to educate the medical community and third party payors on the benefits of TUDRIQEV or our product candidates may require significant resources and may not be successful. If TUDRIQEV or any of our product candidates that 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 TUDRIQEV or any of our product candidates will depend on a number of factors, some of which are out of our control, including the following:

- the efficacy of TUDRIQEV or 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;
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- 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, pricing and reimbursement from third-party payers such as government insurance programs, including, but not limited to, 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, pricing and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate formulary 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, inflation and non-compliance penalties, and subjecting an escalating number of drugs to annual maximum fair 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. Similarly, several states have established prescription drug affordability boards that set upper payment limits (maximum prices that can be charged for specific drugs) for select high-cost drugs. We cannot be sure whether additional state legislation related to price caps will be 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.

If future reimbursement for approved product candidates, if any, is substantially less than we project, or rebate and/or discount, or fees and 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 TUDRIQEV and our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets TUDRIQEV and for our product candidates may be smaller than our estimates.***

The potential market opportunities for TUDRIQEV or our product candidates are difficult to estimate and will depend in large part on the drugs with which TUDRIQEV or 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

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given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec (also referred to as Imlygic<sup>(R)</sup> (Amgen, Inc.)), 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 surveys of clinics. 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 TUDRIQEV or our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of our 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 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.***

Although we have recently received approval from the FDA for TUDRIQEV, we have previously had 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 public and private offerings. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our proprietary RPx platform, including TUDRIQEV and our product candidates. We expect to spend substantial funds to continue the research, development and testing of our products that are in the preclinical and clinical testing stages of development and to prepare to commercialize products in anticipation of FDA approval. 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, 2026 and 2025, we reported a net loss of \$69.8 million and \$86.7 million, respectively. At June 30, 2026, we had an accumulated deficit of \$1,332.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we seek to commercialize TUDRIQEV, continue one or more confirmatory trials of TUDRIQEV, including our ongoing IGYTE-3 clinical trial, and continue our research and development of, and seek marketing approval for our product candidates and any additional product candidates we may develop.

While we expect the net proceeds from our August 2026 offering to provide us with additional liquidity and cash runway to fund our operating expenses, working capital needs, and other corporate uses, we will be required to seek additional financing, and there can be no assurance that such financing will be available on acceptable terms, if at all. If we are unable to obtain additional capital, substantial doubt about our ability to continue as a going concern could arise again, and may adversely affect our business, results of operations and stock price. In addition, 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

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depend, in part, on the rate of future growth of our expenses and our ability to generate revenue, including from sales of TUDRIQEV.

***Our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.***

Although we have recently received approval from the FDA for TUDRIQEV, we have previously had no products approved for commercial sale, and have not generated any revenue from product sales to date. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- successfully launching commercial sales of TUDRIQEV while maintaining full compliance with applicable federal and state laws, rules and regulations;
- completing research regarding, and preclinical and clinical development of our other product candidates;
- maintaining marketing approvals for TUDRIQEV and obtaining marketing approvals for our other product candidates for which we complete clinical trials;
- continuing to generate favorable study results for TUDRIQEV and or other product candidates, including with respect to our confirmatory clinical trials for TUDRIQEV;
- maintaining a sustainable and scalable manufacturing process for TUDRIQEV and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- obtaining market acceptance of TUDRIQEV and our other product candidates as viable treatment options;
- obtaining adequate coverage and reimbursement for TUDRIQEV and or other product candidates;
- 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, training, hiring, and retaining qualified personnel.

We anticipate incurring significant costs associated with commercializing TUDRIQEV and any other product candidate that may be approved for commercial sale. 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

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain and retain marketing approval, the accepted price for the product, the ability to get adequate coverage and reimbursement, 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 TUDRIQEV or any other 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.***

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Our operations have consumed substantial amounts of cash since inception. At June 30, 2026, our cash and cash equivalents and short-term investments were \$195.3 million. We expect to continue to spend substantial amounts to continue the clinical and pre clinical development of our RPx product candidates. Accordingly, we will need to obtain additional funds to achieve our business objectives. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the cost of commercialization activities for TUDRIQEV or any other approved product, including marketing, sales and distribution costs;
- the cost of one or more confirmatory trials of TUDRIQEV;
- the scope, progress, results and costs of researching and developing our other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for our other product candidates if clinical trials are successful;
- the success of any collaborations;
- the cost and timing of operating our manufacturing facility;
- the cost of manufacturing TUDRIQEVour 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.

Other than the Hercules Loan Agreement (as defined below), we do not have any committed external source of funds or other support for our development efforts. Our ability to draw additional amounts under the Hercules Loan Agreement (as defined below) is subject to the satisfaction of specified milestones and other conditions, and those amounts may not become available to us. 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. There can be no assurance that such financing will be available on acceptable terms, if at all. Based on our current operating plan, we expect that our existing cash and cash equivalents and short-term investments, as of June 30, 2026, in addition to the 141.0 million of net proceeds from the issuance of our common stock in August 2026, will enable us to fund operations for greater than twelve months from the issuance of these condensed consolidated financial statements, which includes scale up for the commercialization of TUDRIQEV in advanced melanoma and for working capital and general corporate purposes. 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 our product candidates.

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

Most of 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, or the 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, or 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**

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***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 and proprietary RPx platform, including TUDRIQEV 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 that we may own in the future may be challenged in the courts or patent offices inside or outside of the United States. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be 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, consultants, 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 TUDRIQEV or our 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 TUDRIQEV or our 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 and 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 TUDRIQEV and our 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

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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 TUDRIQEV and our 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, or 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. In November 2022, we filed a petition for inter partes review with the Patent Trial and Appeal Board, or the PTAB, of the United States Patent and Trademark Office, or the USPTO, seeking to invalidate certain claims of the '938 Patent. In August 2023 we entered into a Settlement Agreement with Amgen and mutually agreed to terminate our challenges to their patents. In connection with the Settlement Agreement, we entered into a License and Covenant Agreement with Amgen in which we agreed to pay Amgen low single-digit royalty payments on net sales of our products that, but for the license, could be found to infringe a valid Amgen patent on a country-by-country and product-by-product basis.

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 TUDRIQEV and our 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 TUDRIQEV or our 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.

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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 TUDRIQEV and our 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 products, which are or may be covered by patents or licenses held by third parties, 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 TUDRIQEV or our 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(s) 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 third party collaborators, and in the future may have agreements with other companies, to obtain the supply of co-delivery therapies for the development of our product candidates. If our relationships with these third party collaborators, or any future collaborator or supplier are not successful, we may be delayed or unable to complete the development of our product candidates.***

We have entered into arrangements with BMS as part of our clinical development programs where nivolumab is intended to be used for these clinical programs and with Roche where atezolizumab and bevacizumab are intended to be used for certain of our other clinical programs. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our IGNYTE Phase 1/2 trials with

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TUDRIQEV and our Phase 1/2 clinical trial with RP2 where we intend to use nivolumab and may potentially do so for other clinical trials in the future; Roche has agreed to provide atezolizumab and bevacizumab for use in our RP2 study of hepatocellular cancer, or HCC.

We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies or other co-delivery agents for use in the development of our other product candidates, similar to our agreement with BMS and 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 our product candidates or may otherwise be delayed in the commercialization of our 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 our product candidates or may be otherwise delayed in the commercialization of our 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;
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- 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 clinical trial materials supply, 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, could impact the chance of any such data being accepted by regulatory authorities, 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

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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 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 (remotely or in person) of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs, the applicable study protocols and plans, 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 not accept such data or 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 or use of product that does not meet the applicable quality requirements in clinical trials may compromise the resulting trial data and 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, process consumables or product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.***

We continue to rely on third-party contract manufacturers to manufacture our raw materials and certain clinical trial product supplies. 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 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

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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.

In order to use our in-house Framingham manufacturing site or any third party manufacturing site for the production of product for commercialization, the sites must pass an FDA pre-approval inspection. FDA will not approve a BLA until such inspection demonstrates that product can be adequately and reliably produced. If the FDA or a comparable foreign regulatory authority does not approve these facilities for manufacturing or supply, 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 inspections, may result in regulatory enforcement actions against our manufacturing or us (including criminal fines and civil 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, non- or deferred prosecution 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. Any foreign manufacturing facilities may also be subject to increased FDA scrutiny as there has been an increasing movement to encourage domestic manufacturing of biopharmaceutical products.

***Operating and maintaining our own manufacturing facility may result in unanticipated delays or expenses and we may not experience the anticipated operating efficiencies we intended.***

Our approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts is fully operational. 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 our in-house 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 our in-house facility, which may be delayed or which we may never receive. We will further need to comply with the FDA's and applicable state and 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 state and foreign regulatory authority licensing requirements, inspections and assessments. 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

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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 our in-house 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, 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, if approved, 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 and reputational impact;
- 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

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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, 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 will 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.

As noted above, the significant costs of GDPR and Swiss law compliance, risk of regulatory enforcement actions and private litigation under, and other burdens imposed by these laws as well as under other regulatory schemes throughout the world related to privacy and security of health information and other personal and private data could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry-specific privacy, cybersecurity, data protection, operational and information systems resilience, and artificial intelligence-related laws in Europe which may subject us to additional similar risks and impacts.

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 sanctions, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government procurement and non-procurement programs, 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. 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.

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***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 Drug Supply Chain Security Act, or DSCSA requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, either in the present or future, 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, data protection, security, operational resilience, and AI. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which***

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***could include civil or criminal penalties), private litigation (including from business partners and/or affected individuals) 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 \$7,988 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. 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 privacy, data protection, and security, operational resilience, and AI. For example, the European Union General Data Protection Regulation, the United Kingdom General Data Protection Regulation and related data protection, cybersecurity and e-privacy laws in the European Union, European Economic Area, or the EEA, and the United Kingdom, (collectively referred to herein as the “GDPR, and equivalent Swiss laws may apply to some or all of the clinical or other personal data obtained, transmitted, stored or otherwise processed by us (or on our behalf) relating to or originating from those jurisdictions. The GDPR contains potentially strict requirements with respect to lawfully processing personal data in connection with clinical trials and other business activities in the EEA, UK and Switzerland (collectively, “Europe”) (including with respect to obtaining consents, securing personal data, notifying personal data breaches to supervisory authorities and affected data subjects, and transferring personal data outside Europe).

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 Europe, Switzerland 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 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. 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.

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The GDPR and Swiss law allow supervisory authorities to potentially impose high regulatory fines (among other enforcement tools) in the event of violations, for example, under the GDPR up to 4% of global annual group turnover or EUR 20 million (whichever is the higher amount). Supervisory authorities in the European Union and EEA, and the United Kingdom may potentially levy such fines directly upon on the non-compliant entity and/or on the parent company (so-called “undertaking”) of the non-compliant entity. Supervisory authorities also possess other wide-ranging powers, including conducting unannounced inspections of our facilities and system (so-called “dawn raids”), and issuing “stop processing” orders to us. Separate from regulatory enforcement actions, individuals may bring private actions (including potentially group or representative actions) against us. There is no statutory cap set out in the GDPR on the amount of compensation or the damages which individuals may recover. Claims that we have violated individuals’ privacy and data protection rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Overall, the significant costs of GDPR and Swiss law compliance, risk of regulatory enforcement actions and private litigation under, and other burdens imposed by these laws as well as under other regulatory schemes throughout the world related to privacy and security of health information and other personal and private data could have an adverse impact on our business, reputation, financial condition, and results of operations. We may also be subject to additional industry-specific privacy, cybersecurity, data protection, operational and information systems resilience, and artificial intelligence-related laws in Europe (including the EU AI Act) which may subject us to additional similar risks and impacts.

See Part I, Item 1C, *Cybersecurity*, in the Company's Annual Report on Form 10-K for the year ended March 31, 2026, which was filed with the U.S. Securities and Exchange Commission, or the SEC, on June 29, 2026, for more information regarding our cybersecurity risk management, strategy, and governance.

### **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 clinical 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 any of our 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 any 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, if approved, any of our 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, train 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.

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Changes in our management team resulting from the hiring or departure of executives and key employees from time to time could disrupt our business. 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 or insiders with a wide range of motives and expertise, including state sponsored actors, organized criminal groups, “hacktivists,” insiders, patient groups, disgruntled current or former employees and others. Cyber-attacks (including involving ransomware) are of ever-increasing levels of sophistication, and despite our security measures, our

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information technology, directors, officers and employees, and infrastructure may be vulnerable to such attacks or may be breached, including due to employee or contractor error or malfeasance.

The pervasiveness of cybersecurity and operational resilience incidents in general and the risks of cyber-crime are complex and continue to evolve. There can be no assurance that our security and operational resilience efforts and measures will be effective or that attempted security breaches or disruptions or operational resilience events would not be successful or damaging. Our internal computer systems and those of our contractors and consultants are vulnerable to damage, loss of access or availability, or interruption from computer viruses and other malware, ransomware, unauthorized or inappropriate access or use, natural disasters, pandemics, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of or loss of access to 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, operational resilience event, 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 loss of availability to our data or systems, or inappropriate disclosure of confidential or proprietary information, including 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 our systems, and the development and potential commercialization of our product candidates could be delayed. For additional information, see the Risk Factor captioned, “*We are subject to stringent and changing obligations related to privacy, data protection, security, operational resilience, and AI. 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 (including from business partners and/or affected individuals) and/or adverse publicity and could negatively affect our operating results and business.*”

## **Risks related to our common stock and general risks**

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

Our common stock began trading on the Nasdaq Global Select Market on July 20, 2018 and we can provide no assurances that we will be able to continue to maintain an active trading market on the Nasdaq Global Select Market or any other exchange in the future. 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. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to use our shares as consideration in commercial transactions.

### ***Our authorized share capital limits the number of shares we may issue, and if our stockholders do not approve the proposed increase in our authorized common stock, our ability to raise additional capital, complete strategic transactions and grant equity compensation could be materially constrained.***

Our certificate of incorporation currently authorizes 150,000,000 shares of common stock, of which only 30,258,728 shares remained available for future issuance as of March 31, 2026. A substantial portion of that remaining capacity will be used or reserved in connection with this offering. We are asking our stockholders to approve an increase in the authorized shares of common stock to 300,000,000 shares at our annual meeting scheduled for September 15, 2026, but that increase will not be effective at the time of the closing of this offering and our stockholders may not approve it.

If the increase is not approved, following the closing of this offering, we may not have sufficient authorized shares to fully utilize our ATM (as defined in “Underwriting”) or to pursue other future capital-raising transactions or strategic transactions on a timely basis or at all; we may face challenges in hiring and retaining employees, including members of our executive leadership team, if sufficient shares are not available for equity compensation awards; and we may be required to seek stockholder approval on a transaction-by-transaction basis before issuing shares, which could result in significant delays and additional costs. Given that we expect to require additional financing to fund the commercial launch of TUDRIQEV and our continued development activities, any such constraint could have a material adverse effect on our business and business prospects.

### ***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

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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;
- our success in the commercial launch of TUDRIQEV;
- results of further clinical trials of TUDRIQEV and our 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 further development of TUDRIQEV and our 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, the possibility of an economic recession, international hostilities, 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;
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- the timing and outcomes of further clinical studies for TUDRIQEV and clinical and preclinical studies for our other product candidates or competing product candidates;
- competition from existing and potential future products that compete with TUDRIQEV and our 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 any of our product candidates;
- the level of demand for TUDRIQEV and our 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 TUDRIQEV and our product candidates;
- our ability to commercialize any of our 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;
- natural disasters, public health crises, political and economic crises, negative global climate patterns, or other catastrophic events, the possibility of an economic recession, international hostilities and trade disruptions, including, but not limited to, those resulting from the current U.S. presidential administration, ongoing military conflicts, 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

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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 shares of our common stock in "at-the-market" offerings pursuant to a Sales Agreement entered into on August 3, 2023, and subsequently amended on May 16, 2024, November 25, 2024 and May 22, 2025, with Leerink Partners LLC, or the 2023 Sales Agreement. The sale of a substantial number of shares of our common stock pursuant to the 2023 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 2023 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.
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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 may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity.

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

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

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source 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 and trade conflicts, including the ongoing military conflicts between Russia-Ukraine and Israel-Hamas and the ongoing trade conflict between U.S. and China, 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, economic instability, changes in tax laws and regulations and additional tariffs, including based on the current U.S. presidential administration, export controls, and increased interest rates 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, Ukraine, Israel or China, those conflicts may impact, and if any of those conflicts broaden it may further impact, the markets, 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.***

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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.

***The Hercules Loan and Security Agreement contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay any outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation.***

On October 6, 2022 we and certain of our subsidiaries entered into a Loan and Security Agreement, or the Hercules Loan Agreement with Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent and as a lender, which such agreement was subsequently amended in June 2023, December 2023 and January 2026. The Hercules Loan Agreement contains certain affirmative and negative covenants that could prevent us from taking certain actions without the consent of our lenders. These covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders. The Hercules Loan Agreement also contains customary affirmative and negative covenants that, among other things, may limit our ability, subject to certain exceptions, to incur indebtedness, grant liens, enter into a merger or consolidation, enter into transactions with affiliates, or sell all or a portion of our property, business or assets. The Hercules Loan Agreement contains customary events of default. Upon the occurrence and continuation of an event of default, all amounts due under the Hercules Loan Agreement become (in the case of an insolvency or bankruptcy event), or may become (in the case of all other events of default and at the option of Hercules), immediately due and payable. If an event of default under the Hercules Loan Agreement should occur, we could be required to immediately repay any outstanding indebtedness. If we are unable to repay such debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Hercules Loan Agreement. Even if we are able to repay any indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned.

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

There have been no unregistered sales of securities other than previously disclosed by us in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Mine Safety Disclosure.**

Not applicable.

**Item 5. Other Information.**

None of our directors or officers adopted, modified, or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” in each case as defined in Item 408 of Regulation S-K, during the three months ended June 30, 2026.

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**Item 6. Exhibits.**

| <b>Exhibit<br/>Number</b> | <b>Exhibit Description</b>                                                                                                                   | <b>Incorporated by Reference</b> |             |               |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------------|---------------|
|                           |                                                                                                                                              | <b>Form</b>                      | <b>Date</b> | <b>Number</b> |
| 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 Financial 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 Financial 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.

**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 14, 2026 | By: <u>/s/ Sushil Patel</u><br>Name: Sushil Patel<br>Title: Chief Executive Officer and Director<br>(Principal Executive Officer)    |
| Dated: August 14, 2026 | By: <u>/s/ Emily Hill</u><br>Name: Emily Hill<br>Title: Chief Financial Officer<br>(Principal Financial Officer)                     |
| Dated: August 14, 2026 | By: <u>/s/ Andrew Schwendenman</u><br>Name: Andrew Schwendenman<br>Title: Chief Accounting Officer<br>(Principal Accounting 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, Sushil Patel, 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 14, 2026

By: /s/ Sushil Patel  
Sushil Patel  
*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, Emily Hill, 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 14, 2026

By: /s/ Emily Hill  
Emily Hill  
Chief Financial Officer  
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Replimune Group, Inc. (the “Company”) for the quarter ended June 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Sushil Patel, 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 14, 2026

By: /s/ Sushil Patel  
Sushil Patel  
*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, 2026, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Emily Hill, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of her 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 14, 2026

By: /s/ Emily Hill  
*Emily Hill*  
*Chief Financial Officer*  
*(Principal Financial Officer)*