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Employer Identification No.)500 Unicorn Park DriveSuite 303Woburn MA 01801(Address of principal executive offices)(Zip Code)(781)Â 222-9600(Registrantâ€™s telephone number, including area code)Securities registered pursuant to SectionÂ 12(b)Â of the Act:Title of each classTrading Symbol(s)Name of each exchange on which registeredCommon Stock, par value $0.001 per shareREPLThe Nasdaq Stock Market LLC (Nasdaq Global Select Market)Indicate by check mark whether the registrant (1)Â has filed all reports required to be filed by SectionÂ 13 or 15 (d)Â 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)Â has been subject to such filing requirements for the past 90 days. YesÂ Â Â â˜’Â NoÂ Â Â â˜Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to RuleÂ 405 of Regulation S-T (Â§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).YesÂ Â Â â˜’Â NoÂ Â Â â˜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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in RuleÂ 12b-2 of the Exchange Act.Large accelerated filer â˜Accelerated filer â˜Non-accelerated filer â˜’Smaller reporting company â˜’Emerging growth company â˜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 SectionÂ 13(a)Â of the Exchange Act. â˜Indicate by check mark whether the registrant is a shell company (as defined in RuleÂ 12b-2 of the Exchange Act). YesÂ Â Â â˜Â NoÂ Â Â â˜’The number of shares of the registrantâ€™s Common Stock, par value $0.001 per share, outstanding as of FebruaryÂ 7, 2025 was 77,014,781.Table of ContentsREPLIMUNE GROUP,Â INC.FORMÂ 10-QTable of ContentsPageÂ No.PART I FINANCIAL INFORMATION3Item 1.Condensed Consolidated Financial Statements (Unaudited)3Condensed Consolidated Balance Sheets3Condensed Consolidated Statements of Operations4Condensed Consolidated Statements of Comprehensive Loss5Condensed Consolidated Statements of Stockholdersâ€™ Equity6Condensed Consolidated Statements of Cash Flows7Notes to Unaudited Condensed Consolidated Financial Statements8Item 2.Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations24Item 3.Quantitative and Qualitative Disclosures About Market Risk39Item 4.Controls and Procedures39PART II OTHER INFORMATION40Item 1.Legal Proceedings40Item 1A.Risk Factors40Item 2.Unregistered Sales of Equity Securities and Use of Proceeds76Item 3.Defaults Upon Senior Securities76Item 4.Mine Safety Disclosure76Item 5.Other Information76Item 6.Exhibits76SIGNATURES782Table of ContentsPART I - FINANCIAL INFORMATIONItem 1. Financial Statements.REPLIMUNE GROUP,Â INC.CONDENSED CONSOLIDATED BALANCE SHEETS(Amounts in thousands, except share and per share amounts)(Unaudited)December 31, 2024March 31, 2024AssetsCurrent assets:Cash and cash equivalents$172,245Â $74,457Â Short-term investments364,294Â 346,211Â Research and development incentives receivable3,066Â 4,922Â Prepaid expenses and other current assets7,972Â 8,077Â Total current assets547,577Â 433,667Â Property, plant and equipment, net13,616Â 10,483Â Restricted cash1,700Â 1,700Â Other non-current assets1,200Â â€”Â Right-to-use asset - operating leases4,120Â 4,635Â Right-to-use asset - financing leases35,415Â 37,237Â Total assets$603,628Â $487,722Â Liabilities and Stockholders' EquityCurrent liabilities:Accounts payable$7,188Â $2,578Â Accrued expenses and other current liabilities36,759Â 33,981Â Operating lease liabilities, current1,164Â 1,161Â Financing lease liabilities, current2,779Â 2,718Â Total current liabilities47,890Â 40,438Â Operating lease liabilities, non-current3,225Â 3,771Â Financing lease liabilities, non-current22,913Â 23,410Â Long term debt, net of discount45,960Â 44,809Â Other liabilities, non-current1,266Â 786Â Total liabilities$121,254Â $113,214Â Commitments and contingencies (Note 14)Stockholders' equityCommon stock, $0.001 par value; 150,000,000 shares authorized as of December 31, 2024 and March 31, 2024; 77,009,058 and 61,415,105 shares issued and outstanding as of December 31, 2024 and March 31, 2024, respectively77Â 61Â Additional paid-in capital1,350,587Â 1,070,874Â Accumulated deficit(874,449)(701,282)Accumulated other comprehensive income 6,159Â 4,855Â Total stockholders' equity482,374Â 374,508Â Total liabilities and stockholders' equity$603,628Â $487,722Â The accompanying notes are an integral part of these condensed consolidated financial statements.3Table of ContentsREPLIMUNE GROUP,Â INC.CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS(Amounts in thousands, except share and per share amounts)(Unaudited)Three Months Ended December 31,Nine Months Ended December 31,2024202320242023Operating expenses:Research and development$48,004Â $42,847Â $135,472Â $132,384Â Selling, general and administrative18,015Â 13,693Â 46,827Â 43,633Â Total operating expenses66,019Â 56,540Â 182,299Â 176,017Â Loss from operations(66,019)(56,540)(182,299)(176,017)Other income (expense):Research and development incentives376Â 415Â 1,222Â 1,251Â Investment income5,137Â 5,686Â 15,243Â 17,922Â Interest expense on finance lease liability(528)(540)(1,594)(1,626)Interest expense on debt obligations(1,450)(1,012)(4,314)(3,083)Other (expense) income (3,281)1,344Â (850)1,307Â Total other income (expense), net254Â 5,893Â 9,707Â 15,771Â Loss before income taxes$(65,765)$(50,647)$(172,592)$(160,246)Income tax provision575Â $473Â $575Â $473Â Net loss $(66,340)$(51,120)$(173,167)$(160,719)Net loss per common share, basic and diluted(0.79)(0.77)(2.25)(2.42)Weighted average common shares outstanding, basic and diluted83,498,892Â 66,645,691Â 77,113,695Â 66,532,488Â The accompanying notes are an integral part of these condensed consolidated financial statements.4Table of ContentsREPLIMUNE GROUP,Â INC.CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS(Amounts in thousands)(Unaudited)Three Months Ended December 31,Nine Months Ended December 31,2024202320242023Net loss$(66,340)$(51,120)$(173,167)$(160,719)Other comprehensive loss:Foreign currency translation gain (loss)3,110Â (1,288)773Â (1,285)Net unrealized (loss) gain on short-term investments, net of tax of $0(585)534Â 531Â 290Â Comprehensive loss$(63,815)$(51,874)$(171,863)$(161,714)The accompanying notes are an integral part of these condensed consolidated financial statements.5Table of ContentsREPLIMUNE GROUP,Â INC.Â CONSOLIDATED STATEMENTS OF STOCKHOLDERSâ€™ EQUITY(Amounts in thousands, except share amounts)(Unaudited)Common stockAdditionalpaid-incapitalAccumulateddeficitAccumulatedothercomprehensiveincomeTotalstockholdersâ€™equitySharesAmountBalances as of March 31, 202461,415,105Â $61Â $1,070,874Â $(701,282)$4,855Â $374,508Â Issuance of prefunded warrants to purchase common stock, net of issuance costsâ€”Â â€”Â 48,500Â â€”Â â€”Â 48,500Â Issuance of common stock in connection with private placement, net of placement agent fees and offering costs5,668,937Â 6Â 48,198Â â€”Â â€”Â 48,204Â Foreign currency translation adjustmentâ€”Â â€”Â â€”Â â€”Â (432)(432)Unrealized loss on short-term investmentsâ€”Â â€”Â â€”Â (99)(99)Exercise of pre-funded warrants739,225Â 1Â â€”Â â€”Â â€”Â 1Â Exercise of stock options22,860Â â€”Â 66Â â€”Â â€”Â 66Â Vesting of RSUs463,841Â â€”Â â€”Â â€”Â â€”Â Stock-based compensation expenseâ€”Â â€”Â 9,475Â â€”Â â€”Â 9,475Â Net lossâ€”Â â€”â€(53,772)â€(53,772)Balances as of June 30, 202468,309,968Â 68Â 1,177,113Â (755,054)4,324Â 426,451Â Foreign currency translation adjustmentâ€”Â â€”Â â€”Â â€”Â (1,905)(1,905)Unrealized gain on short-term investmentsâ€”Â â€”Â â€”Â 1,215Â 1,215Â Exercise of stock options34,284Â â€”Â 103Â â€”Â â€”Â 103Â Vesting of RSUs50,336Â â€”Â â€”Â â€”Â â€”Â â€”Â Stock-based compensation expenseâ€”Â â€”Â 8,650Â â€”Â â€”Â 8,650Â Net lossâ€”Â â€”Â â€”Â (53,055)â€”Â (53,055)Balances as of September 30, 202468,394,588Â 68Â 1,185,866Â (808,109)3,634Â 381,459Â Issuance of prefunded warrants to purchase common stock, net of issuance costsâ€”Â â€”Â 48,500Â â€”Â â€”Â 48,500Â Issuance of common stock, net of issuance costs and underwriter fees 8,538,377Â 9Â 107,516Â â€”Â â€”Â 107,525Â Foreign currency translation adjustmentâ€”Â â€”Â â€”Â â€”Â 3,110Â 3,110Â Unrealized loss on short-term investmentsâ€”Â â€”Â â€”Â â€”Â (585)(585)Exercise of stock options22,856Â â€”Â 66Â â€”Â â€”Â 66Â Vesting of RSUs53,237Â â€”Â â€”Â â€”Â â€”Â â€”Â Stock-based compensation expenseâ€”Â â€”Â 8,639Â â€”Â â€”Â 8,639Â Net lossâ€”Â â€”Â â€”Â (66,340)â€”Â (66,340)Balances as of December 31, 202477,009,058Â $77Â $1,350,587Â $(874,449)$6,159Â $482,374Â Balances as of March 31, 202356,676,313Â $57Â $1,034,994Â $(485,488)$5,729Â $555,292Â Foreign currency translation adjustmentâ€”Â â€”â€”â€(1,305)(1,305)Unrealized loss on short-term investmentsâ€”Â â€”â€”â€(458)(458)Exercise of pre-funded warrants1,922,655Â â€”Â â€”Â â€”Â â€”Â â€”Â Exercise of stock options96,146Â â€”Â 1,209Â â€”â€”1,209Â Vesting of RSUs281,211Â â€”Â â€”Â â€”â€”â€”Â Stock-based compensation expenseâ€”Â â€”8,846Â â€”â€”8,846Â Net lossâ€”Â â€”â€”(49,555)â€”(49,555)Balances as of June 30, 202358,976,325Â 57Â 1,045,049Â (535,043)3,966Â 514,029Â Foreign currency translation adjustmentâ€”Â â€”Â â€”Â â€”Â 1,308Â 1,308Â Unrealized gain on short-term investmentsâ€”Â â€”Â â€”Â â€”Â 214Â 214Â Exercise of stock options67,210Â 1Â 549Â â€”Â â€”Â 550Â Vesting of RSUs15,808Â 1Â â€”Â â€”Â â€”Â 1Â Stock-based compensation expenseâ€”Â â€”Â 9,114Â â€”Â â€”Â 9,114Â Net lossâ€”Â â€”Â â€”Â (60,044)â€”Â (60,044)Balances as of September 30, 202359,059,343Â 59Â 1,054,712Â (595,087)5,488Â 465,172Â Foreign currency translation adjustmentâ€”Â â€”Â â€”Â â€”Â (1,288)(1,288)Unrealized gain on short-term investmentsâ€”Â â€”Â â€”Â 534Â 534Â Exercise of pre-funded warrants2,279,967Â 2Â (4)â€”Â â€”Â (2)Vesting of RSUs48,476Â â€”Â â€”Â â€”Â â€”Â â€”Â Stock-based compensation expenseâ€”Â â€”Â 8,241Â â€”Â â€”Â 8,241Â Net lossâ€”Â â€”Â â€”Â (51,120)â€”Â (51,120)Balances as of December 31, 202361,387,786Â $61Â $1,062,949Â $(646,207)$4,734Â $421,537Â The accompanying notes are an integral part of these condensed consolidated financial statements.6Table of ContentsREPLIMUNE GROUP,Â INC.CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS(Amounts in thousands)(Unaudited)Nine Months Ended December 31,20242023Cash flows from operating activities:Net loss$(173,167)$(160,719)Adjustments to reconcile net loss to net cash used in operating activities:Stock-based compensation expense26,764Â 26,201Â Depreciation and amortization2,654Â 1,950Â Net amortization of premiums and discounts on short-term investments(7,008)(9,515)Noncash interest expense1,150Â 786Â Unrealized foreign currency transaction losses (gains)850Â (1,307)Changes in operating assets and liabilities:Research and development incentives receivable1,864Â (1,249)Prepaid expenses and other current assets99Â (2,211)Operating lease, right-of-use-asset506Â 437Â Finance lease, right-of-use-asset1,821Â 1,821Â Other non-current assets(1,200)â€”Â Accounts payable4,700Â (1,505)Accrued expenses and other current liabilities2,501Â 6,123Â Operating lease liabilities(533)(433)Other non-current liabilities480Â 320Â Net cash used in operating activities(138,519)(139,301)Cash flows from investing activities:Purchases of property, plant and equipment and software capitalization(5,553)(3,922)Purchase of short-term investments(331,953)(381,115)Proceeds from sales and maturities of short-term investments321,410Â 459,037Â Net cash (used in) provided by investing activities(16,096)74,000Â Cash flows from financing activities:Proceeds from issuance of common stock, net of fees and offering costs155,729Â â€”Â Proceeds from issuance of prefunded warrants to purchase common stock, net of underwriting fees and offering costs97,000Â â€”Â Proceeds from long-term debtâ€”Â 15,000Â Principal payment of finance lease obligation(436)(345)Proceeds from exercise of stock options and pre-funded warrants235Â 1,758Â Net cash provided by financing activities252,528Â 16,413Â Effect of exchange rate changes on cash, cash equivalents and restricted cash(125)(30)Net increase (decrease) in cash, cash equivalents and restricted cash97,788Â (48,918)Cash, cash equivalents and restricted cash at beginning of period76,157Â 148,226Â Cash, cash equivalents and restricted cash at end of period$173,945Â $99,308Â Supplemental disclosure of cash flow information:Cash paid during the period for interest3,157Â 2,036Â Cash paid for income taxes, net$105Â $300Â Supplemental disclosure of non-cash investing and financing activities:Purchases of property and equipment included in accounts payable and accrued expenses309Â 127Â The accompanying notes are an integral part of these condensed consolidated financial statements.7Table of ContentsREPLIMUNE GROUP,Â INC.NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS(Dollars in thousands, except share and per share amounts)(Unaudited)1. Nature of the businessReplimune Group,Â Inc. (the â€œCompanyâ€) is a clinical-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 candidates are designed and intended to maximally activate the immune system against cancer. Replimune Group,Â Inc., whose predecessor was founded in 2015, is the parent company of its wholly owned, direct and indirect subsidiaries: Replimune Limited (â€œReplimune UKâ€); Replimune,Â Inc. (â€œReplimune USâ€); Replimune Securities Corporation; and Replimune (Ireland) Limited.The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, third-party intellectual property, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Companyâ€™s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.The Company's proprietary oncolytic immunotherapy product candidates, the RPx product candidates, are based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with added payloads intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The Company currently has three RPx product candidates, RP1, RP2 and RP3. RP1 is currently under development in multiple clinical trials, the most advanced being the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial. Basis of presentationThe accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since its inception, including net losses of $66.3 million and $51.1 million for the three months ended DecemberÂ 31, 2024 and 2023, and net losses of $173.2 million and $160.7 million for the nine months ended DecemberÂ 31, 2024 and 2023, respectively. In addition, as of DecemberÂ 31, 2024, the Company had an accumulated deficit of $874.4 million. The Company expects to continue to generate operating losses for the foreseeable future. As of the issuance date of these consolidated financial statements, the Company expects that its cash and cash equivalents and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the issuance of these consolidated financial statements.2. Summary of significant accounting policiesPrinciples of consolidationThe accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its direct and indirect wholly owned subsidiaries, Replimune UK, Replimune US, Replimune Securities Corporation and Replimune (Ireland) Limited after elimination of all intercompany accounts and transactions.Use of estimatesThe preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of stock-based awards. The Company bases its estimates on 8Table of Contentshistorical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances.Unaudited interim financial informationThe accompanying condensed consolidated balance sheet as of DecemberÂ 31, 2024, the condensed consolidated statements of operations, condensed consolidated statements of comprehensive loss and consolidated statements of stockholdersâ€™ equity for the three and nine months ended DecemberÂ 31, 2024 and 2023 and the condensed consolidated statements of cash flows for the nine months ended December 31, 2024 and 2023 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Companyâ€™s financial position as of DecemberÂ 31, 2024 and the results of its operations for the three and nine months ended DecemberÂ 31, 2024 and 2023 and its cash flows for the nine months ended December 31, 2024 and 2023. The financial data and other information disclosed in these consolidated notes related to the three and nine months ended DecemberÂ 31, 2024 and 2023 are unaudited. The results for the three and nine months ended DecemberÂ 31, 2024 are not necessarily indicative of results to be expected for the year ending MarchÂ 31, 2025, 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 FormÂ 10-K for the year ended MarchÂ 31, 2024, which was filed with the Securities and Exchange Commission on May 16, 2024 (the "Annual Report").During the three and nine months ended DecemberÂ 31, 2024, there have been no changes to the Companyâ€™s significant accounting policies as described in the Annual Report.Recently Issued Accounting PronouncementsIn December 2023, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") No. 2023-09, â€œIncome Taxes (Topic 740): Improvements to Income Tax Disclosures.â€ This ASU updates income tax disclosure requirements primarily by requiring specific categories and greater disaggregation within the rate reconciliation and disaggregation of income taxes paid by jurisdiction. This ASU is effective for annual periods beginning after December 15, 2024 and is applicable to the Companyâ€™s fiscal year beginning April 1, 2025, with early application permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.In November 2023, the FASB issued ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures". The amendments in this update expand segment disclosure requirements, including new segment disclosure requirements for entities with a single reportable segment among other disclosure requirements. This update is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company is currently evaluating the potential impact of this adoption on the consolidated financial statements and related disclosures.In November 2024, the FASB issued ASU 2024-03, "Income Statementâ€”Reporting ComprehensiveIncomeâ€”Expense Disaggregation Disclosures: 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.3. Fair value of financial assets and liabilitiesThe following tables present information about the Companyâ€™s financial assets and liabilities measured at fair value on a recurring basis:9Table of ContentsFair Value Measurements as ofDecember 31, 2024 Using:Level 1Level 2Level 3TotalCash equivalentsMoney market funds$â€”Â $73,639Â $â€”Â $73,639Â US Government Agency bondsâ€”Â 9,725Â â€”Â 9,725Â Â Â Â US Treasury bondsâ€”Â 9,697Â â€”Â 9,697Â Short-term investmentsUS Government Agency bondsâ€”Â 99,289Â â€”Â 99,289Â US Treasury bondsâ€”Â 265,005Â â€”Â 265,005Â $â€”Â $457,355Â $â€”Â $457,355Â Fair Value Measurements as ofMarch 31, 2024 Using:Level 1Level 2Level 3TotalCash equivalentsMoney market funds$â€”Â $41,077Â $â€”Â $41,077Â Short-term investmentsUS Government Agency bondsâ€”Â 199,821Â â€”Â 199,821Â US Treasury bondsâ€”Â 146,390Â â€”Â 146,390Â $â€”Â $387,288Â $â€”Â $387,288Â The underlying securities in the money market funds held by the Company are all government backed securities.During the three and nine months ended DecemberÂ 31, 2024 and 2023, there were no transfers between levels.Valuation of cash equivalents and short-term investmentsMoney 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 LevelÂ 2 measurement within the fair value hierarchy. Cash equivalents consisted of money market funds, U.S. Government Agency bonds and U.S. Treasury bonds at DecemberÂ 31, 2024 and money market funds at MarchÂ 31, 2024.4. Short-term investmentsAs of DecemberÂ 31, 2024 and MarchÂ 31, 2024, the Company's available-for-sale investments by type consisted of the following:December 31, 2024AmortizedcostGross unrealizedgainsGross unrealizedlossesCredit LossesFair valueUS Government agency bonds$99,235Â $89Â (35)â€”Â $99,289Â US Treasury bonds264,639Â 418Â (52)â€”Â 265,005Â Â Â Â Â Â Total$363,874Â $507Â (87)â€”Â $364,294Â March 31, 2024Amortized costGross unrealized gainsGross unrealized lossesCredit LossesFair valueUS Government agency bonds199,905Â 33Â (117)$â€”Â 199,821Â US Treasury bonds146,417Â 11Â (38)â€”Â 146,390Â Â Â Â Â Â Total $346,322Â $44Â (155)â€”Â $346,211Â 10Table of ContentsAs of DecemberÂ 31, 2024 and MarchÂ 31, 2024, available-for-sale securities consisted of investments that mature within one year.5. Property, plant and equipment, netProperty, plant and equipment, net consisted of the following:December 31, 2024March 31, 2024Office equipment$1,627Â $1,464Â Computer equipment2,127Â 1,975Â Plant and laboratory equipment10,788Â 10,423Â Leasehold improvements1,853Â 1,886Â Capitalized software7,493Â 3,515Â Construction in progress2,279Â 1,117Â Â Â Â Â Â Total property, plant and equipment26,167Â 20,380Â Less: Accumulated depreciation(12,551) (9,897)Â Â Â Â Â Property, plant and equipment, net$13,616Â $10,483Â Depreciation and amortization expense was $1.0 million and $2.7 million for the three and nine months ended DecemberÂ 31, 2024 and $0.7 million and $2.0 million for the three and nine months ended December 31, 2023, respectively. Amortization on capitalized software for the three and nine months ended DecemberÂ 31, 2024 was $0.3 million and $0.4 million, respectively. The Company did not incur any amortization on capitalized software in the prior year. 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 liabilitiesAccrued expenses and other current liabilities consisted of the following:December 31, 2024March 31, 2024Accrued research and development costs$17,219Â $16,376Â Accrued compensation and benefits costs14,790Â 13,906Â Accrued professional fees438Â 369Â Other4,312Â 3,330Â Â Â Â Â Â Total accrued expenses and other current liabilities$36,759Â $33,981Â 7 DebtOn October 6, 2022, the Company entered into a Loan and Security Agreement (the â€œLoan Agreementâ€), with Hercules Capital, Inc., as administrative agent, collateral agent and as a lender (â€œHerculesâ€). Pursuant to the Loan Agreement, the Company can borrow term loans in an aggregate maximum principal amount of up to $200.0Â million under multiple tranches (the â€œTerm Loan Facilityâ€). Under the Loan Agreement, the Company borrowed an initial amount of $30.0Â million on the closing date, and at the Company's sole option, could have drawn, but did not draw down, an additional $30.0Â 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 $115.0Â 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 $25.0Â 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 $30.0Â million, provided that the aggregate amount of the term loan advances made under tranche 1 do not exceed $30.0Â million, which reflects a decrease of $30.0Â million from the $60.0Â 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, is unchanged, but the option to borrow additional funds were redistributed from tranche 1 to tranche 2. The impact of this amendment is not a modification, as it does not relate to 11Table of Contentsoutstanding debt, but is rather an amendment that provides for a future potential benefit. There is no material impact to the financial statements as a result of the Amendment.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 $15.0Â million, provided that the aggregate amount of the term loan advances made under tranche 2 do not exceed $15.0Â 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 remains as up to $200.0Â million. The Company evaluated the Second Amendment as a modification under relevant accounting guidance, and based on that analysis and the immaterial change in cash flows on current outstanding debt, it was determined that there was no material accounting impact. Upon closing of the Second Amendment, the Company drew down the tranche 2 amount of $15.0Â million.The Term Loan Facility will mature on October 1, 2027 (the â€œMaturity Dateâ€). The outstanding principal balance of the Term Loan Facility bears interest payable in cash at a floating rate per annum equal to the greater of (i) 7.25% and (ii) the sum of the Prime Rate (which is capped at 7.25%) and 1.75%. Accrued interest is payable monthly following the funding of each term loan advance. In addition, the principal balance of the Term Loan Facility will bear â€œpayment-in-kindâ€ interest at the rate of 1.50% (â€œPIK Interestâ€), which PIK Interest will be added to the outstanding principal balance of the Term Loan Facility on each interest payment date. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through September 2026. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until October 2027. At the Company's option, the Company may prepay all or a portion of the outstanding borrowings, subject to a prepayment fee of 3.0% of the principal amount if prepayment had occurred during the 12 months following the closing date, 2.0% after 12 months following the closing date but prior to 36 months following the closing date, and 1.0% thereafter.The Loan Agreement contains customary facility fees, events of default and representations, warranties and affirmative and negative covenants, including a financial covenant requiring 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 â€œUnrestricted Cashâ€) at all times which commenced on January 1, 2024. In addition, the Loan Agreement also contains a financial covenant that beginning on the later of (i) July 1, 2024 and (ii) the date on which the aggregate outstanding principal amount of the Term Loan Facility is equal to or greater than $100.0Â 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 $1.2Â 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 $0.5Â million facility charge and incurred debt issuance costs of $1.5Â 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 Company and repaid on such date, which is being accrued on the Company's consolidated balance sheet. The amount accrued for the final payment is $0.9Â million as of DecemberÂ 31, 2024 and $0.5 million as of MarchÂ 31, 2024.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 $1.0Â million and $1.2Â million were recorded in other assets as of DecemberÂ 31, 2024 and MarchÂ 31, 2024, respectively, related to the Company's right to borrow additional amounts from Hercules in the future and amortized to interest expense over the relevant draw period on a straight-line basis. Interest expense for the three and nine months ended DecemberÂ 31, 2024 was $1.5Â million and $4.3Â million, respectively, and $1.0Â million and $3.1Â million, respectively, for the three and nine months ended December 31, 2023. The summary of obligations under the term loan as of DecemberÂ 31, 2024 and MarchÂ 31, 2024 consisted of the following (in thousands):12Table of ContentsDecember 31, 2024March 31, 2024Principal loan balance$46,276Â $45,749Â Facility charge and diligence fee(221)(266)Unamortized issuance costs(988)(1,191)Accumulated end of term fee893Â 517Â Â Â Â Â Â Â Long term debt, net of discount $45,960Â $44,809Â The annual principal payments due under the Loan Agreement as of fiscal DecemberÂ 31, 2024 and MarchÂ 31, 2024 were as follows:December 31, 2024March 31, 20242025â€”Â â€”Â 2026â€”Â â€”Â 202720,145Â 20,145Â 202827,769Â 27,769Â Total$47,914Â $47,914Â The table of future payments of long-term debt excludes the end of term charge of $2.2 million, which is due upon the maturity of the loan.8 Stockholdersâ€™ equityCommon stockAs of DecemberÂ 31, 2024 and MarchÂ 31, 2024, the Companyâ€™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 Companyâ€™s 2018 Omnibus Incentive Compensation Plan and the Companyâ€™s Employee Stock Purchase Plan (see Note 10) and the exercise of the outstanding warrants to purchase shares of common stock as follows:December 31, 2024March 31, 2024Stock options, issued and outstanding10,213,861Â 8,652,256Â Restricted and performance stock units3,491,335Â 2,397,890Â Stock options and restricted stock units, future issuance1,921,800Â 2,284,141Â Employee stock purchase plan, available for future grants3,405,175Â 2,738,208Â Pre-IPO warrants to purchase common stock497,344Â 497,344Â Pre-funded warrants14,058,153Â 5,281,616Â Â Â Â Â Â Total shares of common stock reserved for future issuance33,587,668Â 21,851,455Â Undesignated preferred stockAs of DecemberÂ 31, 2024, the Companyâ€™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 DecemberÂ 31, 2024.ATM program13Table of ContentsOn AugustÂ 3, 2023, the Company and Leerink Partners LLC (the "Current Agent") entered into a sales agreement, which was subsequently amended on May 16, 2024, and on November 25, 2024 (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 $89.0 million of share of the Company's common stock, $0.001 par value shares (the "Shares"), through the Current 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)Â by methods deemed to be an â€œat the market offeringâ€ (â€œATMâ€) as defined in RuleÂ 415(a)(4)Â promulgated under the Securities Act of 1933, as amended, or if authorized by the Company, in negotiated transactions or block trades, and (ii)Â pursuant to a registration statement on FormÂ S-3 filed by the Company with the Securities and Exchange Commission on August 3, 2023, as amended for an offering of various securities, including shares of the Companyâ€™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 Current Agent will use reasonable efforts to sell the Shares from time to time, based upon the Companyâ€™s instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company will pay the Current 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 Current Agent with customary indemnification rights.During the three and nine months ended DecemberÂ 31, 2024, 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 additional Shares pursuant to the 2023 Sales Agreement. Equity offeringsOn 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 warrant (the "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 Companyâ€™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 Companyâ€™s common stock at a public offering price of $12.9999 per warrant. The company received aggregate net proceeds of approximately $156.0 million after deducting fees and expenses of approximately $5.0 million.9 Pre-funded WarrantsThe Company's pre-funded warrants are exercisable at any time after the date of issuance. Unless otherwise modified by a holder of a pre-funded warrant, no holder may exercise a pre-funded warrant if such holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of the Companyâ€™s common stock outstanding immediately after giving effect to such exercise. 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%, by providing at least 61 daysâ€™ 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 Companyâ€™s common stock as reported on the consolidated balance sheet, though they are included in the Company's annual pool increase calculation as well as the weighted average outstanding common stock in the calculation of basic and diluted net loss per share, as described below in Note 11. During the nine months ended DecemberÂ 31, 2024, a holder of the Company's pre-funded warrants exercised 739,225 of its pre-funded warrants for an exercise price of $0.001 per pre-funded warrant and the Company issued 739,225 shares of Common Stock in exchange thereof.10 Stock-based compensation14Table of ContentsStock-based compensation expenseStock-based compensation expense was classified in the consolidated statements of operations as follows:Three Months EndedDecember 31,Nine Months EndedDecember 31,20242023202420232Research and development$4,573Â $3,784Â $13,927Â $11,529Â Selling, general and administrative4,066Â 4,457Â 12,837Â 14,672Â $8,639Â $8,241Â $26,764Â $26,201Â Â Â Â Â The following table summarizes stock-based compensation expense by award type for the three and nine months ended December 31, 2024 and 2023:Three Months EndedDecember 31,Nine Months Ended December 31,20242023202420232Stock options$4,839Â $5,245Â $15,466Â $16,546Â Restricted and performance stock units3,800Â 2,996Â 11,298Â 9,655Â $8,639Â $8,241Â $26,764Â $26,201Â 2015 Enterprise Management Incentive Share Option PlanThe 2015 Enterprise Management Incentive Share Option Plan of Replimune UK (the â€œ2015 Planâ€) provided for Replimune UK to grant incentive stock options, non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options were granted under the 2015 Plan only to the Companyâ€™s employees, including officers and directors who were also employees. Non-statutory stock options were granted under the 2015 Plan to employees, members of the board of directors, outside advisors and consultants of the Company.2017 Equity Compensation PlanIn July 2017, in conjunction with reorganization by Replimune Limited, pursuant to which each shareholder thereof exchanged their outstanding shares in Replimune Limited for shares in Replimune Group, Inc., on a one-for-one basis (the "Reorganization"), the 2015 Plan was terminated, and all awards were cancelled with replacement awards issued under the 2017 Equity Compensation Plan (the â€œ2017 Planâ€). Subsequent to the Reorganization, no additional grants have been or will be made under the 2015 Plan and any outstanding awards under the 2015 Plan have continued, and will continue with their original terms. The Company concluded that the cancellation of the 2015 Plan and issuance of replacement awards under the 2017 Plan was a modification with no change in the material rights and preferences and therefore no recorded change in the fair value of each respective award.The Companyâ€™s 2017 Plan provides for the Company to grant incentive stock options or non-statutory stock options, stock awards, stock units, stock appreciation rights and other stock-based awards. Incentive stock options were granted under the 2017 Plan only to the Companyâ€™s employees, including officers and directors who were also employees. Restricted stock awards and non-statutory stock options were granted under the 2017 Plan to employees, officers, members of the board of directors, advisors and consultants of the Company. The maximum number of common shares that may be issued under the 2017 Plan was 2,659,885, of which none remained available for future grants as of DecemberÂ 31, 2024. Shares with respect to which awards have expired, terminated, surrendered or cancelled under the 2017 Plan without having been fully exercised will be available for future awards under the 2018 Plan referenced below. In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for the grant of awards.2018 Omnibus Incentive Compensation PlanOn JulyÂ 9, 2018, the Companyâ€™s board of directors adopted, and the Companyâ€™s stockholders approved the 2018 Omnibus Incentive Compensation Plan (the â€œ2018 Planâ€), which became effective immediately prior to the effectiveness of the registration statement filed in connection with the Companyâ€™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 15Table of Contentsawards. 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 Companyâ€™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 5,281,616 shares issuable upon exercise of those pre-funded warrants as of MarchÂ 31, 2024, as described in Note 9 to these consolidated financial statements, or such lesser amount as determined by the Board. On AprilÂ 1, 2024, the number of shares reserved for issuance under the 2018 Plan automatically increased by 2,667,868 shares pursuant to the terms of the 2018 Plan and based on total number of shares of common stock outstanding on MarchÂ 31, 2024. As of DecemberÂ 31, 2024, 1,921,800 shares remained available for future grants under the 2018 Plan.The 2015 Plan, the 2017 Plan and the 2018 Plan are administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. However, the board of directors shall administer and approve all grants made to non-employee directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, except that the exercise price per share of incentive stock options may not be less than 100% of the fair market value of the common stock on the date of grant (or 110% of fair value in the case of an award granted to employees who hold more than 10% of the total combined voting power of all classes of stock at the time of grant) and the term of stock options may not be greater than five years for an incentive stock option granted to a 10% stockholder and greater than ten years for all other options granted. Stock options awarded under both plans expire ten years after the grant date, unless the board of directors sets a shorter term. Vesting periods for the plans are determined at the discretion of the board of directors. Incentive stock options granted to employees and non-statutory options granted to employees, officers, members of the board of directors, advisors, and consultants of the Company typically vest over four years. In 2021 the board of directors initiated the award of restricted stock units ("RSUs"), under the 2018 Plan in addition to stock option awards available as part of the Company's equity incentive for employees, officers, advisors and consultants of the Company. The RSUs typically vest over four approximately equal annual installments with the first such installment occurring on a designated vesting date that is approximately on the one-year anniversary of the date of grant and the subsequent installments occurring on the subsequent three annual anniversaries of the designated vesting date. In 2024 the 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 Companyâ€™s equity incentive for employees, officers, advisors and consultants of the Company. The PSUs will become vested upon the achievement of the approval of the Company's first Biologics License Application ("BLA") for RP1 by the Food and Drug Administration ("FDA") no later than June 30, 2026, and the expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted. 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 granted 246,110 PSUs under the 2018 Plan during the nine months ended December 31, 2024. If the Company does not achieve the approval of the Company's first BLA for RP1 before the expiration of June 30, 2026 then no PSU will be earned or vested. Employee Stock Purchase PlanOn JulyÂ 9, 2018, the Companyâ€™s board of directors adopted and the Companyâ€™s stockholders approved the Employee Stock Purchase Plan (the â€œESPPâ€), which became effective immediately prior to the effectiveness of the registration statement that was filed in connection with the Companyâ€™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 Companyâ€™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 5,281,616 shares issuable upon exercise of those pre-funded warrants described in Note 9 to these consolidated financial statements, or 697,224 shares, whichever is less (or such lesser amount as determined by the Companyâ€™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 AprilÂ 1, 2024, the number of shares reserved for issuance under the ESPP automatically increased by 666,967, for a total of 3,405,175 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 Companyâ€™s ESPP is not currently active.Out-of-Plan Inducement Grants16Table of ContentsFrom 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 was 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. During the nine months ended December 31, 2024 and 2023, the Company granted

124,065 and 125,000 nonqualified stock options to purchase shares of the Company's common stock, and 148,190 and 83,330 restricted stock units under employment inducement grants. Stock option valuationThe 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 Companyâ€™s stock options has been determined utilizing the â€œsimplifiedâ€ method for awards that qualify as â€œplain-vanillaâ€ options.Forfeitures are accounted for as they occur. The fair value of each RSU and PSU is estimated on the date of grant based on the fair value of our common stock on that same dateThe following table presents, on a weighted-average basis, the assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors:Three Months EndedDecember 31,Nine Months EndedDecember 31,20242023Risk-free interest rate4.10Â %4.55Â %4.36Â %3.72Â %Expected term (in years)6.16.16.06.0Expected volatility76.5Â %72.5Â %76.3Â %73.9Â %Expected dividend yield0Â %0Â %0Â %0Â %Stock optionsThe following table summarizes the Companyâ€™s stock option activity:Number ofSharesWeightedAverageExercisePriceWeightedAverageContractualTerm (Years)AggregateIntrinsicValueOutstanding as of March 31, 20248,652,256Â $16.94Â 6.61$5,748Â Granted1,984,141Â $8.07Â Exercised(80,000)$2.97Â Cancelled(342,536)$18.20Â Outstanding as of December 31, 202410,213,861Â $15.28Â 6.42$20,715Â Options exercisable as of December 31, 20246,559,867Â $16.73Â 5.14$11,982Â Options vested and expected to vest as of December 31, 202410,213,861Â $15.28Â 6.42$20,715Â As of DecemberÂ 31, 2024, there was $27.0Â million of unrecognized compensation cost related to unvested common stock options, which is expected to be recognized over a weighted average period of 2.4 years.17Table of ContentsThe weighted average grant-date fair value of stock options granted during the nine months ended December 31, 2024 and 2023 was $5.60 and $12.08, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended December 31, 2024 was $0.5 million.Restricted and performance stock unitsIn January 2024, the Board approved a one-time PSU award under the 2018 Plan for all employees at the vice president level and below as of January 31, 2024, subject to non-market performance and service conditions. The grants will become vested upon the achievement of the approval of the Companyâ€™s first Biologics License Application (â€œBLAâ€) for RP1 by the Food and Drug Administration (â€œFDAâ€) no later than June 30, 2026. If the Company does not achieve the approval of the Company's first BLA for RP1 before the expiration of June 30, 2026 then no PSU will be earned or vested. 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 is recognized over the requisite service period if and when the achievement of such performance condition is determined to be probable by the Company. The Company reassesses the probability of achieving the performance condition at each reporting period. As of DecemberÂ 31, 2024, the Company has not recognized any expense related to PSUs.A summary of the changes in the Company's RSUs and PSUs during the nine months ended December 31, 2024 is as follows:Number of Restricted SharesWeightedAverageGrant Date Fair ValueOutstanding as of March 31, 20242,397,890Â 17.97Â Granted1,897,397Â 8.26Â Vested(567,414)22.00Â Cancelled(236,538)13.26Â Outstanding as of December 31, 20243,491,335Â $12.36Â As of DecemberÂ 31, 2024, there was $29.5Â million of unrecognized compensation cost related to unvested restricted stock units, which is expected to be recognized over a weighted average period of 2.5 years. Of the $29.5Â million of total unrecognized compensation cost, performance based awards tied to the achievement of a company milestone account for approximately $4.8Â million. The performance based awards will vest upon achievement of the performance milestone. The remaining unrecognized compensation cost is related to restricted stock units which vest over time.11 Net loss per shareBasic and diluted net loss per share attributable to common stockholders was calculated as follows:Three Months Ended December 31,Nine Months Ended December 31,20242023Numerator:Net loss $(66,340)$(51,120)$(173,167)$(160,719)Denominator:Weighted average common shares outstanding, basic and diluted83,498,892Â 66,645,691Â 77,113,695Â 66,532,488Â Net loss per share, basic and diluted(0.79)(0.77)(2.25)(2.42)The 14,058,153 shares of the Company's common stock issuable upon exercise of pre-funded warrants described in Note 9 to these consolidated financial statements are included as outstanding common stock in the calculation of basic and diluted net loss per share. The Companyâ€™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 18Table of Contentsseries 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 and Nine Months Ended December 31,20242023Options to purchase common stock10,213,861Â 8,833,069Â Unvested restricted and performance stock units3,491,335Â 2,040,997Â Warrants to purchase common stock497,344Â 497,344Â 14,202,540Â 11,371,410Â 12 Significant agreementsAgreement with Bristol-Myers Squibb CompanyIn February 2018, the Company entered into an agreement with Bristol-Myers Squibb Company (â€œBMSâ€). Pursuant to the agreement, BMS will provide to the Company, at no cost, a compound for use in the Companyâ€™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)Â the completion of the clinical trial, (ii)Â all related clinical trial data have been delivered to both parties and (iii)Â 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)Â in the event of an uncured material breach by the other party, (y)Â in the event the other party is insolvent or in bankruptcy proceedings or (z)Â for safety reasons. Upon termination, the licenses granted to the Company to use BMSâ€™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 Companyâ€™s Phase 1 clinical trial of RP2 in combination with nivolumab. Agreement with Regeneron Pharmaceuticals,Â Inc.In May 2018, the Company entered into an agreement with Regeneron Pharmaceuticals,Â Inc. (â€œRegeneronâ€). Pursuant to the agreement the Company agreed to undertake one or more clinical trials with Regeneron for the administration of the Company's product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types. The first of which, agreed in June 2018, is the Company's ongoing clinical trial testing RP1 in combination with cemiplimab versus cemiplimab alone in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations.Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources needed to fulfill their respective obligations, in each case, under the terms of agreed study plans. The Company does not expect any further reimbursements from Regeneron related to the initial study plan of June 2018 and the CERPASS trial. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain time-based covenants that restrict the Company from entering into a third-party arrangement with respect to the use of its product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 virus, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to the Company's ongoing Phase 2 clinical trial in CSCC.19Table of ContentsThe agreement may be terminated by either party if (i) there is no active study plan for which a final study report has not been completed and the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (ii) in the event of a material breachThe agreement with Regeneron is accounted for under ASC 808, Collaborative Arrangements (â€œASC 808â€), as both parties are active participants and each party pays its own compound costs and share equally in development costs. The Company accounts for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company recognizes any amounts received from Regeneron in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.In July 2022, Regeneron informed the Company that the costs of the study have reached the initial budget for the initial study plan of June 2018 and that Regeneron's reimbursement of CERPASS study costs to the Company have completed in the period ending June 30, 2022 in relation to the initial study budget. As a result of this notice from, and the ongoing communications with, Regeneron, the Company has not recorded any cost-sharing reimbursements from Regeneron in prepaid expenses and other current assets in the consolidated balance sheet or as an offset to research and development expense within the consolidated statement of operations since Regeneron informed it that Regeneronâ€™s reimbursement of CERPASS study costs have completed. The Company does not expect any further reimbursements from Regeneron related to the initial study plan of June 2018.13 Collaboration and other arrangementsRoche 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 has agreed with Roche to terminate the CRC collaboration and pursue the 2L cohort in HCC with RP2 only. Roche has expressed its intent to continue to supply its currently approved drugs, atezolizumab and bevacizumab for the 2L cohort in HCC but is unlikely to share costs following the Company's re-prioritization. The Company is in discussions with Roche about revising these agreements following the Company's changes to its RP2 and RP3 development plans. Under the terms of the initial 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.The agreement with Roche is accounted for under ASC 808, Collaborative Arrangements (â€œASC 808â€), as both parties are active participants and each party pays its own compound costs. The Company accounts for costs incurred as part of the study, including costs to supply compounds for use in the study, as research and development expenses within the consolidated statement of operations. The Company will recognize any amounts received from Roche in connection with this agreement as an offset to research and development expense within the consolidated statement of operations.During the three and nine months ended DecemberÂ 31, 2024 and 2023, the Company did not make any payments to Roche under the terms of the agreement. The Company did not record any costs as an offset to research and development expenses during the three and nine months ended DecemberÂ 31, 2024. The Company recorded $0.8 million and $2.6 million as an offset to research and development expenses during the three and nine months ended DecemberÂ 31, 2023, respectively. During the nine months ended DecemberÂ 31, 2024 and 2023, the Company received payments under the terms of the agreement from Roche of $1.8 million and $1.7 million, respectively. As of DecemberÂ 31, 2024 no receivables were recorded from Roche in connection with this agreement. As of MarchÂ 31, 2024, the Company recorded $1.8 million as receivables from Roche in connection with this agreement.Incyte In July 2023, the Company entered into a Clinical Trial Collaboration and Supply Agreement with Incyte Corporation, or Incyte. Under the agreement, the companies will collaborate in a signal finding study in which Incyte will initiate and sponsor a clinical trial of INCB99280 (oral PD-L1 inhibitor) and RP1 in approximately 40 patients with unresectable, high risk CSCC in the neoadjuvant setting. Under the terms of the agreement, the Company will supply Incyte with RP1 for the study and share costs of the study equally with Incyte. The agreement may be terminated by either party upon (i) a material breach not 20Table of Contentsreasonably cured within thirty (30) days; (ii) the discontinuation of development of its clinical drug candidate; (iii) the unethical or illegal business practices of the other party; or (iv) if the parties have not agreed on the protocol or budget within ninety (90) days of the effective date of the agreement. In addition, the Company may terminate the agreement upon the inappropriate or unsafe use of the RP1 product candidate. On July 30, 2024, Incyte announced it has discontinued further development of its oral small molecule PD-L1 inhibitor, which was the intended study drug in the Company's planned collaboration with Incyte. On August 1, 2024, the Company received notice of termination of the Clinical Trial Collaboration and Supply Agreement from Incyte. During the year ended March 31, 2024, the Company did not make any payments to, or receive any payments from, Inctye under the terms of the agreement. Additionally, no costs were recorded to research and development expenses during the three and nine months ended DecemberÂ 31, 2024 related to this agreement.AmgenIn 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 contingenciesLeasesThe table below presents the lease-related costs which are included in the consolidated statements of operations for the three months ended December 31, 2024 and 2023:Three Months Ended December 31,Nine Months Ended December 31,20242023Lease costFinance lease costs:Amortization of right-to-use asset$607Â $607Â $1,821Â $1,821Â Interest on lease liabilities528Â 540Â 1,594Â 1,626Â Operating lease costs283Â 279Â 849Â 840Â Total lease cost$1,418Â $1,426Â $4,264Â $4,287Â The following table summarizes the classification of lease costs in the consolidated statement of operations for the three months ended December 31, 2024 and 2023 as follows:Three Months Ended December 31,Nine Months Ended December 31,20242023Finance Lease CostsÂ Â Â Research and development$607Â $607Â $1,821Â $1,821Â Other income (expense)528Â 540Â 1,594Â 1,626Â Operating Lease CostsResearch and development197Â 224Â 656Â 681Â Â Â Â Selling, general and administrative86Â 55Â 193Â 159Â Total lease cost$1,418Â $1,426Â $4,264Â $4,287Â 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 financing lease liabilities recognized on its balance sheet as of DecemberÂ 31, 2024:21Table of ContentsDecember 31, 2024Operating

leasesFinancing leaseTotal2025 (remaining three months)$289Â $689Â $978Â 20261,167Â 2,799Â 3,966Â 20271,133Â 2,883Â 4,016Â 20281,082Â 2,969Â 4,051Â 20291,002Â 3,058Â 4,060Â Thereafter918Â 31,995Â 32,913Â Total lease payments5,591Â 44,393Â 49,984Â Less: interest1,202Â 18,701Â 19,903Â Total lease liabilities$4,389Â $25,692Â $30,081Â The following table provides lease disclosure as of DecemberÂ 31, 2024 and MarchÂ 31, 2024:December 31, 2024March 31, 2024LeasesRight-to-use operating lease asset$4,120Â $4,635Â Right-to-use finance lease asset35,415Â 37,237Â Total lease assets$39,535Â $41,872Â Operating lease liabilities, current$1,164Â $1,161Â Finance lease liabilities, current2,779Â 2,718Â Operating lease liabilities, non-current3,225Â 3,771Â Finance lease liabilities, non-current22,913Â 23,410Â Total lease liabilities$30,081Â $31,060Â The following table provides lease disclosure for the three months ended December 31, 2024 and 2023:Nine Months Ended December 31,20242023Other informationCash paid for amounts included in the measurement of lease liabilities:Operating cash flows from operating leases$876Â $724Â Operating cash flows from finance leases$1,594Â $1,626Â Financing cash flows from finance leases$436Â $345Â Right-to-use asset obtained in exchange for new operating lease liabilities$â€”Â $â€”Â Weighted-average remaining lease term - operating leases4.9years5.9yearsWeighted-average remaining lease term - financing leases14.6years15.6yearsWeighted-average discount rate - operating leases10.3Â %10.3Â %Weighted-average discount rate - financing leases8.3Â %8.3Â %The variable lease costs and short-term lease costs were insignificant for the three and nine months ended DecemberÂ 31, 2024 and 2023.Manufacturing commitmentsThe Company has entered into an agreement with a contract manufacturing organization to provide clinical trial products. As of DecemberÂ 31, 2024 and MarchÂ 31, 2024, the Company had committed to minimum payments under these arrangements totaling $0.8 million and $0.9 million, respectively.22Table of ContentsIndemnification agreementsIn the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its executive management team and its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and therefore it has not accrued any liabilities related to such obligations in its consolidated financial statements as of DecemberÂ 31, 2024 or MarchÂ 31, 2024.Legal proceedingsThe Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.15 Income taxesThe Companyâ€™s income tax provision and effective tax rate for the three months ended December 31, 2024 was $0.6 million and 0.9%, respectively. The Companyâ€™s income tax provision and effective tax rate for the three months ended December 31, 2023 was $0.5 million and 0.9%, respectively. The income tax provision and effective tax rate for the three months ended December 31, 2024 is primarily due to forecasted U.S. taxable income for the year that is not fully offset by available net operating loss and tax credit carryforwards as well as a provision to return adjustment. The income tax provision and effective tax rate for the three months ended December 31, 2023 is primarily due to forecasted U.S. taxable income for the year that is not fully offset by available net operating loss carryforwards.The Company's income tax provision and effective tax rate for the nine months ended December 31, 2024 was $0.6 million and 0.3%, respectively. The Companyâ€™s income tax provision and effective tax rate for the nine months ended December 31, 2023 was $0.5 million and 0.3%, respectively. The income tax provision and effective tax rate for the nine months ended December 31, 2024 is primarily due to forecasted U.S. taxable income for the year that is not fully offset by available net operating loss and tax credit carryforwards as well as a provision to return adjustment. The income tax provision and effective tax rate for the nine months ended December 31, 2023 is primarily due to forecasted U.S. taxable income for the year that is not fully offset by available net operating loss carryforwards.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 feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of DecemberÂ 31, 2024 and MarchÂ 31, 2024, the Company has recorded a full valuation allowance against its net deferred tax assets.16 Geographic informationThe Company operates in two geographic regions: the United States (Massachusetts) and the United Kingdom (Oxfordshire). Information about the Companyâ€™s long-lived assets held in different geographic regions is presented in the tables below:December 31, 2024March 31, 2024United States$13,058Â $8,992Â United Kingdom558Â 1,491Â $13,616Â $10,483Â 23Table of ContentsItem 2. Managementâ€™s discussion and analysis of financial condition and results of operations.You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and related notes appearing in PartÂ I,Â Item 1 of this Quarterly Report on FormÂ 10-Q, or this Quarterly Report, and with our audited consolidated financial statements and notes thereto for the year ended MarchÂ 31, 2024, included in our Annual Report on FormÂ 10-K for the fiscal year ended MarchÂ 31, 2024.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 SectionÂ 27A of the Securities Act of 1933, as amended, and SectionÂ 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 PartÂ II,Â Item 1A â€œRisk Factorsâ€ and our other filings with the Securities Exchange Commission, or SEC.We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. Statements made herein are as of the date of the filing of this Quarterly Report with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rulesÂ 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.OverviewGeneralWe are a clinical-stage biotechnology company committed to applying our leading expertise in the field of oncolytic immunotherapy to transform the lives of cancer patients through our novel oncolytic immunotherapies. Our proprietary oncolytic immunotherapy product candidates are intended to maximally activate the immune system against cancer.Oncolytic immunotherapy is an emerging drug class, which we intend to establish as the second cornerstone of immune-based cancer treatments, alongside checkpoint blockade. Oncolytic immunotherapy exploits the ability of certain viruses to selectively replicate in and directly kill tumors, as well as induce a potent, patient-specific, anti-tumor immune response. Our product candidates incorporate multiple mechanisms of action into a practical â€œoff-the-shelfâ€ approach that is intended to maximize the immune response against a patientâ€™s cancer and to offer significant advantages over other approaches to inducing anti-tumor immunity, including personalized vaccine approaches. We believe that the bundling of multiple approaches for the treatment of cancer into single therapies will increase clinical efficacy and simplify the development path of our product candidates, while also improving patient outcomes.Our proprietary RPx platform is based on a novel, engineered strain of herpes simplex virus 1, or HSV-1, backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform 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 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. We currently have three RPx product candidates in our development pipeline, RP1 (vusolimogene oderparepvec), our lead product candidate, RP2 and RP3. Although our fiscal year ends March 31st, our programs and program updates are reported on a calendar year basis. We are conducting a number of clinical trials of RP1, both as a monotherapy and in combination with anti-PD-1 therapy, with a focus on establishing a major skin cancer franchise. Our leading clinical trial of RP1 is our IGNYTE trial, 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. The leading tumor specific cohort in 24Table of Contentsthe IGNYTE trial is our registration directed Phase 2 expansion cohort in anti-PD-1 failed cutaneous melanoma. The anti-PD1 failed melanoma cohort from the IGNYTE clinical trial includes 140 patients who received RP1 plus nivolumab. The primary analysis by independent central review was triggered once all patients had been followed for at least 12 months. The topline results showed the overall response rate, or ORR, was 33.6% by modified RECIST 1.1 criteria, the primary endpoint as defined in the protocol, and 32.9% by RECIST 1.1 criteria, an additional analysis requested by the U.S. Food and Drug Administration, or FDA. Responses from baseline were highly durable with 85% of responses lasting more than 12 months. The median duration of response from baseline was 27.6 months and the median duration of response from treatment initiation was 21.6 months. RP1 combined with nivolumab continues to be well-tolerated, with mainly Grade 1-2 â€œon targetâ€ side effects, observed. In September 2024, we presented the independently reviewed data from the IGNYTE clinical trial, including key secondary endpoints and subgroup analyses as a late-breaking abstract during an oral session at the European Society for Medical Oncology, or ESMO. Data presented at ESMO showed activity across all subgroups, including patients who had prior anti-PD1 and anti-CTLA-4 treatment had an ORR of 27.7% and patients who had primary resistance to anti-PD1 had an ORR of 35.9% by modified RECIST v1.1. In November 2024, we announced submission of a biologics license application (BLA) to the FDA for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD1 containing regimen and that the FDA has granted Breakthrough Therapy designation to RP1 in combination with nivolumab in the same setting. The submission was made under the Accelerated Approval pathway. We recently announced the FDA accepted our BLA and granted priority review with a Prescription Drug User Fee Act goal date of July 22, 2025. Following a Type C meeting with the FDA, a confirmatory study design concept consisting of a 2-arm randomized trial with physicianâ€™s choice of treatment as a comparator arm in anti-PD1 failed melanoma patients, or the IGNYTE-3 trial, was agreed. The FDA requested that the Phase 3 confirmatory IGNYTE-3 trial be underway at the time of a BLA submission under the accelerated approval pathway. In August 2024, we announced the dosing of the first patient in our IGNYTE-3 trial and enrollment in the IGNYTE-3 trial continues. This trial is planned to have over 100 sites globally and will assess RP1 in combination with nivolumab in patients with advanced melanoma who have progressed on anti-PD-1 and anti-CTLA-4 therapies or are ineligible for anti-CTLA-4 treatment. In our non-melanoma skin cancer, or NMSC, cohort of the IGNYTE clinical 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, and angiosarcoma in this cohort. The data showed that treatment with RP1 in combination with nivolumab led to an ORR of 30% which is consistent with data from the anti-PD1 failed melanoma cohort with approximately one-third of patients responding and 60% demonstrating clinical benefit. The combination of RP1 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. Enrollment remains open in this cohort. Furthering development of our RP1 clinical candidate, we have open for enrollment a Phase 1b/2 clinical trial of single agent RP1 in solid organ transplant recipients with skin cancers, including CSCC, which is referred to herein as ARTACUS or the ARTACUS trial, which we believe to be potentially registrational (in its own right or, subject to discussion with regulatory authorities, following enrollment of additional patients, including as a potential label expansion after an initial approval of RP1 in a different indication). We are currently enrolling up to 65 patients in the ARTACUS trial to assess the safety and efficacy of RP1 in liver, kidney, heart, lung, and hematopoietic cell transplant recipients with skin cancers. In November 2023 we presented initial data from the ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancers at the Society for Immunotherapy of Cancerâ€™s (SITC) 38th Annual Meeting. The data included 23 evaluable patients with CSCC (n=20) and Merkel cell carcinoma (n=3), demonstrating an overall response rate, or ORR of 34.5% and a complete response, or CR of 21%. RP1 monotherapy was well tolerated in these patients and the safety profile was similar to that observed in our other RP1 clinical trials in patients who are not immune suppressed. No immune-mediated adverse events or evidence of allograft rejection were observed. This data was also presented during oral presentation at the American Association of Cancer Research 2024 Annual Meeting in April 2024. We continue to enroll patients into this trial.As previously reported, the CERPASS clinical trial of RP1 in patients with CSCC continues as planned to assess duration of response, or DOR, progression free survival and overall survival with greater maturity. We are also developing or have been developing additional product candidates, RP2 and RP3, that have been further engineered to enhance anti-tumor immune responses and are intended to address additional tumor types, including traditionally less immune responsive tumor types. In addition to the expression of GALV-GP R(-) and human GM-CSF as in RP1, RP2 has been engineered to express an antibody-like molecule intended to block the activity of CTLA-4, a protein that inhibits the full activation of an immune response, including to tumors. RP3 has been engineered with the intent to further stimulate an anti-tumor immune response through activation of immune co-stimulatory pathways through the additional expression of the ligands for CD40 and 4-1BBL, as well as anti-CTLA-4 and GALV-GP R(-), but without the expression of GM-CSF.We continue the development of our clinical candidate RP2 with a focus on establishing a rare cancer franchise. 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-PD1 25Table of Contentsand in particular in patients with metastatic uveal melanoma (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 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, or 88.2%) in the study had

progressed on or after immunotherapy with 12 of 17 patients (70.6%) having previously received both anti-PD1 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%. We have initiated and are enrolling patients in a registration-directed study of RP2 in MUM patients who are immune checkpoints inhibitor-naÃ¯ve. The study is a randomized trial of RP2 in combination with nivolumab vs. ipilimumab and nivolumab, or nivolumab for those ineligible for ipilimumab. The Company continues its signal finding trial of RP2 in combination with atezolizumab and bevacizumab in the 2L setting of patients with hepatocellular carcinoma (HCC) in collaboration with Roche. This Phase 2 clinical trial is currently open and enrollment has begun. RP1, 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.FinancialSince our inception, we have devoted substantially all of our resources to developing our proprietary RPx platform, building our intellectual property portfolio, conducting research and development of our product candidates, business planning, raising capital and providing general and administrative support for our operations. To date, we have incurred significant operating losses and we have financed our operations primarily with proceeds from the sale of equity securities and to a lesser extent, the proceeds from the issuance of debt securities. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of one or more of our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales.Since our initial public offering, or IPO, on JulyÂ 20, 2018, we have raised an aggregate of approximately $1,101.8 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 NovemberÂ 2019, JuneÂ 2020, OctoberÂ 2020, December 2022, and November 2024, respectively, $96.7 million was from our private investment in a public entity in June 2024, and $41.9 million was from at-the-market offerings. We sold 7,407,936 shares of common stock in our IPO, an aggregate of 28,968,857 shares of our common stock and pre-funded warrants to purchase 13,330,422 shares of common stock in the Public Offerings, 5,668,937 shares of our common stock and pre-funded warrants to purchase 5,669,578 shares of common stock through our private investment in a public entity in June 2024, and 2,313,997 shares of common stock through our at-the-market facilities.Our net losses were $66.3 million and $51.1 million for the three months ended DecemberÂ 31, 2024 and 2023, respectively and $173.2 million and $160.7 million for the nine months ended December 31, 2024 and 2023, respectively. As of DecemberÂ 31, 2024, we had an accumulated deficit of $874.4 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 in connection with our ongoing development activities, including further advancement of any preclinical activities and clinical trials of our product candidates across our platform, and if and as we:â€¢conduct our current and future clinical trials with RP1, RP2 and RP3;â€¢further preclinical development of our platform;26Table of Contentsâ€¢operate our in-house manufacturing facility;â€¢seek to identify and develop additional product candidates;â€¢seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;â€¢establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;â€¢until our manufacturing facility is fully validated, continued limited manufacturing by third parties for clinical development;â€¢maintain, expand, protect and defend our intellectual property portfolio;â€¢hire and retain additional clinical, quality control, scientific and general and administration personnel;â€¢acquire or in-license other drugs, technologies or intellectual property rights; andâ€¢add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and operations as a public company.Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.As of DecemberÂ 31, 2024, we had cash and cash equivalents and short-term investments of $536.5 million. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least 12Â months from the issuance of the consolidated financial statements included in this Quarterly Report.See â€œâ€”Liquidity and capital resourcesâ€ and â€œRisk factorsâ€”Risks related to our financial position and need for additional capital.â€Components of our results of operationsRevenueÂ To date, we have not generated any revenue from product sales as we do not have any approved products and we can not be certain we will generate any revenue from the sale of products in the future. If our development efforts for RP1 or any other product candidates that we may develop in the future are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from those collaborations or license agreements.Operating expensesOur expenses since inception have consisted solely of research and development costs and general and administrative costs.Research and development expensesResearch 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:â€¢expenses incurred under agreements with third parties, including clinical research organizations, or CROs, that conduct research, preclinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture our product candidates for use in our preclinical and clinical trials;27Table of Contentsâ€¢salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;â€¢costs of outside consultants engaged in research and development functions, including their fees, stock-based compensation and related travel expenses;â€¢the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;â€¢costs related to compliance with regulatory requirements in connection with the development of our product candidates; andâ€¢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.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 and initiate additional clinical trials and continue to discover and develop additional product candidates. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:â€¢the scope, rate of progress, expense and results of our ongoing clinical trials, as well as future clinical trials or other product candidates and other research and development activities that we may conduct;â€¢the number and scope of preclinical and clinical programs we decide to pursue;â€¢our ability to maintain our current research and development programs and to establish new ones;â€¢uncertainties in clinical trial design;â€¢the rate of enrollment in clinical trials;â€¢the successful completion of clinical trials with safety, tolerability, and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;â€¢the receipt of regulatory approvals from applicable regulatory authorities;28Table of Contentsâ€¢our success in operating our manufacturing facility, or securing manufacturing supply through relationships with third parties;â€¢our ability to obtain and maintain patents, trade secret protection, and regulatory exclusivity, both in the United States and internationally;â€¢our ability to maintain, expand, protect and defend our rights in our intellectual property portfolio;â€¢the commercialization of our product candidates, if and when approved;â€¢the acceptance of our product candidates, if approved, by patients, the medical community, and third-party payors;â€¢our ability to successfully develop our product candidates for use in combination with third-party products or product candidates;â€¢negative developments in the field of immuno-oncology;â€¢competition with other products; andâ€¢significant and changing government regulation and regulatory guidance.A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant trial delays due to patient enrollment or other reasons, we could be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in obtaining regulatory approval for any of our product candidates.Selling, general and administrative expensesSelling, general and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate, commercial and business development and administrative functions. Selling, general and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, pre-commercial planning, travel expenses, and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.We expect that our selling, general and administrative expenses will continue to increase in the future as we increase our selling, general and administrative headcount to support our continued research and development and pre-launch activities to prepare for potential commercialization of our product candidates. We also expect to continue to incur increased expenses, including accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements; director and officer insurance costs; and investor and public relations costs.Other income (expense), netResearch and development incentivesResearch and development incentives consists of reimbursements of research and development expenditures. We participate, through our subsidiary in the United Kingdom, in the research and development program provided by the United Kingdom tax relief program, such that a percentage of up to 14.5% of our qualifying research and development expenditures are reimbursed by the United Kingdom government, and such incentives are reflected as other income.Investment incomeInvestment income consists of income earned on our cash and cash equivalents and short-term investments.Interest expense on debt obligationsInterest expense on debt obligations consists of the amortization of debt discount and cash paid for interest under the Â Â Â Â loan agreement with Hercules.29Table of ContentsInterest expense on finance lease liabilityInterest expense on finance lease liability consists of amortization of finance charges under our financing lease. Other income (expense), netOther income (expense), net consists primarily of realized and unrealized foreign currency transaction gains and losses.Income taxesThe Companyâ€™s tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate (â€œAETRâ€), adjusted for the effect of discrete items arising in that quarter. The impact of such inclusions could result in a higher or lower effective tax rate during a particular quarter, based upon the mix and timing of actual earnings or losses versus annual projections. In each quarter, the Company updates its estimate of the annual effective tax rate, and if the estimated annual tax rate changes, a cumulative adjustment is made in that quarter. For the nine months ended December 31, 2024 and 2023, the Company excluded the United Kingdom from the calculation of the AETR as the Company anticipates an ordinary loss in this jurisdiction for which no tax benefit can be recognized.The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets both in the United States and United Kingdom, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of DecemberÂ 31, 2024 and MarchÂ 31, 2024, the Company has recorded a full valuation allowance against its net deferred tax assets. Results of operationsComparison of the three months ended DecemberÂ 31, 2024 and 2023The following chart summarizes our results of operations for the three months ended DecemberÂ 31, 2024 and 2023:Three Months Ended December 31,20242023Change(Amounts in thousands)Operating expenses:Research and development$48,004Â $42,847Â $5,157Â Selling, general and administrative18,015Â 13,693Â 4,322Â Total operating expenses66,019Â 56,540Â 9,479Â Loss from operations(66,019)(56,540)(9,479)Other income (expense):Research and development incentives376Â 415Â (39)Investment income5,137Â 5,686Â (549)Interest expense on finance lease liability(528)(540)12Â Interest expense on debt obligations(1,450)(1,012)(438)Other (expense) income(3,281)1,344Â (4,625)Total other income (expense), net254Â 5,893Â (5,639)Loss before income taxes$(65,765)$(50,647)$(15,118)Income tax provision$575Â $473Â $102Â Net loss$(66,340)$(51,120)$(15,220)Research and development expenses30Table of ContentsResearch and development expenses for the three months ended DecemberÂ 31, 2024 were $48.0 million, compared to $42.8 million for the three months ended DecemberÂ 31, 2023. The following table summarizes our research and development expenses for the three months ended December 31, 2024 and 2023:Three Months Ended December 31,20242023ChangeDirect research and development expenses by programÂ Â RP1 program costs by

study:Â Â Â Â Â IGNYTE3,226Â 3,490Â (264)Â Â Â Â ARTACUS1,787Â 1,547Â 240Â Â Â Â Â CERPASS1,611Â 3,460Â (1,849)Â Â Â Â IGNYTE-32,375Â 1,483Â 892Â Â Â Â Â Other RP1 study costs1,590Â 2,545Â (955)Â Â Â Â Â Â Total RP1 costs10,589Â 12,525Â (1,936)Â Â Â Â RP24,409Â 2,308Â 2,101Â Â Â Â Â RP31,434Â 3,100Â (1,666)Unallocated research and development expenses:Â Â Â Â Â Â Personnel related (including stock-based compensation)23,653Â 19,994Â 3,659Â Â Â Â Other7,919Â 4,920Â 2,999Â Total research and development expenses$48,004Â $42,847Â $5,157Â The overall increase of $5.2Â million in total research and development expenses was driven by an increase of approximately $6.7Â million in our unallocated expenses which is driven by a $3.7Â million increase in personnel related costs, as well as a $3.0Â million increase in other costs primarily attributable to increased consultants and facility costs. The decrease of $1.5Â million in direct research costs is primarily a result of the wind down of the CERPASS study and completion of enrollment in the IGNYTE advanced melanoma cohort, as well as the Company's reprioritization spending during the current fiscal year. More specifically, the decrease of $1.9Â million in costs related to RP1 is the result of decreased enrollment as patients come off the CERPASS study and the IGNYTE advanced melanoma cohort. In addition, the decrease of $1.7Â million in costs related to RP3 is a reflection of the deprioritization of development efforts on this product candidate, which the Company began to taper in the second half of the prior fiscal year. These decreases are partially offset by an increase in spending on RP2 of $2.1Â million as the Company began to ramp up costs for the MUM study.Selling, general and administrative expensesSelling, general and administrative expenses were $18.0Â million for the three months ended DecemberÂ 31, 2024, compared to $13.7 million for the three months ended DecemberÂ 31, 2023. The increase of $4.3 million is primarily the result of an increase of $3.0 million in sales and marketing costs as the Company prepares for its first potential commercial launch of RP1. In addition, there is an increase of $1.7 million in personnel related costs, including an increase of $2.1 million in payroll and fringe benefits, slightly offset by a $0.4 million decrease in stock-based compensation expense. The increase in personnel related costs during the quarter was driven by additional hiring in our selling, general and administrative functions, focusing on additional pre-launch planning and continued building of the Company's commercial infrastructure. Consulting costs during the quarter are down year over year by approximately $1.4 million in selling, general and administrative functions as a result of hiring more full time employees in the current year. Total other income (expense), netOther income (expense), net was $0.3 million for the three months ended DecemberÂ 31, 2024, compared to income of $5.9 million for the three months ended DecemberÂ 31, 2023. The net change of $5.6 million is primarily attributable to an increase in expense of $4.6 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. In addition, investment income decreased by approximately $0.5 million year over year and the interest expense on debt obligations increased by approximately $0.4 million, as the Company drew down an additional $15.0Â million under the Loan Agreement at the end of December 2023.31Table of ContentsIncome tax provisionDuring the three and nine months ended December 31, 2024 and 2023, the Company recorded no income tax benefits for the net operating losses incurred in the United Kingdom in each period due to its uncertainty of realizing a benefit from those items. During the three and nine months ended December 31, 2024, the Company recorded $0.6 million of an income tax provision in the United States related to uncertain tax positions. During the three and nine months ended December 31, 2023, the Company recorded an income tax provision of $0.5 million, which was primarily due to forecasted United States taxable income for the year that was not fully offset by available net operating loss carryforwards.Comparison of the nine months ended DecemberÂ 31, 2024 and 2023The following chart summarizes our results of operations for the nine months ended December 31, 2024 and 2023:Nine Months Ended December 31,20242023Change(Amounts in thousands)Operating expenses:Research and development$135,472Â $132,384Â $3,088Â Selling, general and administrative46,827Â $43,633Â 3,194Â Total operating expenses182,299Â 176,017Â 6,282Â Loss from operations(182,299)(176,017)(6,282)Other income (expense):Research and development incentives1,222Â 1,251Â (29)Investment income15,243Â 17,922Â (2,679)Interest expense on finance lease liability(1,594)(1,626)32Â Interest expense on debt obligations(4,314)(3,083)(1,231)Other (expense) income(850)1,307Â (2,157)Total other income (expense), net9,707Â 15,771Â (6,064)Loss before income taxes$(172,592)$(160,246)$(12,346)Income tax provision$575Â $473Â $102Â Net loss$(173,167)$(160,719)$(12,448)Research and development expensesResearch and development expenses for the nine months ended DecemberÂ 31, 2024 were $135.5Â million, compared to $132.4Â million for the nine months ended DecemberÂ 31, 2023. The following table summarizes our research and development expenses for the nine months ended December 31, 2024 and 2023:32Table of ContentsNine Months Ended December 31,20242023ChangeDirect research and development expenses by programÂ Â RP1 program costs by study:Â Â Â Â Â IGNYTE10,831Â 11,775Â (944)Â Â Â Â ARTACUS5,211Â 4,433Â 778Â Â Â Â Â CERPASS5,573Â 13,530Â (7,957)Â Â Â Â IGNYTE-34,909Â 1,496Â 3,413Â Â Â Â Â Other RP1 study costs7,075Â 10,210Â (3,135)Â Â Â Â Â Â Total RP1 costs33,599Â 41,444Â (7,845)Â Â Â Â RP28,322Â 6,489Â 1,833Â Â Â Â Â RP33,856Â 11,196Â (7,340)Unallocated research and development expenses:Â Â Â Â Â Â Personnel related (including stock-based compensation)67,712Â 58,698Â 9,014Â Â Â Â Other21,983Â 14,557Â 7,426Â Â Â Â Â Â Total research and development expenses$135,472Â $132,384Â $3,088Â The total increase of $3.1 million in research and development expenses was driven by an increase of $16.4 million in unallocated expenses, partially offset by a decrease of $13.4 million in our direct research and development costs. The increase in unallocated expenses includes $9.0 million in personnel-related costs and $7.4 million in other costs. The increase in personnel-related costs is attributable to a $5.6Â million increase in payroll and fringe benefits as well as a $3.4Â million increase in stock-based compensation expense. The increase in personnel-related costs largely reflected the hiring of additional personnel in our research and development functions as we expand the development plan in multiple indications. The increase in other costs is driven primarily by an increase in consulting costs, medical affairs and facility costs. The decrease of approximately $13.4 million in our direct research and development costs primarily relates to a decrease of $7.8 million in RP1 as a result of declining enrollment and the wind down of the CERPASS study and completion of enrollment in the IGNYTE advanced melanoma cohort, combined with a decrease of $7.3 million related to RP3 as a result of the deprioritization of development efforts on this product candidate, which the Company began to taper in the second half of the prior fiscal year. These decreases are slightly offset by an increase in setup costs and Clinical Research Organization ("CRO"), costs for RP2 as the Company began to ramp up costs for the MUM study. In addition, in the prior year, the Company incurred costs related to manufacturing batches for RP1, as well as significant costs related to the CERPASS trial in the areas of CROs, investigators and imaging costs in preparation of the primary data release, which did not recur in the current year. Selling, general and administrative expensesSelling, general and administrative expenses were $46.8 million for the nine months ended DecemberÂ 31, 2024, compared to $43.6 million for the nine months ended DecemberÂ 31, 2023. The increase of approximately $3.2 million in sales, general and administrative costs is driven by an increase of $4.3 million in sales and marketing costs related to promotional materials, market access and insights and analytics, as the Company prepares for a potential commercial launch of RP1. Total other income (expense), netOther income, net was $9.7 million for the nine months ended DecemberÂ 31, 2024, compared to income of $15.8 million for the nine months ended DecemberÂ 31, 2023. The net change of $6.1 million is primarily attributable to a decrease in investment income of $2.7 million as a result of the cash and investment balance being lower throughout the year as compared to the prior year due to normal cash burn, as well as an increase in expense of $2.2 million in the current year compared to the prior year due to exchange rate fluctuations related to the changes in foreign exchange rates of the British Pound Sterling to the United States Dollar, specifically on intercompany and other non-functional currency transactions. Additionally, there is an increase in interest expense on debt obligations in the amount of $1.2 million as a result of a higher debt balance during the current year vs. the prior year as there was an additional draw under the Loan Agreement during the end of the third quarter of the prior year.Liquidity and capital resources33Table of ContentsSince our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we can not predict when we may generate revenue from sales of any products, if at all.Sources of liquidityTo 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 DecemberÂ 31, 2024, we had received net proceeds of $1,101.8Â million through the sale of shares of common stock and pre-funded warrants exercisable for common stock in public offerings, a private investment in a public entity, and at-the-market offerings, as well as net $42.8 million from our incurrence of debt under the term loan agreement with Hercules. As of DecemberÂ 31, 2024, we had cash and cash equivalents and short-term investments of $536.5Â million.Cash flowsThe following table summarizes our cash flows for each of the periods presented:Nine Months Ended December 31,20242023(Amounts in thousands)Net cash used in operating activities$(138,519)$(139,301)Net cash (used in) provided by investing activities(16,096)74,000Â Net cash provided by financing activities252,528Â 16,413Â Effect of exchange rate changes on cash and cash equivalents(125)(30)Net increase (decrease) in cash and cash equivalents$97,788Â $(48,918)Operating activitiesDuring the nine months ended December 31, 2024, net cash used in operating activities was $138.5 million, primarily resulting from our net loss of $173.2 million partially offset by non-cash charges of $24.4 million, which primarily consist of stock-based compensation expense of $26.8 million, somewhat offset by net amortization of premiums and discounts on short-term investments of $7.0 million, and an increase in cash of $10.2 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the nine months ended December 31, 2024 consisted primarily of a $4.7 million increase in accounts payable, a $2.5 million increase in accrued expenses and other current liabilities, a $1.9 million decrease in research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures, and a net $1.8 million change in operating and financing right-of-use assets and lease liabilities. During the nine months ended December 31, 2023, net cash used in operating activities was $139.3 million, primarily resulting from our net loss of $160.7 million, partially offset by non-cash charges of $18.1 million, which primarily consist of stock-based compensation expense of $26.2 million, somewhat offset by net amortization of premiums and discounts on short-term investments of $9.5 million, and an increase in cash of $3.0 million related to changes in our operating assets and liabilities. Changes in our operating assets and liabilities for the nine months ended December 31, 2023 consisted primarily of a $6.1 million increase in accrued expenses and other current liabilities, a $2.2 million increase in prepaid expenses and other current assets, a net $1.8 million change in operating and financing right-of-use assets and lease liabilities, a $1.5 million decrease in accounts payable, and a $1.2 million increase in research and development incentives receivable from the United Kingdom government due to the timing and amount of our qualifying expenditures.Investing activitiesDuring the nine months ended December 31, 2024, net cash used in investing activities was $16.1 million, consisting of $332.0 million in purchases of available for sale securities and $5.6 million in purchases of property, plant and equipment and capitalized software, partially offset by $321.4 million in proceeds from sales and maturities of short-term investments.34Table of ContentsDuring the nine months ended December 31, 2023, net cash provided by investing activities was $74.0 million, consisting of $459.0 million in proceeds from sales and maturities of short-term investments, partially offset by $381.1 million in purchases of available for sale securities, and $3.9 million in purchases of property, plant and equipment and capitalized software.Financing ActivitiesDuring the nine months ended December 31, 2024, net cash provided by financing activities was $252.5 million, consisting primarily of $252.7 million in proceeds from the Company's private investment in a public entity in June 2024 as well as the Company's November 2024 public offering.During the nine months ended December 31, 2023, net cash provided by financing activities was $16.4 million, consisting primarily of $15.0 million in proceeds from long-term debt, as well as $1.8 million in proceeds from the exercise of stock options.Funding requirementsOur plan of operation is to continue implementing our business strategy, continue research and development of RP1 and our other product candidates and continue to expand our research pipeline and our internal research and development capabilities. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates and if and as we:â€¢conduct our current and future clinical trials with RP1, RP2 and RP3;â€¢further preclinical development of our RPx platform;â€¢operate, qualify and maintain our in-house manufacturing facility and qualify and maintain our product candidates made therein for use in our clinical trials;â€¢seek to identify and develop additional product candidates;â€¢seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;â€¢establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;â€¢until our planned manufacturing facility is fully validated, continued limited manufacturing by third parties for clinical development.â€¢maintain, expand, protect and defend our intellectual property portfolio;â€¢hire and retain additional clinical, quality control, scientific and general and administration personnel;â€¢acquire or in-license other drugs, technologies or third-party intellectual property; andâ€¢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 DecemberÂ 31, 2024, we had cash and cash equivalents and short-term investments of $536.5 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of DecemberÂ 31, 2024, will enable us to fund operations into the fourth quarter of 2026 which includes scale up for the potential commercialization of RP1 in skin cancers and for working capital and general corporate purposes and excludes any potential revenue. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the development of RP1 and other product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements 35Table of Contentswill depend on many factors, including those described in this section and above under â€œâ€”Operating expensesâ€”Research and development expenses.â€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 shareholdersâ€™ interest may be diluted, and the

terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring debt adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.Contractual obligations and commitmentsDuring the nine months ended December 31, 2024, there were no material changes to our contractual obligations and commitments from those described under the heading â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€”Contractual Obligations and Commitmentsâ€ in our Annual Report on FormÂ 10-K for the year ended MarchÂ 31, 2024, which was filed with the SEC on MayÂ 16, 2024.CollaborationsBMSIn 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 JanuaryÂ 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)Â the completion of the clinical trial, (ii)Â all related clinical trial data have been delivered to both parties and (iii)Â 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)Â in the event of an uncured material breach by the other party, (y)Â in the event the other party is insolvent or in bankruptcy proceedings or (z)Â 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.Regeneron36Table of ContentsIn May 2018, we entered into a Master Clinical Trial Collaboration and Supply Agreement with Regeneron. Pursuant to the agreement we agreed to undertake one or more clinical trials with Regeneron for the administration of our product candidates in combination with cemiplimab, an anti-PD-1 therapy developed by Regeneron, across multiple solid tumor types, the first of which, agreed in June 2018, is our ongoing PhaseÂ 2 clinical trial testing RP1 in combination with cemiplimab versus cemiplimab alone in patients with CSCC. Each clinical trial will be conducted pursuant to an agreed study plan which, among other things, will identify the name of the sponsor and which party will manage the particular study, and include the protocol, the budget and a schedule of clinical obligations. The first study plan related to the PhaseÂ 2 clinical trial in CSCC has been agreed.Pursuant to the terms of the agreement, each party granted the other party a non-exclusive license of their respective intellectual property and agreed to contribute the necessary resources needed to fulfill their respective obligations, in each case, under the terms of agreed study plans. Development costs of an agreed study plan will be split equally. In July 2022, Regeneron informed the Company that the costs of the study have reached the initial budget for the initial study plan of June 2018 and that Regeneron's reimbursement of CERPASS study costs to the Company have completed in the period ending June 30, 2022 in relation to the initial study budget. As a result of this notice from, and the ongoing communications with, Regeneron, we have not recorded any cost-sharing reimbursements from Regeneron in prepaid expenses and other current assets in the consolidated balance sheet or as an offset to research and development expense within the consolidated statement of operations since Regeneron informed us that Regeneronâ€™s reimbursement of CERPASS study costs have completed. The Company does not expect any further reimbursements from Regeneron related to the initial study plan of June 2018. The agreement contains representations, warranties, undertakings and indemnities customary for a transaction of this nature. The agreement also contains certain time-based covenants that restrict us from entering into a third-party arrangement with respect to the use of our product candidates in combination with an anti-PD-1 therapy and that restrict Regeneron from entering into a third-party arrangement with respect to the use of cemiplimab in combination with an HSV-1 virus, in each case, for the treatment of a tumor type that is the subject of a clinical trial to which the covenants apply. Unless otherwise mutually agreed in a future study plan, these covenants are only applicable to our ongoing PhaseÂ 2 clinical trial in CSCC.The agreement may be terminated by either party if (i)Â there is no active study plan for which a final study report has not been completed andÂ the parties have not entered into a study plan for an additional clinical trial within a period of time after the delivery of the most recent final study report or (ii)Â in the event of a material breach.Roche In December 2022, we announced entering into a Master Clinical Trial Collaboration and Supply Agreement with Roche in relation to our RP2 and RP3 programs in colorectal cancer, or CRC, and hepatocellular carcinoma, or HCC. Under the agreement, the companies will collaborate in two 30 patient cohort signal finding studies in third-line, or 3L, CRC and in two 15 patient cohort signal finding studies in second-line, or 2L, HCC. Under the terms of the agreement, the companies will share costs and Roche will supply its currently approved drugs, atezolizumab and bevacizumab for 2L HCC and 3L CRC combined with RP3. Roche will also supply atezolizumab and bevacizumab for 2L HCC and 3L CRC combined with RP2. We have retained the responsibility of operating the clinical trials as well as retaining all the rights to the development and commercialization of our product candidates. The agreement may be terminated by either party upon sixty (60) days prior written notice to the other party. We are in discussions with Roche about revising these agreements following our changes to our RP2 and RP3 development plans. Incyte In July 2023, we entered into a Clinical Trial Collaboration and Supply Agreement with Incyte Corporation, or Incyte. Under the agreement, the companies will collaborate in a signal finding study in which Incyte will initiate and sponsor a clinical trial of INCB99280 (oral PD-L1 inhibitor) and RP1 in approximately 40 patients with unresectable, high risk CSCC in the neoadjuvant setting. Under the terms of the agreement, we will supply Incyte with RP1 for the study and share costs of the study equally with Incyte. The agreement may be terminated by either party upon (i) a material breach not reasonably cured within thirty (30) days; (ii) the discontinuation of development of its clinical drug candidate; (iii) the unethical or illegal business practices of the other party; or (iv) if the parties have not agreed on the protocol or budget within ninety (90) days of the effective date of the agreement. In addition, the Company may terminate the agreement upon the inappropriate or unsafe use of the RP1 product candidate. On July 30, 2024, Incyte announced it has discontinued further development of its oral small molecule PD-L1 inhibitor, which was the intended study drug in the Company's planned collaboration with Incyte. On August 1, 2024, the Company received notice of termination of the Clinical Trial Collaboration and Supply Agreement from Incyte. Critical accounting policies and estimates37Table of ContentsOur managementâ€™s discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.Accrued research and development expensesAs part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:â€¢CROs in connection with performing research activities and conducting preclinical studies and clinical trials on our behalf;â€¢CMOs in connection with the production of preclinical and clinical trial materials;â€¢investigative sites or other service providers in connection with clinical trials;â€¢vendors in connection with preclinical and clinical development activities; andâ€¢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 compensationWe 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, Compensationâ€‰â€”â€‰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 38Table of Contentsexpected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. See Note 10 to our consolidated financial statements appearing elsewhere in this Quarterly Report for more information. Forfeitures are accounted for as they occur. The fair value of each stock-based award is estimated on the date of grant based on the fair value of our common stock on that same date.We classify stock-based compensation expense in our consolidated statements of operations in the same manner in which the award recipientâ€™s payroll costs are classified or in which the award recipientâ€™s service payments are classified.Recently issued accounting pronouncementsA description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in NoteÂ 2 to our 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 ProceduresThe term â€œdisclosure controls and procedures,â€ 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 SECâ€™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 companyâ€™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 DecemberÂ 31, 2024. Based on this evaluation, our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of DecemberÂ 31, 2024.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 reportingThere have been no changes in our internal control over financial reporting for the nine months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.39Table of ContentsPARTÂ II â€” OTHER INFORMATIONItemÂ 1. Legal Proceedings.We are not currently a party to any material legal proceedings.Â Item 1A. Risk FactorsInvesting 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 FormÂ 10-Q, including our consolidated financial statements and related notes and â€œManagementâ€™s discussion and analysis of results of operations and financial condition.â€ 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 factorsMaterial risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:â€¢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;â€¢our ability to develop and advance any future product candidates based on our novel proprietary RPx platform and successfully complete clinical trials and prepare for and successfully complete inspections, submissions and reviews of licensing applications; â€¢our ability to develop our product candidates for use in combination with other checkpoint blockade therapies, including anti-PD-1;â€¢our ability to successfully commercialize any product candidate for which we receive regulatory approval and our expectations regarding the size of the patient populations or the market acceptance of our product candidates if approved for commercial use;â€¢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;â€¢negative developments in the field of immuno-oncology including clinical or commercial developments that may be attributed to our product candidates;â€¢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;â€¢our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation or alleged violation of any third-party intellectual property rights;â€¢our ability to successfully qualify, obtain approval for, and maintain successful operation, approval and qualification of our in-house manufacturing operations; â€¢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;40Table of Contentsâ€¢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; â€¢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;â€¢our compliance with domestic and foreign laws, rulesÂ and regulations and the consequences in the event that we fail to comply with such laws, rulesÂ and regulations;â€¢our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;â€¢our competitive position, and developments and projections relating to our competitors and our industry; â€¢the impact of the COVID-19 coronavirus, or COVID-19, as a global pandemic and related public health issues, including potential material supplies and supply chain disruptions, hiring and retaining talent, and global or national economic impacts such as inflation; andâ€¢the ongoing Russian-Ukrainian and Israel-Hamas military 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 product developmentOur 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 have never generated any revenue from product sales and may never be profitable.All of our product candidates are in research or development. We have not generated any revenues from the sale of any product. Our lead product candidate, RP1, and any other product candidates will require extensive preclinical and/or clinical testing and regulatory review prior to approval and commercial use. Our research and development efforts may not be successful. Even if our clinical development efforts result in positive data, our product candidates may not receive regulatory approval or be successfully introduced and marketed at prices that would permit us to operate profitably. We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates.Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.The results of preclinical studies, preliminary study results, and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect in humans, and may not ultimately prove to be safe and effective.Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage, the data is being reviewed or during the license application process.41Table of ContentsWe 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:â€¢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;â€¢regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;â€¢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;â€¢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;â€¢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;â€¢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;â€¢changes in manufacturing facilities or the manufacturing process for our product candidates may impact how our product candidates perform in clinical trials; â€¢changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;â€¢statutes or regulations could be amended or new ones could be adopted;â€¢changes could be adopted in the regulatory review process for submitted product applications;â€¢the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a Biologics License Application, or BLA, or equivalent authorizations from comparable foreign regulatory authorities;â€¢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;â€¢we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs. By example, the FDA may determine that larger trials, Phase 3 trials, randomized and controlled clinical trials, or clinical trials designed to replicate results found in our registrational or pivotal trials are required before we may file a BLA or before the FDA will approve or maintain a marketing application; â€¢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;42Table of Contentsâ€¢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;â€¢we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;â€¢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;â€¢there may be regulatory questions or disagreements regarding interpretations of data and results;â€¢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 candidateâ€™s benefits do not outweigh its safety risks;â€¢the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;â€¢the FDA or comparable foreign regulatory authorities may disagree with our intended indications;â€¢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;â€¢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;â€¢the FDA may decide that our intended pathways, including accelerated approval, are not appropriate for our product candidates, requiring that we conduct additional studies. By example, in recent years the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, depending on the results of our studies, the FDA may be more conservative in granting accelerated approval or, if granted, may be more apt to withdrawal approval if clinical benefit is not confirmed. Even if accelerated approval is granted, payors, including governmental payors, may be less welling to provide sufficient reimbursement for products approved via accelerated approval; â€¢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;â€¢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; andâ€¢we, the third parties on which we rely, and the FDA may have delays in the conduct of our respective operations as a result of the effects of the COVID-19 pandemic, which could result in delays or prevent our ability to receive marketing approval or commercialize our product candidates.Our development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.43Table of ContentsTopline data may not accurately reflect the complete results of a particular study or trial.We may publicly disclose topline or interim data from time to time, which is based on a preliminary analysis of then-available efficacy and safety data which are based on preliminary analysis of key efficacy and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions or analyses or may request different calculations or analysis than conducted and may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or drug and our company in general. In addition, the information we may publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from a future analysis of results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.We anticipate that our product candidates will be used in combination with third-party drugs, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.Our product candidates may be administered in combination with checkpoint blockade drugs, a class of drugs that are intended to stop tumor cells from â€œswitching offâ€ 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 trials with RP1, our Phase 1/2 clinical trial with RP2 and our Phase 1 and Phase 2 clinical trials with RP3 where we decide to use nivolumab. We have also entered into a clinical collaboration agreement with Regeneron, which includes the supply of cemiplimab, its anti-PD-1 therapy, for clinical trials conducted thereunder. We are using cemiplimab in the CERPASS

trial, our first planned clinical trial under the Regeneron agreement. We may enter into additional agreements for the supply of anti-PD-1 products for use in combination with and for the continued development of one or more of our product candidates. 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 or any other checkpoint blockade therapy will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint blockade therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.Moreover, the development of our product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. While we have opened a clinical trial for use of RP1 as a monotherapy, we are generally developing RP1 and our other product candidates for use in combination with anti-PD-1 or potentially anti-PD(L)-1 therapies, and may develop RP1 or our other product candidates for use with other therapies. Although we intend our IGNYTE anti-PD-1 failed melanoma cohort to be registration directed, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the therapy with which our products were combined and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross-labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other productâ€™s safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.44Table of ContentsIn the event that BMS, Regeneron or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms or at all, we would need to identify alternatives for accessing an anti-PD-1 therapy. Additionally, should the supply of products from BMS, Regeneron or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed, interrupted or halted. In the event we are unable to source a supply of an acceptable alternative anti-PD-1 therapy, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.An underlying problem with our proprietary RPx platform would adversely affect our business and may require us to discontinue development of product candidates based on the same or similar therapeutic approaches.We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of product candidates based on our RPx platform. Our ability to generate any revenues from the sale of our product candidates will depend heavily on the successful development, regulatory approval and commercialization of one or more of these product candidates using our RPx platform. Since all of the product candidates in our current pipeline are based on our proprietary RPx platform, if any of our product candidates fail in development as a result of any underlying problem with our proprietary RPx platform, then we may be required to discontinue development of all product candidates that are based on our therapeutic approach. If we were required to discontinue development of our product candidates that are based on our therapeutics approach, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.If we fail to develop additional product candidates, our commercial opportunity could be limited.Our lead product candidate is RP1. A key part of our strategy is to pursue clinical development of RP1 and additional product candidates, including RP2 and, when appropriate 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 approvalEven if our development efforts are successful, we may not obtain regulatory approval for any of our product candidates in the United States or other jurisdictions, which would prevent us from commercializing our product candidates. Even if we obtain regulatory approval for our product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize our product candidates.We are not permitted to market or promote or sell any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidateâ€™s safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA or comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:â€¢be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;45Table of Contentsâ€¢contain significant safety warnings, including boxed warnings, contraindications, and precautions;â€¢not be approved with label statements necessary or desirable for successful commercialization; â€¢if approved under the accelerated approval process, require a confirmatory trial and full approval to maintain the right to commercialize the product; orâ€¢contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.We have not received marketing approval from the FDA or a comparable foreign regulatory authority for any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or at all.The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue may be materially impaired.The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidateâ€™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 candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.There can be no assurance that undesirable side effects or serious adverse events will not be caused by or associated with RP1 or our other product candidates as they continue through or enter clinical development. Serious adverse events or undesirable side effects caused by our product candidates could cause us,Â 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 studyâ€™s design, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our product candidates.Undesirable side effects caused by any of our product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-46Table of Contentsmarketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post approval study requirements, or other testing and surveillance.If any of our product candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk/benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.Changes in product candidate manufacturing or formulation may result in additional costs or delay.As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, facilities, equipment and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or â€œoff labelâ€ 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 Servicesâ€™ Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off label uses, and our business, financial condition, results of operations, stock price and prospects may be materially harmed. We also must sufficiently substantiate any claims that we make for our products, including claims comparing our products to other companiesâ€™ products, and must abide by the FDAâ€™s strict requirements regarding the content of promotion and advertising.While physicians may choose to prescribe products for uses that are not described in the productâ€™s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA. These off label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off label use.If we are found to have impermissibly promoted any of our product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off label promotion. The FDA has also requested

that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.47Table of ContentsIn the United States, engaging in the impermissible promotion of our products, following approval, for off label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines and agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, shortage reporting, risk management plans, supply chain security, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post approval.The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a productâ€™s indicated uses or marketing, or impose ongoing requirements for potentially costly post approval studies or post-market surveillance. Any such restrictions could limit sales of the product.We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA preapproval for product and manufacturing changes.In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:â€¢restrictions on manufacturing, distribution, or marketing of such products;48Table of Contentsâ€¢restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;â€¢modifications to promotional pieces;â€¢issuance of corrective information;â€¢requirements to conduct post-marketing studies or other clinical trials;â€¢clinical holds or termination of clinical trials;â€¢requirements to establish or modify a REMS or similar strategy;â€¢changes to the way the product candidate is administered;â€¢liability for harm caused to patients or subjects;â€¢reputational harm;â€¢the product becoming less competitive;â€¢warning, untitled, or cyber letters;â€¢suspension of marketing or withdrawal of the products from the market;â€¢regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;â€¢refusal to approve pending applications or supplements to approved applications that we submit;â€¢recalls of products;â€¢fines, restitution or disgorgement of profits or revenues;â€¢suspension or withdrawal of marketing approvals;â€¢refusal to permit the import or export of our products;â€¢product seizure or detention;â€¢FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; orâ€¢injunctions or the imposition of civil or criminal penalties, including imprisonment.Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.The FDAâ€™s policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.49Table of ContentsIf 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 FDAâ€™s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from and, in some cases, greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Additionally, with the full departure of the United Kingdom from the European Union in January 2021, commonly referred to as Brexit, there is continuing regulatory uncertainty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, and the degree to which the United Kingdom and European Union regulatory regimes align or diverge could materially impact the execution of our clinical trials or approval of our product candidates in the United Kingdom or the European Union.Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.Risks related to commercialization50Table of ContentsIf we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.If we are successful in obtaining marketing approval from applicable regulatory authorities for RP1 or any of our other product candidates, our ability to generate revenues from our product candidates will depend on our success in:â€¢launching commercial sales of our product candidates, whether alone or in collaboration with others;â€¢receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market the product candidates;â€¢creating market demand for our product candidates through marketing, sales and promotion activities;â€¢hiring, training, and deploying a sales force or contracting with third parties to commercialize product candidates in the United States;â€¢manufacturing product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;â€¢establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;â€¢creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;â€¢maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;â€¢our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering RP1 and our other product candidates, claims others may make regarding rights in our intellectual property, and any potential infringement, misappropriation or other violation or alleged violation of any third-party intellectual property rights;â€¢achieving market acceptance of our product candidates by patients, the medical community, and third- party payors;â€¢achieving appropriate reimbursement for our product candidates;â€¢effectively competing with other therapies; andâ€¢maintaining a continued acceptable safety profile of our product candidates following launch.To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.51Table of ContentsWhile our product candidates are intended to be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers, other third-party

payors coverage decisions or third-party intellectual property rights that another may allege are violated by our product candidates.Certain of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our product candidates. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:52Table of Contentsâ€¢the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;â€¢the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe our product candidates;â€¢our inability to effectively oversee a geographically dispersed sales and marketing team;â€¢the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;â€¢an inability to secure adequate coverage and reimbursement by government and private health plans;â€¢the clinical indications for which the products are approved and the claims that we may make for the products;â€¢limitations or warnings, including distribution or use restrictions, contained in the productsâ€™ approved labeling;â€¢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; â€¢third-party intellectual property rights that another may allege are violated by our product candidates;â€¢liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;â€¢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; andâ€¢unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.We have concentrated all of our research and development efforts on product candidates based on our proprietary RPx platform, and our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA and foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies. Only one oncolytic immunotherapy, T-Vec, has received FDA approval to date. Any product candidates that are approved may be subject to extensive post approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements.If our product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. 53Table of ContentsMarket acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.Efforts to educate the medical community and third party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:â€¢the efficacy of our product candidates in combination with marketed checkpoint blockade drugs;â€¢the commercial success of the checkpoint blockade drugs with which our products are co-administered;â€¢the prevalence and severity of adverse events associated with our product candidates or those products with which they are co-administered;â€¢the clinical indications for which the products are approved and the approved claims that we may make for the products;â€¢limitations or warnings contained in the productâ€™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;â€¢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;â€¢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;â€¢the relative convenience and ease of administration of any products with which our product candidates are co-administered;â€¢the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;â€¢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;â€¢the price concessions required by third-party payors to obtain coverage;â€¢the extent and strength of our marketing and distribution of our product candidates;â€¢the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;â€¢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;â€¢the timing of market introduction of our product candidates, as well as competitive products;â€¢our ability to offer our product candidates for sale at competitive prices;â€¢the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;â€¢the extent and strength of our manufacturing operations and our third-party manufacturer and supplier support;â€¢the actions of companies that market any products with which our product candidates are co-administered;54Table of Contentsâ€¢the approval of other new products;â€¢adverse publicity about our product candidates or any products with which they are co-administered, or favorable publicity about competitive products; andâ€¢potential product liability claims.The successful commercialization of our product candidates, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer adequate coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly-approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm our business and reduce our revenue. In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. For example, the Inflation Reduction Act of 2022, or IRA, includes several measures intended to lower the cost of prescription drugs and related healthcare reforms, including limits on price increases and subjecting an escalating number of drugs to annual price negotiations with CMS. We cannot be sure whether additional legislation related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.If future reimbursement for approved product candidates, if any, is substantially less than we project, or rebate obligations associated with them are substantially greater than we expect, our future net revenue and profitability could be materially diminished.The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for oncolytic immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved oncolytic immunotherapy, T-Vec, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.Negative developments in the field of immuno-oncology could damage public perception of our product candidates and negatively affect our business.The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of RP1 or our other product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for our product candidates. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the 55Table of Contentsmedical 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 capitalWe are a clinical stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.We are a clinical stage biopharmaceutical company with a limited operating history, and we are early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities, including the sale of our common stock and pre-funded warrants in our public offerings. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our proprietary RPx platform, including our lead product candidate, RP1, and our other product candidates. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.We are not profitable and have incurred losses in each period since our inception. For the nine months ended December 31, 2024 and 2023, we reported a net loss of $173.2 million and $160.7 million, respectively. At DecemberÂ 31, 2024, we had an accumulated deficit of $874.4 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, RP1, our other product candidates and any additional product candidates we may develop. Even if we succeed in receiving marketing approval for and commercialize RP1 or our other product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional potential products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholdersâ€™ equity and working capital.Our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals.We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:â€¢completing research regarding, and preclinical and clinical development of, RP1 and our other product candidates;â€¢obtaining marketing approvals for RP1 and our other product candidates for which we complete clinical trials;â€¢developing a sustainable and scalable manufacturing process for RP1 and our other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;â€¢launching and commercializing RP1 and our other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;â€¢obtaining market acceptance of RP1 and our other product candidates as viable treatment options;56Table of Contentsâ€¢addressing any competing technological and market developments;â€¢identifying, assessing, acquiring and developing new product candidates;â€¢negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;â€¢obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; andâ€¢attracting, hiring, and retaining qualified personnel.Even if our product candidates or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the FDA or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.If we are successful in obtaining regulatory approvals to market RP1 or our other product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.We will require additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.Our operations have consumed substantial amounts of cash since inception. At DecemberÂ 31, 2024, our cash and cash equivalents and short-term investments were $536.5 million. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of RP1 and our other product candidates. Accordingly, we will need to obtain additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.Our future capital requirements depend on many factors, including:â€¢the scope, progress, results and costs of researching and developing RP1 and our other product candidates, and conducting preclinical studies and clinical trials;â€¢the timing of, and the costs involved in, obtaining marketing approvals for RP1 and our other product candidates if clinical trials are successful;â€¢the success of any collaborations;â€¢the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;â€¢the cost and timing of operating our manufacturing facility;â€¢the cost of manufacturing RP1 and our other product candidates for clinical trials in preparation for marketing approval and commercialization;â€¢our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;57Table of Contentsâ€¢the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;â€¢the timing, receipt, and amount of sales of, or royalties on, our future products, if any; andâ€¢the emergence of competing cancer therapies and other adverse market developments.We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. Based on our current operating plan, we expect that our existing cash and cash equivalents and short-term investments, as of DecemberÂ 31, 2024 will enable us to fund operations into the fourth quarter of 2026, which includes scale up for the potential commercialization of RP1 in skin cancers and for working capital and general corporate purposes and excludes any potential revenue. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RP1 or our other product candidates.We maintain our cash at financial institutions, often in balances that exceed federally insured limits.Our cash, cash equivalents and short-term investments are held in accounts with banking institutions. The balances of some of these accounts have in the past, and may in the future, exceed the Federal Deposit Insurance Corporation (â€œFDICâ€) 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 (â€œSVBâ€), 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 holdersâ€™ 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 propertyIf we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, proprietary RPx platform, including our lead product candidate, RP1, and our other product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection.The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation and subject to change with regulatory agencies and court decisions. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information, use by third parties of our products or infringement of our intellectual property rights, both inside and outside of the United States.Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our issued patents and issued patents that we license from third parties or may own have been and in the future may be challenged in the courts or patent offices in the United States and abroad. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be interpreted or reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. In addition, defending against challenges in respect of the inventorship, scope, validity or enforceability of our patents may be expensive, time consuming, difficult and in some cases may not be possible. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable 58Table of Contentsaspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, the patent prosecution process is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. If we are unable to obtain and maintain patent protection for our technology or inventions, or for RP1 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize RP1 or our other product candidates and future technologies or inventions may be adversely affected.Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated. Given the amount of time required for the development, testing and regulatory review of our product candidates, such as RP1 and our other product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.Filing, prosecuting and defending patents on our technology or inventions in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries or religions outside the United States can be less protective of our products than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect RP1 and our other product candidates. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies or inventions in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement or misappropriation may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. Although we enter into confidentiality agreements with our employees, consultants, collaborators, suppliers, manufacturers and other third parties who have access to our trade secrets, and our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms or may have conflicting agreements with third parties. In addition, in the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. If any of our trade secrets, know-how or confidential or proprietary information were to be lawfully obtained, patented or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and may be blocked from using such trade secrets, know-how or confidential or proprietary information ourselves. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.Third parties may in the future initiate legal proceedings

alleging that we are infringing their intellectual property rights, and we may become involved in lawsuits or other administrative procedures to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell RP1 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual 59Table of Contentsproperty rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates. For example, we are aware of U.S. Patent 10,034,938 (the â€˜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. On November 2, 2022, we filed a petition for inter partes review with the Patent Trial and Appeal Board (PTAB) of the USPTO, seeking to invalidate certain claims of United States Patent 10,034,938 (the â€˜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 partyâ€™s intellectual property and these attempts may not be successful. If we are found to infringe a third partyâ€™s intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid, unenforceable or otherwise not infringed, we could be required to obtain a license from such third-party to continue developing, manufacturing and commercializing RP1 and our other product candidates. Such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies and inventions licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing RP1 or our other product candidates or we could be found liable for significant monetary damages if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their know-how, confidential or proprietary information or trade secrets could have a similar material adverse effect on our business, financial condition, results of operations, stock price and prospects.If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology or inventions, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on RP1 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, stock price and prospects.Â 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 individualâ€™s current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third-party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all.In addition, we are developing certain of our product candidates in combination with nivolumab and cemiplimab, which are covered by patents or licenses held by BMS and Regeneron, respectively, to which we do not have a license other than for use in connection with the applicable clinical trial. We also may develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with RP1 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which license may not be available on commercially reasonable terms, or at all.Competitors may infringe any future licensed patents or any patent we own in the future or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our 60Table of Contentsintellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others.These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigation or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our trade secrets, know-how, or proprietary or confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.Risks related to manufacturing and our reliance on third partiesWe have agreements with BMS and Regeneron, and in the future may have agreements with other companies, to obtain the supply of anti-PD-1 therapies for the development of our product candidates. If our relationships with BMS, Regeneron, or any future collaborator or supplier are not successful, we may be delayed in completing the development of our product candidates.We have entered into arrangements with BMS and Regeneron as part of our clinical development for our product candidates where nivolumab or cemiplimab, respectively, are intended to be used for these clinical programs. BMS is providing nivolumab, its anti-PD-1 therapy, for use in our ongoing IGNYTE Phase 1/2 trials with RP1 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; Regeneron agreed to provide cemiplimab, its anti-PD-1 therapy, for use in our CERPASS PhaseÂ 2 clinical trial and may potentially do so for other clinical trials in the future. We may also enter into agreements with additional companies for the supply of anti-PD-1 therapies for use in the development of RP1 and our other product candidates, similar to our agreement with Roche. The outcome of these clinical trials is dependent, in part, both on the performance of our partnersâ€™ products and product candidates and also on our partnersâ€™ ability to deliver sufficient quantities of adequately produced product. Should any of our partnersâ€™ products or product candidates fail to produce the results that we anticipate, we may have to re-run clinical trials for RP1 or our other product candidates or may otherwise be delayed in the commercialization of RP1 or our other product candidates. Similarly, should any partner fail to provide us with a product or product candidate that suits our requirements, we may have to re-run clinical trials for RP1 or our other product candidates or may be otherwise delayed in the commercialization of RP1 or our other product candidates. Additionally, we are subject to specific risks associated with our collaboration partners, including possible discrepancies as to the timing, nature and the extent of development plans, contract interpretations, and the costs and allocation of costs related to the conduct of our clinical trials. If we and any collaboration partner are unable to agree or fail to perform our respective obligations or effectively manage our relationship, our clinical trials performed under such collaboration could incur additional costs, be delayed or could result in costly or time-consuming legal proceedings that could have an adverse effect on a collaboration or on our business. Our collaboration agreements with any future partners may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement.Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.Any future collaborations we might enter into may pose a number of risks, including the following:61Table of Contentsâ€¢collaborators may not perform their obligations as expected;â€¢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 collaboratorsâ€™ strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;â€¢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;â€¢collaborators could fail to make timely regulatory submissions for a product candidate;â€¢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;â€¢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;â€¢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;â€¢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;â€¢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;â€¢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; andâ€¢collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might de-emphasize or terminate development or commercialization of any product candidate it licenses to us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend upon, among other things, our assessment of the collaboratorâ€™s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaboratorâ€™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 62Table of Contentsother 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 for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or

commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDAâ€™s Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and may result in delays that could compromise our ability to meet our desired development timelines.63Table of ContentsWe also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.If the manufacturers upon which we rely fail to produce our raw materials or process consumables in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our product candidates and may lose potential revenues.We continue to rely on third-party contract manufacturers to manufacture our raw materials and 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 approved for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of raw materials or clinical trial material or guaranteed prices for our product candidates or their components. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party manufacturers of raw materials or our product candidates, or the third parties that we engage in the future, should cease to work with us, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. Any replacement of our contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our raw materials or product candidates that meet the necessary quality standards may delay our development or commercialization.If our manufacturers of raw materials, equipment or process consumables do not perform as agreed or encounter difficulties in production costs and yields, quality control, shortages of qualified personnel or key raw materials, compliance with strictly enforced federal, state, and foreign regulations, or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.In addition, if our Framingham manufacturing site cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we will not be able to secure or maintain regulatory approval for our manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining raw materials, products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization.We are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, but, other than through our contractual arrangements, we have limited control over our raw materials or process consumables manufacturersâ€™ compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. We must also receive FDA approval for the use of any new manufacturers for clinical or commercial supply, including our own manufacturing facility.A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturing failures to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.The transition of our manufacturing operations to, and operating and maintaining, our own manufacturing facility may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.64Table of ContentsOur approximately 63,000 square foot manufacturing facility in Framingham, Massachusetts is now fully operational. We have completed the process of transferring the manufacturing of RP1, RP2 and RP3 from our third-party contract manufacturer. Comparability analysis of RP1, RP2 and RP3 produced at our in-house Framingham facility with the contract manufacturer material used in our clinical studies is complete. The FDA and some European regulatory agencies have approved the use of material produced at our Framingham facility in ongoing and future clinical trials. The Framingham facility is intended to give us control over key aspects of the supply chain for our products and product candidates. However, we may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility. Any such delays may disrupt or delay the supply of our product candidates if we have not maintained a sufficient backup supply of our product candidates through third-party manufacturers. Moreover, changing manufacturing facilities may also require that we conduct additional studies, make notifications to the regulatory authorities, make additional filings to the regulatory authorities, and obtain regulatory authority approval for the new facilities, which may be delayed or which we may never receive. We will further need to comply with the FDAâ€™s and applicable foreign regulatory authoritiesâ€™ cGMP requirements for the production of our product candidates for clinical trials and, if approved, commercial supply, and will be subject to FDA and comparable foreign regulatory authority inspections. We may not be able to develop or acquire the internal expertise and resources necessary for compliance with these requirements. If we are not able to comply with the applicable regulatory requirements or produce product that meets our requirements and specifications, we will be subject to the same risks that we would be subject to should third party manufacturers be unable to comply with the applicable regulatory requirements or produce product meeting our requirements or specifications, as described above. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which could have a material adverse impact on our operating results.In operating our own manufacturing facility, we may be forced to devote greater resources and management time than anticipated, particularly in areas relating to operations, quality, raw material supply, regulatory, facilities and information technology. Further, should corrective or preventative actions be required, we will be fully responsible for these. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate from the new facility, which may negatively affect our product development timeline, product candidate supplies and, if approved, our commercial productsupplies. If we experience any unanticipated shortages of key raw materials, or other difficulties related to our raw material supply, we may not be able to effectively manage our ongoing manufacturing timelines and costs which may negatively affect our product development schedule and our ability to provide clinical trial supplies to patients in our clinical trials, and if approved, our commercial product supplies. Any problems or delays we experience in preparing for commercial scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.Any such problems could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.Risks related to legal and compliance mattersWe 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:65Table of Contentsâ€¢loss of revenue from decreased demand for our products and/or product candidates;â€¢impairment of our business reputation or financial stability;â€¢costs of related litigation;â€¢substantial monetary awards to patients or other claimants;â€¢diversion of management attention;â€¢withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;â€¢the inability to commercialize our product candidates;â€¢significant negative media attention;â€¢decreases in our stock price;â€¢initiation of investigations and enforcement actions by regulators; andâ€¢product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.We are subject to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and other anticorruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.Our operations are subject to anticorruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or the Bribery Act, and other anticorruption laws that apply in countries where we do business. We also may participate in collaborations and relationships with third parties whose actions, if noncompliant, could potentially subject us to liability under the FCPA, Bribery Act or local anticorruption laws. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and the United Kingdom and authorities in the European Union, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anticorruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anticorruption laws or trade control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of

operations, stock price and prospects.66Table of ContentsIf we fail to comply with federal and state healthcare laws, including fraud and abuse and health and other information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.We are subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, or VHCA, the federal Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economics and Clinical Health Act, or HITECH), or HIPAA, the FCPA, the ACA, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws, and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patientsâ€™ rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the European Union, the data privacy laws are generally stricter than those that apply in the United States and include specific requirements for the collection of personal data of European Union persons or the transfer of personal data outside of the European Union to the United States to ensure that European Union standards of data privacy will be applied to such data.If we, our operations or in some instances our partners actions under clinical trials in which we are the sponsor, are found to be in violation of any federal or state healthcare law, or any other laws or regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our managementâ€™s attention from the operation of our business.We are subject to new legislation, regulatory proposals and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products, which could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or 67Table of Contentsmisrepresentation 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 workersâ€™ compensation insurance to cover costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.We are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.In the United States, numerous federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including personal data privacy laws, health information privacy laws, data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.Additionally, the California Consumer Privacy Act, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA also allows for statutory fines for noncompliance (up to $7,500 per violation) and includes a private right of action for certain data breaches. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential liability. In addition, it is anticipated that the California Privacy Rights Act, or CPRA, which became operative on January 1, 2023, will expand the CCPA, including by expanding consumersâ€™ rights with respect to certain sensitive personal data. The CPRA also creates the new California Privacy Protection Agency to implement and enforce the CCPA and the CPRA, which could increase compliance costs. Similar laws have passed in Virginia, Utah, Connecticut and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. 68Table of ContentsOutside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Unionâ€™s General Data Protection Regulation, or EU GDPR, and the United Kingdomâ€™s GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines up to the greater of â‚¬20 million or 4% of annual global revenue. Further, individuals may initiate litigation related to processing of their personal data. Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other jurisdictions outside of the United States). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the United States. The European Commission released a set of â€œStandard Contractual Clauses,â€ or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. The SCCs, though approved by the European Commission as a suitable alternative, have faced challenges in European courts, and may be further challenged, suspended or invalidated. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Other countries in Europe, such as the UK, similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Risks related to our operationsWe will need to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Our future financial performance and our ability to commercialize RP1 and our other product candidates will depend, in part, on our ability to effectively manage any future growth, which would impose significant additional responsibilities on members of management and may divert their attention away from day-to-day activities.We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing, as well as support for our financial reporting and accounting functions. If the services of independent organizations, advisors and consultants become unavailable to us or we are unable to effectively manage our outsourced activities, or if the quality or accuracy of such services is compromised for any reason, our clinical trials may be extended, delayed or terminated, we may not comply with our financial reporting and accounting obligations on a timely basis and we may not be able to obtain marketing approval of RP1 and our other product candidates or otherwise advance our business.If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize RP1 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.Our future success depends on our ability to retain our key employees and consultants, and to attract and motivate highly qualified personnel.Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our executive leadership team, as well as our other scientific, manufacturing, quality and medical personnel. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, without our inability to find suitable replacements, could result in delays in product development and harm our business.69Table of ContentsChanges 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 SectionÂ 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 SectionÂ 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities.We believe that any internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.Our business and operations could suffer in the event of system failures or unauthorized or inappropriate use of or access to our systems.In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack or unauthorized access and use by third parties with a wide range of motives and expertise, including organized criminal groups, â€œhacktivists,â€ patient groups, disgruntled current or former employees and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.70Table of ContentsThe pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. There can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Our internal computer systems and those of our contractors and consultants are vulnerable to damage or interruption from computer viruses, unauthorized or inappropriate access or use, natural disasters, pandemics (including COVID-19), terrorism, war (including the ongoing conflicts in Ukraine and Israel), and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of pre-clinical trial data or data from clinical trials for our product candidates could result in delays in our regulatory filings and development efforts, as well as delays in the commercialization of our products, and significantly increase our costs. To the extent that any disruption, security breach or unauthorized or inappropriate use or access to our systems were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, including but not limited to patient, employee or vendor information, we could incur notification obligations to affected individuals and government agencies, liability, including potential lawsuits from patients, collaborators, employees, stockholders or other third parties and liability under foreign, federal and state laws that protect the privacy and security of personal information, and the development and potential commercialization of our product candidates could be delayed. or additional information, see the Risk Factor captioned â€œWe are subject to stringent and changing obligations related to privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.â€Risks related to our common stock and general risk factorsAn active trading market for our common stock may not be sustained.Our common stock began trading on the Nasdaq Global Select Market on JulyÂ 20, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for shares of our common stock may not be sustained. In the absence of an active trading market for shares of our common stock, our stockholders may not be able to sell their common stock at or above the price at which such stockholder acquired our common stock or at the time that they would like to sell.The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.Our stock price has been and is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which it was acquired. The market price for our common stock may be influenced by many factors, including:â€¢the success of competitive products or technologies;â€¢results of clinical trials of RP1 and our other product candidates or those of our competitors;â€¢regulatory or legal developments in the United States and other countries;â€¢developments or disputes concerning patent applications, issued patents or other proprietary rights;â€¢the recruitment or departure of key personnel;â€¢the level of expenses related to the development of RP1 and our other product candidates or clinical development programs;â€¢the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;â€¢actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;â€¢variations in our financial results or those of companies that are perceived to be similar to us;â€¢changes in the structure of healthcare payment systems;71Table of Contentsâ€¢market conditions in the pharmaceutical and biotechnology sectors;â€¢general economic, industry and market conditions;â€¢political and economic instability, including the impact of COVID-19, the possibility of an economic recession, international hostilities including, but not limited to, the ongoing Russian-Ukrainian and Israel-Hamas military conflicts, acts of terrorism, governmental restrictions and sanctions, inflation, global supply chain disruptions, trade relationships and military and political alliances; andâ€¢the other factors described in this â€œRisk Factorsâ€ 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 employeeâ€™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:â€¢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;â€¢the total expenses we incur in connection with equipping and operating our manufacturing facility;â€¢our ability to engage clinical trial sites in the U.S. and in foreign territories, obtain the approval for conducing 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;â€¢the cost of manufacturing our current and any future product candidates, which may vary depending on the FDAâ€™s and comparable foreign regulatory authoritiesâ€™ guidelines and requirements, the quantity of production and the terms of any agreements with manufacturers;â€¢expenditures that we will or may incur to acquire or develop additional product candidates and technologies;â€¢the timing and outcomes of clinical and preclinical studies for RP1 and our other product candidates or competing product candidates;â€¢competition from existing and potential future products that compete with RP1 and our other product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;â€¢any delays in regulatory review or approval of RP1 or our other product candidates;â€¢the level of demand for RP1 and our other product candidates, if approved, which may fluctuate significantly and be difficult to predict;72Table of Contentsâ€¢the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with RP1 and our other product candidates;â€¢our ability to commercialize RP1 and our other product candidates, if approved, inside and outside of the United States, either independently or working with third parties;â€¢the success of and our ability to establish and maintain collaborations, licensing or other arrangements;â€¢our ability to adequately support future growth;â€¢potential unforeseen business disruptions that increase our costs or expenses;â€¢political and economic instability, including the impact of COVID-19, the possibility of an economic recession, international hostilities, including, but not limited to, those resulting from the ongoing Russian-Ukrainian and Israel-Hamas military conflicts, acts of terrorism, governmental restrictions and sanctions, inflation, global supply chain disruptions, trade relationships and military and political alliances;â€¢future accounting pronouncements or changes in our accounting policies; andâ€¢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 managementâ€™s judgment with only limited information about our specific intentions for the use of our resources. We may use our resources for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash, cash equivalents and investments in a manner that does not produce income or that loses value.We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration of contractual or legal restrictions on resale lapse, the market price of our common stock could decline. These sales may make it more difficult for us to sell equity or equity related securities in the future at a time and price that we deem appropriate, or to use equity as consideration for future acquisition.In addition, a significant number of shares of common stock that are either subject to outstanding options and restricted stock units, reserved for future issuance under our equity incentive plans or subject to outstanding warrants are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and RuleÂ 144 and RuleÂ 701 under the 73Table of ContentsSecurities Act, including our ESPP if activated. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.Certain holders of shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration under the Securities Act of shares of our common stock pursuant to the amended and restated investors' rights agreement by and among us and certain of our stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.We may sell up to $89.0 million of shares of our common stock in â€œat-the-marketâ€ offerings pursuant to a Sales Agreement entered into on August 3, 2023, as amended, 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 stockholdersâ€™ 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:â€¢increased operating expenses and cash requirements;â€¢the assumption of additional indebtedness or contingent liabilities;â€¢the issuance of our equity securities;â€¢assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;â€¢the diversion of our managementâ€™s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;â€¢retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;â€¢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; andâ€¢our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense or intangible asset impairment charges. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair 74Table of Contentsour ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.Unfavorable market and economic conditions may have serious adverse consequences on our business, financial condition, results of operations, stock price and prospects.Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely impact our business.Global financial markets have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices. We are unable to predict the likely duration and severity of the current disruptions in financial markets and adverse economic conditions throughout the world. These economic developments affect businesses such as ours and those of third parties on which we rely in a number of ways that could result in unfavorable consequences to us. Current economic conditions or a deepening economic downturn in the United States and elsewhere have reduced and may continue to reduce our ability or willingness to access capital, which could negatively impact our short-term and long-term liquidity.Although we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents or short-term investments, we cannot assure you that deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or short-term investments, or our ability to meet our financing objectives. Furthermore, our stock price may decline due, in part, to the volatility of the stock market and general economic downturns.Exchange rate fluctuations may materially affect our results of operations and financial conditions.Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the U.S. dollar and the British pound and the euro, may adversely affect us. Although we are based in the United States, we have significant research and development operations in the United Kingdom, and source third-party manufacturing, consulting and other services in the United Kingdom and the European Union. As a result, our business and the price of our common stock may be affected by fluctuations in foreign exchange rates, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.Unfavorable global economic conditions and geopolitical events could adversely affect our business, financial condition or results of operations.Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing Russian-Ukrainian and Israel-Hamas military conflicts, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also adversely impact our clinical trials, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. A weak or declining economy or political disruption, including any international trade disputes, could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Although we do not currently operate in Russia, Ukraine, Israel or territories under Hamas control, if these conflicts broaden it may impact countries or territories in which we do operate or intend to operate, which could have a negative impact on our ability to achieve our objectives or timelines. The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.There has been increasing public focus by investors, customers, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our sustainability goals and measure 75Table of Contentsachievement 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.ItemÂ 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 our Current Report on Form 8-K, as filed with the SEC on June 13, 2024.Item 3. Defaults Upon Senior Securities.Not applicable.Item 4. Mine Safety Disclosure.Not applicable.Item 5. Other Information.Rule 10b5-1 Plan Trading ArrangementsNone of our directors or officers adopted, modified, or terminated a â€œRule 10b5-1 trading arrangementâ€ or â€œnon-Rule 10b5-1 trading arrangement,â€ in each case as defined in Item 408 of Regulation S-K, during the three months ended DecemberÂ 31, 2024.Item 6. Exhibits.ExhibitIncorporated by ReferenceNumberExhibit DescriptionFormDateNumber31.1*Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).31.2*Certification of the Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).32.1*Certification of the Chief Executive Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).32.2*Certification of the Chief Financial Officer, as required by Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350).101.INS*XBRL Instance Document.101.SCH*XBRL Taxonomy Extension Schema Document.101.CAL*XBRL Taxonomy Extension Calculation Linkbase Document.101.DEF*XBRL Taxonomy Extension Definition Linkbase Document.101.LAB*XBRL Taxonomy Extension Label Linkbase Document.101.PRE*XBRL Taxonomy Extension Presentation Linkbase Document.104*Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).* Filed or furnished herewith. The certifications furnished in ExhibitÂ 32.1 and ExhibitÂ 32.2 hereto are deemed to accompany this Quarterly Report on FormÂ 10-Q and will not be deemed â€œfiledâ€ for purposes of SectionÂ 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.â€ Indicates management contract or compensatory plan.*â€¡ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.76Table of Contents77Table of ContentsSIGNATURESPursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.REPLIMUNE GROUP, INC.Dated: February 12, 2025By:/s/ Sushil PatelName: Sushil PatelTitle: Chief Executive Officer and Director(Principal Executive Officer)Dated: February 12, 2025By:/s/ Emily HillName: Emily HillTitle: Chief Financial Officer(Principal Financial Officer)Dated: February 12, 2025By:/s/ Andrew SchwendenmanName: Andrew SchwendenmanTitle: Chief Accounting Officer(Principal Accounting Officer)78DocumentExhibit 31.1CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIESEXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THESARBANES-OXLEY ACT OF 2002I, 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 registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.Â Â Â Â The registrantâ€™s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting.Date: February 12, 2025By:/s/ Sushil PatelSushil PatelChief Executive Officer(Principal Executive Officer)DocumentExhibit 31.2CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIESEXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THESARBANES-OXLEY ACT OF 2002I, 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 registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.The registrantâ€™s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting.Date: February 12, 2025By:/s/ Emily HillEmily HillChief Financial Officer(Principal Financial Officer)DocumentExhibit 32.1CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002In connection with the Quarterly Report on Form 10-Q of Replimune Group, Inc. (the â€œCompanyâ€) for the quarter ended DecemberÂ 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), 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: February 12, 2025By:/s/ Sushil PatelSushil PatelChief Executive Officer(Principal Executive Officer)DocumentExhibit 32.2CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002In connection with the Quarterly Report on Form 10-Q of Replimune Group, Inc. (the â€œCompanyâ€) for the quarter ended DecemberÂ 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the â€œReportâ€), 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: February 12, 2025By:/s/ Emily HillEmily HillChief Financial Officer(Principal Financial Officer)