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

# FORM 10-Q

**(Mark One)**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the quarterly period ended September 30, 2022**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**

**Commission File Number: 001-40356**

# Rain Therapeutics Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **82-1130967** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **8000 Jarvis Avenue, Suite 204 Newark, CA** | **94560** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (510) 953-5559**

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| Emerging growth company | ☒ | | |

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 3, 2022, the registrant had 26,564,826 shares of common stock, $0.001 par value per share, outstanding, comprised of 18,837,356 shares of common stock, $0.001 par value per share and 7,727,470 shares of non-voting common stock, $0.001 par value per share.

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## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**Rain Therapeutics Inc.**
**Condensed Consolidated Balance Sheets**
**(In thousands, except share and per share data)**
**(unaudited)**

| | September 30, 2022 | December 31, 2021 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 39,834 | $ 24,780 |
| Short-term investments | 50,874 | 115,438 |
| Prepaid and other current assets | 3,037 | 5,928 |
| Total current assets | 93,745 | 146,146 |
| Property and equipment, net | 103 | 165 |
| Operating lease right-of-use asset | 291 | 386 |
| Other assets | 496 | 443 |
| Total assets | $ 94,635 | $ 147,140 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,084 | $ 6,112 |
| Accrued research and development | 4,353 | 4,349 |
| Other accrued liabilities | 4,413 | 5,694 |
| Operating lease liability, current portion | 163 | 160 |
| Total current liabilities | 13,013 | 16,315 |
| Operating lease liability, net of current portion | 149 | 252 |
| Other long-term liabilities | 64 | 69 |
| Total liabilities | 13,226 | 16,636 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 250,000,000 shares authorized as of September 30, 2022 and December 31, 2021, respectively; 26,564,826 shares (comprised of 18,837,356 shares of common stock and 7,727,470 shares of non-voting common stock) and 26,475,812 shares (comprised of 18,748,342 shares of common stock and 7,727,470 shares of non-voting common stock) issued and outstanding as of September 30, 2022 and December 31, 2021, respectively | 27 | 27 |
| Additional paid-in capital | 224,694 | 220,530 |
| Accumulated other comprehensive loss | (302) | (89) |
| Accumulated deficit | (143,010) | (89,964) |
| Total stockholders' equity | 81,409 | 130,504 |
| Total liabilities and stockholders' equity | $ 94,635 | $ 147,140 |

(1) The balance sheet at December 31, 2021 has been derived from the audited financial statements included in Rain Therapeutics Inc.'s Annual Report on Form 10-K filed on March 3, 2022.

See accompanying notes to condensed consolidated financial statements.

**Rain Therapeutics Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share data)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 14,510 | $ 15,284 | $ 42,322 | $ 26,101 |
| General and administrative | 3,901 | 3,154 | 11,257 | 7,334 |
| Total operating expenses | 18,411 | 18,438 | 53,579 | 33,435 |
| Loss from operations | (18,411) | (18,438) | (53,579) | (33,435) |
| Other income: | | | | |
| Interest income | 370 | 11 | 533 | 25 |
| Other income | — | 1 | — | 1 |
| Total other income, net | 370 | 12 | 533 | 26 |
| Net loss | $ (18,041) | $ (18,426) | $ (53,046) | $ (33,409) |
| Net loss per share, basic and diluted | $ (0.68) | $ (0.70) | $ (2.00) | $ (1.96) |
| Weighted-average shares used to compute net loss per share, basic and diluted | 26,564,615 | 26,466,746 | 26,535,474 | 17,025,032 |
| | | | | |
| Net loss | $ (18,041) | $ (18,426) | $ (53,046) | $ (33,409) |
| Other comprehensive loss: | | | | |
| Unrealized gain (loss) on short-term investments | 71 | 5 | (213) | 5 |
| Comprehensive loss | $ (17,970) | $ (18,421) | $ (53,259) | $ (33,404) |

See accompanying notes to condensed consolidated financial statements.

**Rain Therapeutics Inc.**
**Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**
**(In thousands, except share amounts)**
**(unaudited)**

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2021** | — | $ — | — | $ — | 26,475,812 | $ 27 | $ 220,530 | $ (89,964) | $ (89) | $ 130,504 |
| Exercise of stock options | — | — | — | — | 24,262 | — | 106 | — | — | 106 |
| Issuance of common stock from employee stock purchase plan | — | — | — | — | 26,804 | — | 293 | — | — | 293 |
| Stock-based compensation expense | — | — | — | — | — | — | 1,242 | — | — | 1,242 |
| Unrealized loss on investments | — | — | — | — | — | — | — | — | (300) | (300) |
| Net loss | — | — | — | — | — | — | — | (17,394) | — | (17,394) |
| **Balance as of March 31, 2022** | — | $ — | — | $ — | 26,526,878 | $ 27 | $ 222,171 | $ (107,358) | $ (389) | $ 114,451 |
| Exercise of stock options | — | — | — | — | 3,000 | — | 12 | — | — | 12 |
| Stock-based compensation expense | — | — | — | — | — | — | 1,417 | — | — | 1,417 |
| Unrealized gain on investments | — | — | — | — | — | — | — | — | 16 | 16 |
| Net loss | — | — | — | — | — | — | — | (17,611) | — | (17,611) |
| **Balance as of June 30, 2022** | — | $ — | — | $ — | 26,529,878 | $ 27 | $ 223,600 | $ (124,969) | $ (373) | $ 98,285 |
| Exercise of stock options | — | — | — | — | 3,890 | — | 15 | — | — | 15 |
| Issuance of common stock from employee stock purchase plan | — | — | — | — | 31,058 | — | 147 | — | — | 147 |
| Stock-based compensation expense | — | — | — | — | — | — | 932 | — | — | 932 |
| Unrealized gain on investments | — | — | — | — | — | — | — | — | 71 | 71 |
| Net loss | — | — | — | — | — | — | — | (18,041) | — | (18,041) |
| **Balance as of September 30, 2022** | — | $ — | — | $ — | 26,564,826 | $ 27 | $ 224,694 | $ (143,010) | $ (302) | $ 81,409 |

| | Series A Convertible Preferred Stock | | Series B Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| **Balance as of December 31, 2020** | 3,731,208 | $ 20,147 | 12,542,198 | $ 74,550 | 3,530,975 | $ 4 | $ 1,149 | $ (38,570) | $ — | $ (37,417) |
| Stock-based compensation expense | — | — | — | — | — | — | 165 | — | — | 165 |
| Net loss | — | — | — | — | — | — | — | (6,800) | — | (6,800) |
| **Balance as of March 31, 2021** | 3,731,208 | $ 20,147 | 12,542,198 | $ 74,550 | 3,530,975 | $ 4 | $ 1,314 | $ (45,370) | $ — | $ (44,052) |
| Conversion of convertible preferred stock to common stock | (3,731,208) | (20,147) | (12,542,198) | (74,550) | 15,069,330 | 15 | 94,682 | — | — | 94,697 |
| Issuance of common stock upon IPO, net of issuance cost | — | — | — | — | 7,845,011 | 8 | 121,486 | — | — | 121,494 |
| Exercise of stock options | — | — | — | — | 21,430 | — | 85 | — | — | 85 |
| Stock-based compensation expense | — | — | — | — | — | — | 793 | — | — | 793 |
| Net loss | — | — | — | — | — | — | — | (8,183) | — | (8,183) |
| **Balance as of June 30, 2021** | — | $ — | — | $ — | 26,466,746 | $ 27 | $ 218,360 | $ (53,553) | $ — | $ 164,834 |
| Stock-based compensation expense | — | — | — | — | — | — | 862 | — | — | 862 |
| Unrealized gain on investments | — | — | — | — | — | — | — | — | 5 | 5 |
| Net loss | — | — | — | — | — | — | — | (18,426) | — | (18,426) |
| **Balance as of September 30, 2021** | — | $ — | — | $ — | 26,466,746 | $ 27 | $ 219,222 | $ (71,979) | $ 5 | $ 147,275 |

See accompanying notes to condensed consolidated financial statements.

**Rain Therapeutics Inc.**
**Condensed Consolidated Statements of Cash Flows**
**(In thousands)**
**(unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2022** | **2021** |
| **Operating activities** | | |
| Net loss | $ (53,046) | $ (33,409) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| In-process research and development expense | (1,000) | 5,500 |
| Depreciation and amortization expense | 62 | 50 |
| Stock-based compensation expense | 3,591 | 1,820 |
| Amortization of premium and accretion of discounts on short-term investments, net | (35) | 33 |
| **Changes in operating assets and liabilities:** | | |
| Prepaid and other current assets | 2,891 | (6,663) |
| Operating lease right-of-use asset and liability, net | (5) | 20 |
| Other assets | (53) | 366 |
| Accounts payable | (2,028) | 2,862 |
| Accrued research and development | 4 | 3,834 |
| Other accrued liabilities | (286) | (2,117) |
| Net cash used in operating activities | (49,905) | (27,704) |
| | | |
| **Investing activities** | | |
| Purchases of short-term investments | (34,764) | (136,852) |
| Purchases of property and equipment | — | (128) |
| Payment of in-process research and development expense | — | (2,500) |
| Maturities of short-term investments | 99,150 | — |
| Net cash provided by (used in) investing activities | 64,386 | (139,480) |
| | | |
| **Financing Activities** | | |
| Proceeds from initial public offering | — | 121,494 |
| Proceeds from the issuance of common stock under the Company's equity incentive plans and employee stock purchase plan | 573 | 85 |
| Net cash provided by financing activities | 573 | 121,579 |
| | | |
| **Net increase (decrease) in cash and cash equivalents** | 15,054 | (45,605) |
| Cash and cash equivalents at beginning of period | 24,780 | 58,863 |
| **Cash and cash equivalents at end of period** | $ 39,834 | $ 13,258 |
| | | |
| **Supplemental schedule of non-cash investing and financing activities:** | | |
| Conversion of convertible preferred stock to common stock | $ — | $ 94,697 |
| Non-cash in-process research and development accrual | $ (1,000) | $ 3,000 |

See accompanying notes to condensed consolidated financial statements.

**Rain Therapeutics Inc.**
**Notes to Condensed Consolidated Financial Statements (unaudited)**

## Note 1 – Organization and Nature of Operations

### *Description of Business*

Rain Therapeutics Inc. ("Rain" or the "Company") was incorporated in the state of Delaware in April 2017. Rain is a late-stage precision oncology company developing therapies that target oncogenic drivers for which the Company is able to genetically select patients the Company believes will most likely benefit. This approach includes using a tumor-agnostic strategy to select patients based on their tumors' underlying genetics rather than histology. Rain's lead product candidate, milademetan, is a small molecule, oral inhibitor of the MDM2-p53 complex that reactivates p53. In addition to milademetan, the Company is also developing a preclinical program that is focused on inducing synthetic lethality in cancer cells by inhibiting RAD52. The Company operates in one business segment and its principal operations are in the United States, with its headquarters in Newark, California.

On June 22, 2022, the Company formed Rain Oncology Australia Pty Ltd ("Rain Oncology Australia"), a wholly owned subsidiary incorporated under the laws of Australia. As of September 30, 2022, Rain Oncology Australia was not yet operational.

### *Initial Public Offering*

On April 27, 2021, the Company completed its initial public offering ("IPO") in which the Company issued and sold 7,352,941 shares of common stock at a public offering price of $17.00 per share. On May 11, 2021, the Company issued an additional 492,070 shares of common stock in connection with the exercise of the underwriters' option to purchase additional shares at the public offering price. The Company's net proceeds from the sale of shares in the IPO, including the sale of shares pursuant to the exercise of the underwriters' option to purchase additional shares, was $121.5 million, net of underwriting discounts and commissions, and other offering fees.

Immediately prior to the closing of the IPO, 8,344,905 shares of the Company's convertible preferred stock were exchanged for 7,727,470 shares of non-voting common stock. Upon the closing of the IPO, 7,928,501 shares of the Company's convertible preferred stock were automatically converted into 7,341,860 shares of common stock. As of September 30, 2022, there were no shares of convertible preferred stock outstanding.

### *Basis of Presentation*

The accompanying interim unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") related to a quarterly report on Form 10-Q. These condensed consolidated financial statements include the accounts of the Company and Rain Oncology Australia. All significant inter-company transactions, balances and expenses have been eliminated upon consolidation. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB"). The year-end balance sheet data was derived from the Company's audited financial statements but does not include all disclosures required by GAAP. These condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K, filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act). The unaudited financial information for the interim periods presented herein reflects all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operation for the periods presented, with such adjustments consisting only of normal recurring adjustments.

### *Liquidity and Capital Resources*

The Company has devoted substantially all of its efforts to drug discovery and development, raising capital and building operations. The Company has a limited operating history and has not generated any revenue since its inception, and the sales and income potential of the Company's business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development of its product candidates. From inception through September 30, 2022,

the Company has funded its operations through net proceeds from its IPO in April 2021, and the issuance of convertible promissory notes and convertible preferred stock.

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. Management believes that the Company's current cash, cash equivalents and short-term investments will provide sufficient funds to enable the Company to meet its obligations for at least twelve months from the filing date of this report.

**Note 2 – Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent liabilities in the Company's condensed consolidated financial statements and accompanying notes. The most significant estimate in the Company's condensed consolidated financial statements relates to the clinical trial expense accruals. Management evaluates its estimates on an ongoing basis. Although these estimates are based on the Company's historical experience, knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents include commercial paper, readily available money market and checking accounts.

***Available-for-Sale Investments***

The Company holds investment grade securities consisting of money market funds, commercial paper, corporate debt securities, U.S. government securities and U.S. agency bonds, classified as available-for-sale ("AFS") securities at the time of purchase, since it is the Company's intent that these investments be available for current operations. The Company has classified all of its AFS securities as current assets on the condensed consolidated balance sheets even though the stated maturity date may be one year or more beyond the current condensed consolidated balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary.

The Company carries these securities at fair value and reports unrealized gains and losses, if any, as a separate component of accumulated other comprehensive loss. The cost of debt securities is adjusted for amortization of purchase premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income (expense) in the condensed consolidated statements of operations and comprehensive loss. Realized gains and losses on sales of securities are determined using the specific identification method and recorded in other income (expense), net in the condensed consolidated statement of operations and comprehensive loss.

Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company consults with its investment managers and considers available quantitative and qualitative evidence in evaluating potential impairment of its investments on a quarterly basis. If the cost of an individual investment exceeds its fair value, the Company evaluates among other factors, general market conditions, the duration and extent to which the fair value is less than cost, and the Company's intent and ability to hold the investment. Once an impairment is determined to be other-than-temporary, an impairment charge is recorded and a new cost basis in the investment is established. Declines in the value of AFS securities determined to be other than temporary are included in other income (expense), net.

***Deferred Offering Costs***

The Company capitalized deferred offering costs consisting of all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's IPO. Upon the completion of the IPO in April 2021, the total deferred offering costs of $2.5 million were reclassified to additional paid-in capital on the condensed consolidated balance sheets.

***Research and Development Costs***

Research and development costs primarily consist of costs associated with the Company's research and development activities, including its drug discovery efforts, and the preclinical and clinical development of its product candidates. Research and development costs are expensed as incurred.

***Preclinical Studies and Clinical Trial Accruals***

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, clinical research organizations and clinical site agreements in connection with conducting preclinical activities and clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects preclinical study and clinical trial expenses in its condensed consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical study or clinical trial as measured by the timing of various aspects of the preclinical study, clinical trial or related activities. The Company determines accrual and prepaid estimates through review of the underlying contracts along with preparation of financial models taking into account correspondence with clinical and other key personnel and third-party service providers as to the progress of preclinical studies, clinical trials or other services being conducted. During the course of a preclinical study or clinical trial, the Company adjusts its expense recognition if actual results differ from its estimates. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

***Stock-Based Compensation***

Stock-based compensation expense represents the grant date fair value of equity awards recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis. The Company recognizes forfeitures as they occur. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model. The fair value of restricted stock units ("RSUs") granted is based on the Company's closing stock price on the date of grant. Prior to the IPO, the exercise price for all stock options granted was at the estimated fair value of the underlying common stock as determined on the date of grant by the Company's board of directors (the "Board of Directors").

***Income Taxes***

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the condensed consolidated financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Effective January 1, 2022, we adopted ASU 2019-12 - Simplifying the Accounting for Income Taxes. The adoption of this standard did not impact the Company's condensed consolidated financial statements or related disclosures.

***Comprehensive Loss***

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss includes unrealized gains / losses from short-term investments.

***Net Loss Per Share***

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the sum of the weighted-average number of shares of common stock plus the potential dilutive effects of potential dilutive securities outstanding during the period. Potential dilutive securities are excluded from diluted earnings or loss per share if the effect of such inclusion is antidilutive. The Company's potentially dilutive securities, which include convertible preferred stock, shares from the 2021 Employee Stock Purchase Plan (the "ESPP"), and outstanding stock options and RSUs under the Company's equity incentive plan, have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For the periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

***Recent Developments Regarding the COVID-19 Pandemic***

Efforts to control the outbreak of COVID-19 have resulted in challenges to businesses and facilities in various industries around the world, including disruptions to the global economy and supply chains. To date, COVID-19 has not had a material impact on the Company's expenditures.

The Company is unable to predict the ultimate effects of COVID-19 on the U.S. or global economy or its operations. The Company continues to monitor developments affecting its workforce, suppliers, and operations. The extent of the impact of COVID-19 will depend on its duration, actions by government authorities, and impacts on the Company's employees, or vendors. These developments are continuously evolving, and the Company cannot predict whether COVID-19 will have a material impact on its financial condition, results of operations or cash flows.

***Recent Accounting Pronouncements***

*Financial Instruments.* In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than temporary impairments on investment securities are recorded. The guidance is effective for the Company beginning on January 1, 2023, with early adoption permitted. The Company does not anticipate that the adoption of ASU 2016-13 will have a significant impact on its condensed consolidated financial statements or the related disclosures.

There were no other significant updates to the recently issued accounting standards other than as disclosed herein for the nine months ended September 30, 2022. Although there are several other new accounting pronouncements issued or proposed by the FASB, based on the Company's preliminary assessment, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

**Note 3 – Fair Value Measurements**

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

*Level 1*: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

*Level 2*: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

*Level 3*: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The carrying amounts of cash, prepaid expenses and other current assets, accounts payable, accrued research and development and other current liabilities are reasonable estimates of their fair value due to the short-term nature of these accounts.

The Company's money market funds under cash and cash equivalents are classified using Level 1 inputs within the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. There were no transfers between levels of the fair value hierarchy during the nine months ended September 30, 2022.

The following table summarizes financial assets that the Company measured at fair value on a recurring basis, classified in accordance with the fair value hierarchy (in thousands):

| | Fair Value Measurements at Reporting Date Using: | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **As of September 30, 2022:** | | | | |
| Money market funds | $ 7,874 | $ — | $ — | $ 7,874 |
| Commercial paper | — | 44,774 | — | 44,774 |
| U.S. government securities | 20,080 | — | — | 20,080 |
| U.S. agency bonds | — | 16,167 | — | 16,167 |
| Corporate debt securities | — | 992 | — | 992 |
| Total cash equivalents and short-term investments | $ 27,954 | $ 61,933 | $ — | $ 89,887 |
| Reported as: | | | | |
| Cash and cash equivalents (includes cash of $821) | | | | $ 39,834 |
| Short-term investments | | | | 50,874 |
| Total cash, cash equivalents and short-term investments | | | | $ 90,708 |

| | Fair Value Measurements at Reporting Date Using: | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **As of December 31, 2021:** | | | | |
| Money market funds | $ 10,585 | $ — | $ — | $ 10,585 |
| Commercial paper | — | 84,616 | — | 84,616 |
| U.S. government securities | 27,824 | — | — | 27,824 |
| U.S. agency bonds | — | 8,531 | — | 8,531 |
| Corporate debt securities | — | 8,265 | — | 8,265 |
| Total cash equivalents and short-term investments | $ 38,409 | $ 101,412 | $ — | $ 139,821 |
| Reported as: | | | | |
| Cash and cash equivalents (includes cash of $397) | | | | $ 24,780 |
| Short-term investments | | | | 115,438 |
| Total cash, cash equivalents and short-term investments | | | | $ 140,218 |

**Note 4 – Investments**

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and AFS securities. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers.

Investments are classified as Level 1 within the fair value hierarchy if their quoted prices are available in active markets for identical securities. Investments in money market funds and U.S. government securities were classified as Level 1 instruments.

Investments in commercial paper, corporate debt securities and U.S. agency bonds are valued using Level 2 inputs. The Company classifies investments within Level 2 if the investments are valued using model driven valuations using observable inputs such as quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. Investments are held by custodians who obtain investment prices from a third-party pricing provider that incorporates standard inputs in various asset pricing models.

The following table summarizes, by major types of cash equivalents, and investments that are measured at fair value on a recurring basis (in thousands):

| | September 30, 2022 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Money market funds | $ 7,874 | $ — | $ — | $ 7,874 |
| Commercial paper | 44,823 | 1 | (50) | 44,774 |
| U.S. government securities | 20,259 | — | (179) | 20,080 |
| U.S. agency bonds | 16,228 | 2 | (63) | 16,167 |
| Corporate debt securities | 1,005 | — | (13) | 992 |
| Cash equivalents and investments | $ 90,189 | $ 3 | $ (305) | $ 89,887 |

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Money market funds | $ 10,585 | $ — | $ — | $ 10,585 |
| Commercial paper | 84,642 | 2 | (28) | 84,616 |
| U.S. government securities | 27,870 | — | (46) | 27,824 |
| U.S. agency bonds | 8,546 | — | (15) | 8,531 |
| Corporate debt securities | 8,267 | — | (2) | 8,265 |
| Cash equivalents and investments | $ 139,910 | $ 2 | $ (91) | $ 139,821 |

The contractual maturities of the Company's AFS securities were as follows (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Due within one year | $ 50,133 | $ 105,173 |
| Due within one to two years | 741 | 10,265 |
| Total | $ 50,874 | $ 115,438 |

The available-for-sale investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current condensed consolidated balance sheet date, which reflects management's intention to use the proceeds from sales of these securities to fund the Company's operations, as necessary. There were no realized gains or losses due to investment sales for the three and nine months ended September 30, 2022 and 2021. As of September 30, 2022, $66.4 million of the Company's marketable securities were in gross unrealized loss positions, of which none had been in such position for greater than 12 months and $41.8 million will mature within three months of September 30, 2022.

At each reporting date, the Company performs an evaluation of its marketable securities to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include (i) the financial strength of the issuing institution, (ii) the length of time and extent for which fair value has been less than the cost basis and (iii) the Company's intent and ability to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on the Company's evaluation, it determined that its unrealized losses were not other-than-temporary at September 30, 2022 and December 31, 2021. The Company does not intend to sell the

investments before maturity, and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost bases.

**Note 5 - Condensed Consolidated Balance Sheet Details**

***Prepaid and Other Current Assets***

Prepaid and other current assets consist of the following (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Prepaid insurance | $ 1,521 | $ 827 |
| Prepaid research | 835 | 4,329 |
| Prepaid other | 259 | 96 |
| FICA tax credit receivable | 321 | 452 |
| Other current assets | 82 | 205 |
| Deposits | 19 | 19 |
| Prepaid and other current assets | $ 3,037 | $ 5,928 |

Property and equipment, net, consist of the following (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Furniture and equipment | $ 204 | $ 204 |
| Leasehold improvements | 67 | 67 |
| Computer equipment | 50 | 50 |
| | $ 321 | $ 321 |
| Less: accumulated depreciation and amortization expense | (218) | (156) |
| Property and equipment, net | $ 103 | $ 165 |

Depreciation and amortization expense for the nine months ended September 30, 2022 and 2021 was $62,000 and $50,000, respectively.

***Other Non-Current Assets***

Other non-current assets consist of the following (in thousands):

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Deposits | $ 75 | $ 75 |
| FICA tax credit receivable | 53 | 298 |
| Other | 368 | 70 |
| Other non-current assets | $ 496 | $ 443 |

**Note 6 – Convertible Preferred Stock and Stockholders' Equity**

In connection with the reverse stock split on April 16, 2021, the Company filed a certificate of amendment to its certificate of incorporation, which authorized 260,000,000 shares of capital stock, consisting of 250,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.001 per share that may be issued from time to time by the Board of Directors in one or more series. Of the 250,000,000 shares of common stock, 200,000,000 shares were designated as "Common Stock" and 50,000,000 shares were designated as "Non-Voting Common Stock".

Rights, preferences, powers, privileges and restrictions, qualifications and limitations for holders of the Company's Common Stock and Non-Voting Common Stock are:

a) Voting Common Stock Voting Rights. Each holder of Voting Common Stock, as such, shall be entitled to one vote for each share of Voting Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that, except as otherwise required by law, holders of Voting Common Stock, as such, shall not be entitled to vote on any amendment to the Certificate of Incorporation, including any certificate of designations relating to any series of Preferred Stock (each hereinafter referred to as a "Preferred Stock Designation"), that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation (including any Preferred Stock Designation).

b) Non-Voting Common Stock Voting Rights. Non-Voting Common Stock (i) shall be non-voting except as may be required by law and (ii) shall not entitle the holder thereof to vote on the election of directors at any time.

c) Non-Voting Common Stock Conversion. Each holder of shares of Non-Voting Common Stock shall have the right to convert each share of Non-Voting Common Stock held by such holder into one share (subject to appropriate adjustment in the event of any stock dividend, stock split, reverse stock split, combination or other similar recapitalization with respect to the Voting Common Stock) of Voting Common Stock at such holder's election by providing written notice to the Company; provided, however, that such shares of Non-Voting Common Stock may only be converted into shares of Voting Common Stock during such time or times as immediately prior to or as a result of such conversion would not result in the holder(s) thereof beneficially owning (for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder (collectively, the "Exchange Act")), when aggregated with affiliates with whom such holder is required to aggregate beneficial ownership for purposes of Section 13(d) of the Exchange Act, in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" means initially 9.99% of the Voting Common Stock. Any holder of Non-Voting Common Stock may increase the Beneficial Ownership Limitation with respect to such holder, not to exceed 19.99% of the Voting Common Stock, upon 61 days' prior written notice to the Company and may decrease the Beneficial Ownership Limitation at any time upon providing written notice of such election to the Company; provided, however, that no holder may make such an election to change the percentage with respect to such holder unless all holders managed by the same investment advisor as such electing holder make the same election. Before any holder of Non-Voting Common Stock shall be entitled to convert any shares of Non-Voting Common Stock into shares of Voting Common Stock, such holder shall (A) surrender the certificate or certificates therefor (if any), duly endorsed, at the principal corporate office of the Company or of any transfer agent for the Non-Voting Common Stock, and (B) provide written notice to the Company, during regular business hours at its principal corporate office, of such conversion election (in form satisfactory to the Company) and shall state therein the name or names (i) in which the certificate or certificates representing the shares of Voting Common Stock into which the shares of Non-Voting Common Stock are so converted are to be issued (if such shares of Voting Common Stock are certificated) or (ii) in which such shares of Voting Common Stock are to be registered in book-entry form (if such shares of Voting Common Stock are uncertificated). If the shares of Voting Common Stock into which the shares of Non-Voting Common Stock are to be converted are to be issued in a name or names other than the name of the holder of the shares of Non-Voting Common Stock being converted, such notice shall be accompanied by a written instrument or instruments of transfer, in form satisfactory to the Company, duly executed by the holder. The Company shall, as soon as practicable thereafter, issue and deliver at such office to such holder, or to the nominee or nominees of such holder, a certificate or certificates representing the number of shares of Voting Common Stock to which such holder shall be entitled upon such conversion (if such shares of Voting Common Stock are certificated) or shall register such shares of Voting Common Stock in book-entry form (if such shares of Voting Common Stock are uncertificated). Such conversion shall be deemed to be effective immediately prior to the close of business on the date of such surrender of the shares of Non-Voting Common Stock to be converted following or contemporaneously with the provision of written notice of such conversion election as required by this section, the shares of Voting Common Stock issuable upon such conversion shall be deemed to be outstanding as of such time, and the person or persons entitled to receive the shares of Voting Common Stock issuable upon such conversion shall be deemed to be the record holder or holders of such shares of Voting Common Stock as of such time. Notwithstanding anything herein to the contrary, shares of Non-Voting Common Stock represented by a lost, stolen or destroyed stock certificate may be converted if the holder thereof notifies the Company or its transfer agent that such certificate

has been lost, stolen or destroyed and makes an affidavit of that fact acceptable to the Company and executes an agreement acceptable to the Company to indemnify the Company from any loss incurred by it in connection with such certificate. The effectiveness of any conversion of any shares of Non-Voting Common Stock into shares of Voting Common Stock is subject to the expiration or early termination of any applicable premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

d) Dividends. Subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive any dividends to the extent permitted by law when, as and if declared by the Board of Directors.

e) Liquidation. Upon the dissolution, liquidation or winding up of the Company, subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive the assets of the Company available for distribution to its stockholders ratably in proportion to the number of shares held by them. The Non-Voting Common Stock shall rank on parity with the Voting Common Stock as to distributions of assets upon dissolution, liquidation or winding up of the Company, whether voluntary or involuntary.

***Convertible Preferred Stock***

*Series A Convertible Preferred Stock.* In April 2018, the Company entered into a Series A convertible preferred stock purchase agreement, pursuant to which the Company issued 2,098,269 shares of Series A convertible preferred stock for an aggregate purchase price of $11.0 million, net of issuance costs. In December 2018, the Company issued an additional 1,390,788 shares of Series A convertible preferred stock for an aggregate purchase price of $7.3 million, net of issuance costs.

*Series B Convertible Preferred Stock.* In September 2020, the Company entered into a Series B convertible preferred stock purchase agreement, pursuant to which the Company issued 10,636,510 shares of Series B convertible preferred stock for an aggregate purchase price of $63.2 million, net of issuance costs.

Rights, preferences, powers, privileges and restrictions, qualifications and limitations for holders of the Company's Series A convertible preferred stock and Series B convertible preferred stock were:

- Dividends: Each holder of the Company's Series A and Series B convertible preferred stock was entitled to receive non-cumulative dividends, when and if declared by the Board of Directors. No dividends have been declared to date.

- Liquidation Preferences: In the event of any liquidation, dissolution or winding up of the Company, the holders of the Series A and Series B convertible preferred stock were entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of common stock, an amount per share equal to the original issue price plus declared but unpaid dividends.

- Conversion: Each share of Series A and Series B convertible preferred stock was convertible at the option of the holder, at any time, into the number of shares of common stock determined by dividing the applicable purchase price by the applicable conversion price at the time of conversion. Each share of Series A and Series B convertible preferred stock will be automatically converted into common stock immediately upon (i) the closing of a firm commitment underwritten IPO resulting in at least $50.0 million of gross proceeds to the Company or (ii) the receipt by the Company of a written request for automatic conversion from the holders of a majority of the outstanding shares of Series A and Series B convertible preferred stock.

- Voting: The holders of the Series A and Series B convertible preferred stock were entitled to one vote for each share of common stock into which such shares of Series A and Series B convertible preferred stock could then be converted; and with respect to such vote, such holders shall have full voting rights and powers equal to the voting rights and powers of the holders of the common stock.

- Redemption: The Series A and Series B convertible preferred stock were not explicitly redeemable at the option of the holder at a specified date in the future or at the option of the Company.

Prior to the IPO, the Company's Series A and Series B convertible preferred stock were classified as temporary equity on the condensed consolidated balance sheet instead of in stockholders' equity (deficit), as events triggering redemption that were not solely within the Company's control because the preferred stockholders had the ability to effect a liquidation event. The Company determined not to adjust the carrying values of the Series A and Series B convertible preferred stock to the liquidation preferences of such shares because of the uncertainty of whether or when such liquidation events would occur.

On April 27, 2021, immediately prior to the closing of the IPO, 8,344,905 shares of the Company's convertible preferred stock were exchanged for 7,727,470 shares of Non-Voting Common Stock and 7,928,501 shares of the Company's convertible preferred stock converted into 7,341,860 shares of Common Stock. There were no outstanding shares of the Company's convertible preferred stock as of September 30, 2022.

**Equity Incentive Plan**

In August 2020, the Board of Directors amended the Amended and Restated 2018 Stock Option—Stock Issuance Plan (the "2018 Plan") to increase the maximum number of shares of common stock that may be issued over the term of the plan. The 2018 Plan provided for the grant of stock options, non-statutory stock options, incentive stock options and stock issuances to employees, nonemployees and consultants of the Company.

In April 2021, the Company's 2021 Equity Incentive Plan (the "2021 Plan") was approved by the Board of Directors and became effective on April 15, 2021. Upon the effectiveness of the 2021 Plan, no further grants may be made under the 2018 Plan.

The 2021 Plan allows the Company to grant equity-based awards to its officers, employees, directors and other key persons (including consultants). The Company initially reserved up to 3,246,120 shares of common stock for issuance under the 2021 Plan, plus (i) 1,722 shares that remained available for the issuance of awards under the 2018 Plan at the time the 2021 Plan became effective, and (ii) any shares subject to outstanding options or other share awards that were granted under the 2018 Plan that terminate or expire prior to exercise or settlement; are forfeited because of the failure to vest; or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through January 31, 2032, by 4.0% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Board of Directors. As a result, the number of shares of common stock reserved for issuance under the 2021 Plan increased by 1,059,032 shares on January 1, 2022.

***Stock Options***

A summary of the Company's stock option activities during the nine months ended September 30, 2022 is as follows:

| | Total Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contract Term (in years) | Aggregate Intrinsic Value (in millions) |
|---|---|---|---|---|
| Outstanding as of December 31, 2021 | 1,734,696 | $ 8.50 | 8.8 | $ 7.6 |
| Granted | 1,170,928 | $ 8.04 | | |
| Exercised | (31,152) | $ 4.26 | | |
| Forfeited or cancelled | (244,214) | $ 10.39 | | |
| Outstanding as of September 30, 2022 | 2,630,258 | $ 8.17 | 8.6 | $ 1.4 |
| Vested and expected to vest as of September 30, 2022 | 2,630,258 | $ 8.17 | 8.6 | $ 1.4 |
| Vested and exercisable as of September 30, 2022 | 905,005 | $ 6.51 | 7.7 | $ 0.8 |

The weighted-average grant date fair values of option grants during the nine months ended September 30, 2022 and 2021 were $6.66 and $11.91 per share, respectively. The weighted-average grant date fair values of options forfeited during the nine months ended September 30, 2022 and 2021 were $9.05 and $7.57 per share, respectively.

***Restricted Stock Units***

A summary of the Company's RSU activities during the nine months ended September 30, 2022 is as follows:

| | Total Restricted Stock Units | Weighted-Average Grant Date Fair Values | Aggregate Intrinsic Value (in millions) |
|---|---|---|---|
| Outstanding as of December 31, 2021 | — | $ — | $ — |
| Granted | 9,289 | $ 6.25 | |
| Vested | — | $ — | |
| Forfeited or cancelled | — | $ — | |
| Outstanding as of September 30, 2022 | 9,289 | $ 6.25 | $ — |

There were no RSUs vested during the nine months ended September 30, 2022.

***Employee Stock Purchase Plan***

The ESPP was approved by the Board of Directors and became effective on April 15, 2021. The ESPP initially reserved and authorized the issuance of up to 259,689 shares of common stock to participating employees. Under the ESPP, eligible employees can contribute up to 15% of their eligible compensation, as defined in the ESPP, towards the purchase of the Company's common stock at a price of 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the last trading day of the offering period. The ESPP provides for twenty-four-month offering periods with four six-month purchase periods in each offering period. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through January 31, 2032, by 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year. As a result, the number of shares of common stock reserved for issuance under the ESPP increased by 264,758 shares on January 1, 2022. Under the ESPP, the Company issued 57,862 shares of common stock for aggregate cash proceeds of $0.4 million during the nine months ended September 30, 2022.

***Stock-Based Compensation Expense***

The Company recognized stock-based compensation expense as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | $ 728 | $ 683 | $ 2,821 | $ 1,452 |
| General and administrative | 204 | 179 | 770 | 368 |
| Total stock-based compensation expense | $ 932 | $ 862 | $ 3,591 | $ 1,820 |

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the stock option grants were as follows:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Risk-free interest rate | 3.24% | 0.90% | 1.60% - 3.24% | 0.80% - 1.12% |
| Expected volatility | 103.3% | 115.5% | 88.1% - 112.1% | 115.3% -118.7% |
| Expected term (in years) | 6.1 | 6.1 | 5.3 - 6.1 | 5.0 - 6.1 |
| Expected dividend yield | 0% | 0% | 0% | 0% |

As of September 30, 2022, the total unrecognized compensation cost related to outstanding stock options and restricted stock units was $12.3 million and is expected to be recognized as expense over approximately 2.9 years.

The weighted average assumptions used in the Black-Scholes option pricing model to estimate the fair value of purchase rights granted under the ESPP were as follows:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Risk-free interest rate | 0.1% | 0.1% |
| Expected volatility | 143.2% | 127.8% |
| Expected term (in years) | 1.9 | 1.4 |
| Expected dividend yield | 0% | 0% |

As of September 30, 2022, there was $0.2 million of unrecognized compensation cost related to the ESPP and is expected to be recognized over approximately 0.7 year.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes option-pricing model is affected by the Company's stock price and the following assumptions:

*Risk-free interest rate.* The risk-free interest rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company's stock-based awards.

*Expected volatility.* Due to the Company's limited operating history and lack of company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

*Expected term.* The expected term represents the weighted-average period the stock-based awards are expected to be outstanding. The Company uses the simplified method for estimating the expected term. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of the stock-based awards.

*Expected dividend yield.* The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not intend to pay dividends.

*Forfeitures*. The Company reduces stock-based compensation expense for actual forfeitures during the period.

***Common Stock Reserved for Future Issuance***

Common stock reserved for future issuance consist of the following:

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Stock options | 2,630,258 | 1,734,696 |
| Restricted stock units | 9,289 | — |
| Reserved for future equity award grants | 3,056,959 | 2,933,930 |
| Reserved for future ESPP issuances | 466,585 | 259,689 |
| Total | 6,163,091 | 4,928,315 |

**Note 7 – License Agreements**

The Company has entered into license agreements, accounted for as asset acquisitions, under which the Company is required to use commercially reasonable efforts to meet certain specified development and regulatory milestones related to the licensed technologies within specified time periods. In consideration of the rights granted to the Company under the agreements, the Company is required to make cash milestone payments to the licensors upon the completion of certain development, regulatory and commercial milestones. For the arrangements that the Company accounted for as asset

acquisitions, contingent consideration liabilities are recorded as an additional cost of the acquired assets when the contingency is resolved, and the consideration is paid or becomes payable. Additionally, the Company has agreed to pay royalties on net sales of products applicable to the license agreements. The Company may terminate the agreements upon written notice to the licensors.

***Daiichi Sankyo License Agreement***

On September 2, 2020, the Company licensed the rights to milademetan (DS-3032b) for all human prophylactic or therapeutic uses in all countries and territories of the world from Daiichi Sankyo Company, Limited, ("Daiichi Sankyo"), a Japanese corporation (the "Daiichi Sankyo License Agreement"). Daiichi Sankyo conducted clinical studies of milademetan prior to the Company's licensing the rights to this product. The Company refers to this product candidate as milademetan.

In accordance with the terms of the Daiichi Sankyo License Agreement, the Company paid Daiichi Sankyo an initial upfront payment of $5.0 million in September 2020.

Under the Daiichi Sankyo License Agreement, the Company obtained worldwide, sublicensable exclusive rights to seven families of patents with respect to milademetan (the "Licensed Compound"). The Company is solely responsible under the Daiichi Sankyo License Agreement for the research, development and registration of milademetan. Pursuant to the Daiichi Sankyo License Agreement, Daiichi Sankyo had the right to continue to conduct three clinical trials and prepare final reports with respect to these clinical trials, and such right expires upon all subjects completing the study treatment. The Company has agreed to reimburse Daiichi Sankyo certain third-party expenses incurred while conducting such trials. On March 3, 2022, the Company and Daiichi Sankyo entered into a Memorandum of Understanding, which provides that Daiichi Sankyo will terminate its U105 study, and the Company will reimburse a total of $2.0 million to Daiichi Sankyo for expenses related to such study in four installments of $0.5 million each until December 31, 2022. As of September 30, 2022, the Company paid total installments of $1.5 million. The remaining $0.5 million installment is payable on December 31, 2022. Under the Daiichi Sankyo License Agreement, the Company made other clinical trials payments of $31,000 and $36,000 during the three months ended September 30, 2022 and 2021, respectively and $118,000 and $36,000 during the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022 and December 31, 2021, the accrued Daiichi Sankyo reimbursable clinical trials costs were $0.5 million and $2.0 million, respectively, which were recorded in accrued research and development in the condensed consolidated balance sheet.

The Company is required to make aggregate future milestone payments of up to $223.5 million, contingent on the attainment of certain development, regulatory and sales milestones. The $223.5 million aggregate future milestone payments include a $2.0 million increase that was agreed upon in the Memorandum of Understanding with Daiichi Sankyo. On July 20, 2021, the Company announced that the first patient has been randomized in the multicenter, open-label, Phase 3 registrational trial (MANTRA) evaluating milademetan for the treatment of de-differentiated liposarcoma. Accordingly, pursuant to the Daiichi Sankyo License Agreement, the Company recorded $5.5 million in milestone fees as research and development expense in the condensed consolidated statement of operations and comprehensive loss during the three months ended September 30, 2021. Of the $5.5 million milestone fees, $2.5 million was paid in the third quarter of 2021 and $3.0 million was accrued as part of accrued research and development in the condensed consolidated balance sheet as of September 30, 2021. On June 29, 2022, the Company and Daiichi Sankyo entered into an amendment to the Daiichi Sankyo License Agreement. The amendment reduced the $3.0 million milestone fee liability associated with the previously achieved milestone to $2.0 million and accordingly reduced research and development expense on the condensed consolidated statements of operations and comprehensive loss by $1.0 million for the nine months ended September 30, 2022. The amendment also extended the due date of the milestone fee payment to June 30, 2023. During the three and nine months ended September 30, 2022, the Company incurred no milestone research and development expense under the Daiichi Sankyo License Agreement.

Additionally, the Company is required to pay Daiichi Sankyo a high single digit royalty based on the annual net sales of products containing milademetan as an active pharmaceutical ingredient (the "Products"), subject to reduction at an agreed rate upon expiration of the licensed patent in the particular country where the Products are sold. To date, no royalty payments have been made to Daiichi Sankyo under the Daiichi Sankyo License Agreement. The royalty obligation terminates on a country-by-country and on a product-by-product basis on the later of: (i) loss of all market exclusivity for such Product in such country, (ii) the last-to-expire patent that covers the Licensed Compound or the Product in such country and (iii) twelve years from launch of the first Product sold by the Company in such country.

Unless sooner terminated or extended, the Daiichi Sankyo License Agreement will remain in full force and effect until the Company, its affiliates and its sublicensees cease all development and commercial activity related to milademetan. Either party may terminate the Daiichi Sankyo License Agreement for cause in the event of an uncured material breach (subject to a 90-day cure period). However, the Company may only terminate the Daiichi Sankyo License Agreement with respect to the countries affected by such uncured material breach. Daiichi Sankyo may also terminate the Daiichi Sankyo License Agreement in the event of Rain's bankruptcy or insolvency. Additionally, Daiichi Sankyo may terminate the Daiichi Sankyo License Agreement immediately upon written notice if the Company, its affiliates or its sublicensors initiate or join any challenge to the validity or enforceability of a licensed patent, subject to certain exclusions. Furthermore, the Company may terminate the Daiichi Sankyo License Agreement in its entirety or on a country-by-country basis for bona fide material concerns regarding the (i) lack of safety for human use arising from toxicity of the Licensed Compound or Product(s), (ii) lack of efficacy of the Licensed Compound or Product(s) or (iii) adverse economic impact to the Company in connection with its continued development of the Products, in each case, upon six months' prior written notice to Daiichi Sankyo. In addition, if the Company is acquired by a third party that is developing and commercializing a competing compound and the acquiring party decides not to discontinue the development or commercialization of such competing compound, such third party must terminate the Daiichi Sankyo License Agreement within 30 days of such acquisition if it does not discontinue such development or commercialization. Upon termination of the Daiichi Sankyo License Agreement by Daiichi Sankyo for the Company's uncured material breach or by the Company for its bona fide material concerns regarding the safety, efficacy or adverse economic impacts relating to the Licensed Compound or Products, or its development thereof, the Company is required to, among other actions, if requested by Daiichi Sankyo (i) transfer to Daiichi Sankyo ongoing clinical trials, data, reports, records and materials, (ii) grant to Daiichi Sankyo an exclusive, irrevocable, sublicensable, fully paid-up license under any patents and know-how that are controlled and actually used by the Company at the time of termination in connection with the Products to allow Daiichi Sankyo exploit the Licensed Compound or Products in countries that are affected by the termination, (iii) grant to Daiichi Sankyo an exclusive, irrevocable, sublicensable, fully paid up license to use trademarks that are specific to the Products and (iv) assign any applicable sublicenses.

***Drexel License Agreement and Sponsored Research Agreement***

On July 30, 2020 (the "Effective Date"), the Company entered into an intellectual property license agreement (the "Drexel License Agreement") with Drexel University ("Drexel"). Pursuant to the Drexel License Agreement, Drexel granted to the Company (i) a worldwide, exclusive license to make and commercialize products under a single issued patent and two patent applications related to RAD52 inhibitors for the treatment of cancer (the "Patent Rights") and (ii) a worldwide, nonexclusive license to make, use and commercialize certain technical information and know-how related to the Patent Rights. The license grant includes the right to sublicense after the first anniversary of the Effective Date, subject to express conditions set forth in the Drexel License Agreement.

The Company is obligated to use commercially reasonable efforts to (i) develop, commercialize, market and sell licensed products in a manner consistent with a development plan and (ii) achieve certain milestone events, including, among other things, receiving investigational new drug application ("IND") approval for a licensed product by the fourth anniversary of the Effective Date. Under the Drexel License Agreement, for a period of five years from the Effective Date, the Company is granted a first option to license Drexel's rights in certain improvements, developments or inventions developed by Drexel (or jointly by the parties) during the five-year period that are directly related to the licensed products or to RAD52 or compounds that have been generated to specifically target RAD52.

In addition to a one-time, non-refundable initiation fee of $20,000 paid in four equal installments of $5,000 each within ten days after the Effective Date and six, twelve and eighteen months after the Effective Date, the Drexel License Agreement requires the Company to make further payments to Drexel of up to an aggregate of $6.25 million, for the achievement of specified development milestones for certain licensed products. The Company is also required to reimburse Drexel (i) after the filing of the first IND for the first licensed product, for all costs related to the filing, prosecution and maintenance of the Patent Rights accumulated prior to the Effective Date, and (ii) for all reasonable costs related to the filing, prosecution and maintenance of the Patent Rights after the Effective Date. In addition, the Company is also required to pay Drexel, on a quarterly basis, a low single digit royalty on net sales by the Company, its affiliates and sublicensees of certain licensed products, subject to specified reductions and a minimum quarterly royalty payment of up to $6,250.

Lastly, the Company is also obligated to pay Drexel (i) an annual license maintenance fee of $15,000 commencing upon filing of the first IND for a licensed product until the first sale of the first licensed product, (ii) a sublicense fee of low double digits percentage on all consideration received by the Company from its sublicensees, subject to certain reductions and (iii) a one-time transaction fee equal to the actual amount of Drexel's licensing and legal expenses in connection with

the Drexel License Agreement and the Sponsored Research Agreement the parties simultaneously entered into with the Drexel License Agreement (the Sponsored Research Agreement).

The Company made payments of nil and $38,000 under the Drexel License Agreement for the three and nine months ended September 30, 2022, respectively. The Company made payments of $12,000 and $31,000 under the Drexel License Agreement for the three and nine months ended September 30, 2021, respectively.

Unless sooner terminated or extended, the term of the Drexel License Agreement with respect to any licensed product and country continues until the later of (i) the expiration or abandonment of the last-to-expire valid claim of the Patent Rights that covers the sale of such licensed product in such country, (ii) the expiration of any granted statutory period of marketing and/or data exclusivity for such licensed product that confers upon the Company exclusive commercialization, (iii) the month of the first sale of a generic equivalent of such licensed product in such country and (iv) ten years after the first sale of the first licensed product.

The Company may terminate the Drexel License Agreement at any time by providing 60 days' prior written notice to Drexel, in which case the Company will be required to cease exploitation of all licensed products, terminate all permitted sublicenses and pay all amounts owed to Drexel under the Drexel License Agreement and the Sponsored Research Agreement through the effective date of termination. Drexel may terminate the Drexel License Agreement for the Company's uncured material breach (with 30 to 135-day cure periods), for the Company's bankruptcy or insolvency, for the Company's uncured material default under the Sponsored Research Agreement, or if the Company challenges the validity or enforceability of the licensed patent rights.

***Roche Clinical Supply Agreement***

In December 2021, the Company entered into a clinical supply agreement with Roche for the supply of the anti-Programmed Death Ligand-1 (PD-L1) monoclonal antibody, atezolizumab. Clinical trials are planned to evaluate milademetan, in combination with atezolizumab for the treatment of patients in genetically selected populations. Under this agreement, Rain is the sponsor of the anticipated clinical trials, and Roche will supply atezolizumab. The Company does not have any financial commitments to Roche under this agreement.

**Note 8 – Commitments and Contingencies**

***Leases***

In September 2018, the Company entered into a noncancelable operating lease agreement for office space for its corporate headquarters in Newark, California with an initial term of 5.25 years. The lease commenced in January 2019 and ends March 2024. Under the terms of the lease, the Company pays annual base rent, subject to an annual fixed percentage increase of 2% on March 1st of each year. The Company is obligated to pay for its share of direct expenses including operating expense and taxes, which are considered variable lease costs and are expensed as incurred.

In March 2020, Governor Newsom issued State of California Executive Order No. N-33-20 instructing all individuals in California to stay at home due to the COVID-19 pandemic. In connection with such order, the Company entered into an amendment to the noncancelable operating lease agreement in June 2020. The amendment provided the Company rent relief for three months in 2020. In consideration of the rent relief, the Company agreed to adjust the base rent annual fixed percentage increase of 3% on February 1st of each year and extend the lease until September 2024. The amendment was determined to be a lease modification that qualified as a change of accounting on the existing lease and not a separate contract. Remeasurement of the right-of-use asset and operating lease liabilities at the date of modification did not result in a material increase of the right-of-use asset and operating lease liabilities.

In October 2022, the Company entered into an amendment to its corporate headquarters lease agreement to expand the leased premises by approximately 3,880 square feet. The lease commencement date for the expansion premises is expected to be January 2023 and will expire in September 2024 concurrently with the existing lease. Total future lease payments over the life of the lease are estimated to increase by approximately $0.4 million as a result of the amendment.

The future minimum lease payments required under the operating lease are summarized as follows (in thousands):

| | As of September 30, 2022 |
|---|---|
| 2022 - remainder | $ 42 |
| 2023 | 171 |
| 2024 | 129 |
| Total minimum lease payments | $ 342 |
| Less: amount representing interest | (30) |
| Present value of operating lease liabilities | $ 312 |
| Operating lease liabilities, current | 163 |
| Operating lease liabilities, non-current | 149 |
| Total operating lease liabilities | $ 312 |
| Weighted-average remaining lease term (in years) | 1.9 |
| Weighted-average incremental borrowing rate | 10.0% |

The table below summarizes the Company's lease costs and cash payments in connection with operating lease obligations (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Total operating lease expense | $ 40 | $ 40 | $ 120 | $ 120 |
| Operating cash flows used for operating lease | $ 42 | $ 40 | $ 124 | $ 121 |

***Contingencies***

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

**Note 9 – Employee Benefits**

The Company has a defined contribution 401(k) plan available to eligible employees. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain contributions to the 401(k) plan. The Company made matching contributions of $320,000 and $182,000 for the nine months ended September 30, 2022 and 2021, respectively.

**Note 10 – Net Loss Per Share**

The following tables summarize the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **Numerator:** | | | | |
| Net loss | $ (18,041) | $ (18,426) | $ (53,046) | $ (33,409) |
| **Denominator:** | | | | |
| Weighted-average shares of common stock outstanding, basic and diluted | 26,564,615 | 26,466,746 | 26,535,474 | 17,025,032 |
| Weighted-average shares used to compute net loss per share, basic and diluted | 26,564,615 | 26,466,746 | 26,535,474 | 17,025,032 |
| Net loss per share, basic and diluted | $ (0.68) | $ (0.70) | $ (2.00) | $ (1.96) |

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

| | As of September 30, | |
|---|---|---|
| | 2022 | 2021 |
| Stock options | 2,630,258 | 1,605,486 |
| Restricted stock units | 9,289 | — |
| Series A convertible preferred stock | — | — |
| Series B convertible preferred stock | — | — |
| ESPP shares | 27,379 | — |
| Total | 2,666,926 | 1,605,486 |

**Note 11 – Subsequent Events**

In October 2022, the Company entered into an amendment to its corporate headquarters lease agreement to expand the leased premises by approximately 3,880 square feet. See Note 8 to the Condensed Consolidated Financial Statements.

In November 2022, the Company entered into an underwriting agreement (as amended, the “Underwriting Agreement”) with Guggenheim Securities, LLC, as the representative of the underwriters named therein (the “Underwriters”) relating to the offering, issuance and sale (the “Offering”) of 5,961,080 shares of the Company’s common stock and 2,615,250 shares of the Company’s non-voting common stock. The offering price per share was $5.83, for gross proceeds to the Company from the Offering of approximately $50 million, before deducting customary underwriting discounts and offering expenses. In addition, the Company granted the Underwriters a 30-day option to purchase up to an additional 1,286,449 shares of its common stock on the same terms and conditions as the common stock sold in the Offering.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section titled "Risk Factors" and included in our Annual Report on Form 10-K for the year ended December 31, 2021. You should carefully read the sections titled "Note Regarding Forward-Looking Statements" and "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from the results described below.*

**Overview**

We are a late-stage precision oncology company developing therapies that target oncogenic drivers to genetically select patients we believe will most likely to benefit. This approach includes using a tumor-agnostic strategy to select patients based on their tumors' underlying genetics rather than histology. We have in-licensed product candidates, each with a differentiated profile relative to available therapies, and we intend to continue strengthening our pipeline through focused business development and internal research efforts.

Our lead product candidate, milademetan (also known as RAIN-32) is an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53. We in-licensed milademetan from Daiichi Sankyo in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) LPS patients in the Phase 1 clinical trial of milademetan demonstrated median progression-free survival (mPFS) of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition unlocking the potential for milademetan in a broad range of MDM2-dependent cancers. Based on these data, we commenced a pivotal Phase 3 trial in LPS (MANTRA) in July 2021. We also commenced a Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2) in November 2021. We anticipate commencing a Phase 1/2 clinical trial to evaluate the safety, tolerability and efficacy of milademetan in combination with atezolizumab in patients with loss of cyclin-dependent kinase inhibitor 2A (CDKN2A) and wildtype p53 advanced solid tumors (MANTRA-4) in the first quarter of 2023. In addition to milademetan, we are also developing a preclinical program that is focused on inducing synthetic lethality in cancer cells by inhibiting RAD52.

Since our inception in 2017, we have incurred significant operating losses and have utilized substantially all of our resources to date in-licensing and developing our product candidates, organizing and staffing our Company and providing other general and administrative support for our operations. As of September 30, 2022, we had an accumulated deficit of $143.0 million and we incurred net losses of approximately $18.0 million and $53.0 million for the three and nine months ended September 30, 2022, respectively. Our operations to date have been funded primarily through the issuance of convertible promissory notes, the issuance of convertible preferred stock, as well as issuance and sale of common stock through our initial public offering ("IPO"). From our inception through September 30, 2022, we have raised aggregate gross proceeds of $9.9 million from the issuance of convertible promissory notes and $81.9 million from the issuance of convertible preferred stock. On April 27, 2021, we completed our IPO in which we issued and sold 7,352,941 shares of common stock at a public offering price of $17.00 per share. On May 11, 2021, we issued an additional 492,070 shares of common stock in connection with the exercise of the underwriters' option to purchase additional shares at the public offering price. Our net proceeds from the sale of shares in the IPO, including the sale of shares pursuant to the exercise of the underwriters' option to purchase additional shares, was $121.5 million, net of underwriting discounts and commissions, and other offering fees. As of September 30, 2022, we had cash, cash equivalents and short-term investments of $90.7 million. In November 2022, we entered into an underwriting agreement (as amended, the "Underwriting Agreement") with Guggenheim Securities, LLC, as the representative of the underwriters named therein (the "Underwriters") relating to the offering, issuance and sale (the "Offering") of 5,961,080 shares of our common stock and 2,615,250 shares of our non-voting common stock. The offering price per share was $5.83, for gross proceeds to us from the Offering of approximately $50 million, before deducting customary underwriting discounts and offering expenses. In addition, we granted the Underwriters a 30-day option to purchase up to an additional 1,286,449 shares of our common stock on the same terms and conditions as the common stock sold in the Offering. Although we believe, based on our current business plans, that our existing cash, cash equivalents and short-term investments will be sufficient to meet our obligations for at least the next twelve months, we anticipate that we will require additional capital in the future in order to continue the research and

development of our drug candidates. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products, seek to expand our product pipeline, invest in our organization, as well as incur expenses associated with operating as a public company.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates, which will not be for many years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings or other capital sources which may include strategic collaborations, licensing arrangements or other arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms or at all. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or we may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts. Our ability to raise additional funds may be adversely impacted by potential worsening of global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic or otherwise. Because of the numerous risks and uncertainties associated with our product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities. Based upon our current operating plan, we estimate that our cash, cash equivalents and short-term investments as of September 30, 2022 will be sufficient to fund our milademetan program.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely and expect to continue to rely for the foreseeable future, on third parties for the manufacture of our drug candidates for preclinical and clinical testing, as well as for commercial manufacture of any drugs that we may commercialize. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities. For the milademetan program, we have transferred Daiichi Sankyo Company, Limited (Daiichi Sankyo) processes to suitable third-party contract manufacturing organizations to supply active pharmaceutical ingredients and clinical drug product for our clinical trials and in preparation for submission of marketing applications and potential future commercial supplies.

**COVID-19**

The ongoing COVID-19 pandemic continues to rapidly evolve, and we will continue to monitor the COVID-19 situation closely. The extent of the impact of the COVID-19 pandemic on our business, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, clinical trial sites, contract research organizations (“CROs”), third-party manufacturers and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. To the extent possible, we are conducting business as usual, with necessary or advisable modifications, and most of our employees are working remotely. The increased reliance on our personnel working from home has not negatively impacted productivity, or disrupted, delayed or otherwise seriously harmed our business. The collection and integrity of subject data and clinical trial endpoints have not been negatively impacted by the COVID-19 pandemic. We will continue to monitor the evolving situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, including the ability of the FDA and other regulatory authorities to perform routine functions or that we determine are in the best interests of our employees and other third parties with whom we do business. If global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and clinical development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain and is subject to change.

**Recent Developments**

In August 2022, we announced the completion of enrollment into our MANTRA Phase 3 randomized, global, registrational trial of our lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53. We anticipate topline data from our MANTRA Phase 3 trial in the first quarter of 2023.

***MANTRA-2 Preliminary Data***

On November 4, 2022, we announced preliminary data in the multicenter, single arm, open-label, Phase 2 basket trial evaluating milademetan, an MDM2 inhibitor, for the treatment of MDM2-amplified advanced solid tumors (MANTRA-2). The MANTRA-2 trial is designed to evaluate the safety and efficacy of milademetan monotherapy in patients with advanced or metastatic solid tumors refractory or intolerant to standard-of-care therapy and that exhibit wild-type p53 and a prespecified minimum MDM2 gene copy number. Approximately 65 patients are anticipated to be enrolled to receive milademetan. As of the latest data cutoff on October 26, 2022, 17 patients have been enrolled. The primary endpoint of the trial is objective response rate as measured by RECIST criteria. Secondary endpoints include duration of response, disease control rate progression-free survival by investigator assessment, overall survival and growth modulation index.

***Preliminary Interim Data***

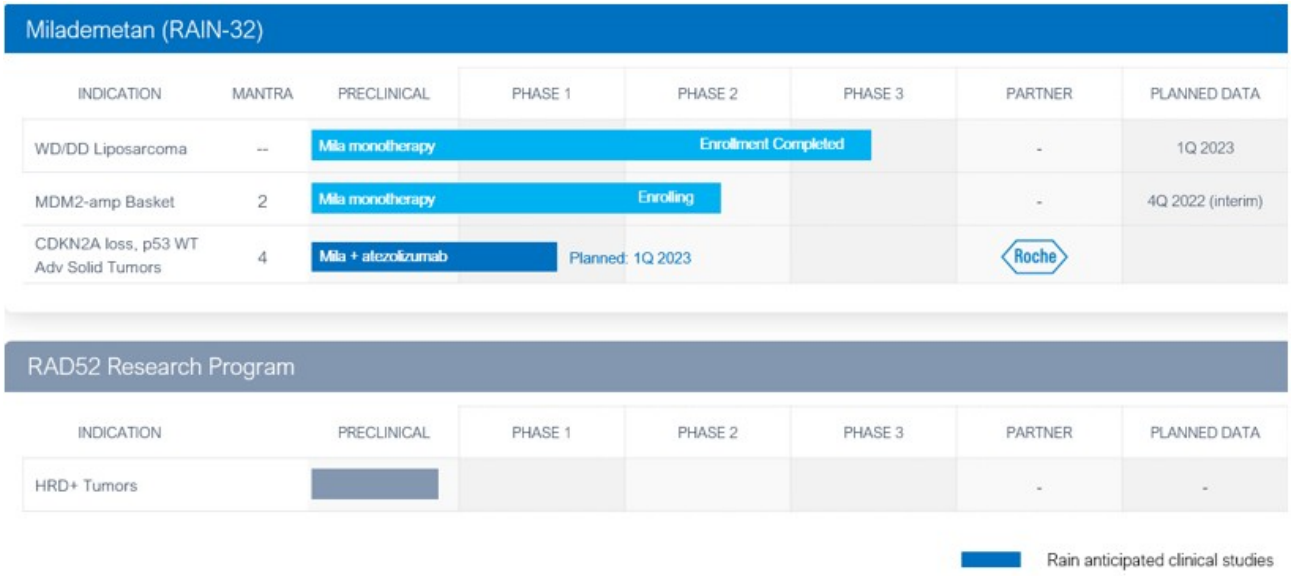
- As of the latest data cutoff on October 26, 2022, 17 patients have been enrolled, 15 of whom have been dosed with milademetan.
- Ten patients were efficacy-evaluable with CN ≥8 by central testing.
    - A diverse set of tumor histologies were enrolled amongst the evaluable patients.
    - Most tumors had co-alterations in oncogenes or tumor suppressors, including KRAS, EGFR, and PIK3CA amongst others.
- Two unconfirmed partial responses were observed with tumor regression of 34% and 30% (pancreatic and lung cancer, respectively).
    - The patient with pancreatic cancer is pending response confirmation and ongoing treatment.
    - The patient with lung cancer is deceased due to COVID-19.
- Two patients exhibited promising activity with tumor regression of 29% and 27% (biliary tract and breast cancer, respectively) and the patients are continuing with the investigational therapy.
- Observed anti-tumor effect of milademetan in heavily pretreated, refractory patients, with a median of four prior therapies.
- Safety profile to date is preliminarily consistent with prior Phase 1 trial of milademetan.

***Other Key Development Updates***

With respect to our other ongoing and planned clinical trials, we now expect to report topline data from our Phase 3 MANTRA registrational trial evaluating milademetan for the treatment of DD LPS in the first quarter of 2023. We also expect to commence a Phase 1/2 MANTRA-4 clinical trial to evaluate the safety, tolerability and efficacy of milademetan in combination with atezolizumab in patients with loss of CDKN2A and wildtype p53 advanced solid tumors in the first quarter of 2023. We are deprioritizing the Phase 2 MANTRA-3 trial in Merkel cell carcinoma as an area of focus due to our continued effort to rationalize use of capital in the current market environment. We are now focusing our development efforts on our MANTRA, MANTRA-2 and MANTRA-4 clinical trials within our milademetan program.

**Our Development Pipeline**

Our development pipeline is unified by a strategy to target oncogenic drivers through differentiated therapies for which we are able to genetically select the patients we believe will be most likely to benefit from treatment. We currently retain global development and commercialization rights to all of our product candidates.




***Milademetan Overview***

Our lead product candidate, milademetan, is a small molecule, oral inhibitor of MDM2 and is being developed in patients with MDM2-dependent cancers. Historically, MDM2 inhibition has presented treatment challenges due to dose-limiting, on-target hematologic toxicities. We believe an MDM2-targeted therapy must possess certain pharmacological characteristics related to potency and pharmacokinetics to allow for the design of an optimized dosing schedule. An optimized dosing schedule is intended to improve peak drug exposure leading to apoptosis and cell cycle arrest during the dosing period, while permitting hematopoietic precursor cell recovery during the dosing break, thereby minimizing hematologic toxicity. Milademetan's differentiated profile, as a potent MDM2 inhibitor has enabled a rationally designed dosing schedule that we believe has the potential to reduce toxicities while preserving activity. We anticipate that this dosing schedule may also be applicable to other MDM2-dependent cancer populations across solid and hematologic tumor types.

In September 2020, we in-licensed milademetan from Daiichi Sankyo. Daiichi Sankyo previously conducted a Phase 1 clinical trial in WD/DD LPS patients. Liposarcomas are the most common sarcomas in adults. WD and DD LPS represent subtypes of LPS. The DD subtype often develops within WD tumor mass at disease progression or recurrence of resected WD LPS. WD/DD LPS tumors have nearly universal MDM2 amplification and wild type (WT) p53, and hence we believe WD/DD LPS patients represent an appropriate population for MDM2 inhibition therapy. Data from a WD/DD LPS patients in the Phase 1 clinical trial of milademetan demonstrated mPFS of approximately seven to eight months. Importantly, this result was accomplished with a rationally designed dosing schedule designed to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition, establishing potential for a differentiated profile. In July 2021, we announced that the first patient has been randomized in the multicenter Phase 3 registrational trial (MANTRA) evaluating milademetan for the treatment of DD LPS. Accordingly, pursuant to the Daiichi Sankyo License Agreement, $2.5 million in milestone fees was paid in the third quarter of 2021 and $2.0 million is accrued as of September 30, 2022, which is payable in the second quarter of 2023.

The MANTRA trial is designed to evaluate the safety and efficacy of milademetan compared to trabectedin, a current standard of care, in patients with unresectable or metastatic DD LPS with or without a WD LPS component that has progressed on one or more prior systemic therapies, including at least one anthracycline-based therapy. One hundred seventy-five patients were enrolled and randomized in a 1:1 ratio to receive milademetan or trabectedin. The primary

objective of the trial is to compare progression-free survival (PFS) by blinded independent review between the milademetan treatment arm and the trabectedin control arm. Secondary endpoints include overall survival, PFS by investigator assessment, objective response rate, duration of response, disease control rate, safety and patient reported outcomes. We anticipate top-line data from this trial in the first quarter of 2023. Our commencement of a Phase 3 trial following the Phase 1 trial referenced above is based on the data observed in the Phase 1 trial and FDA feedback with respect to our development plan.

In July 2021, we provided an update on patients who received milademetan monotherapy from the concluded Phase 1 dose escalation and expansion study. As of July 1, 2021, three WD/DD LPS patients received therapy with milademetan monotherapy for greater than 51 months. Two of these patients received therapy with durations of 51 and 57 months without disease progression, and an additional patient received therapy for greater than 59 months before discontinuation in the second quarter of 2021. We believe this highlights the potential for milademetan to have a favorable long-term tolerability and safety profile.

In November 2021, we commenced a multicenter, single arm open-label, Phase 2 basket trial evaluating milademetan, for the treatment of MDM2-amplified advanced solid tumors (MANTRA-2). The MANTRA-2 trial is designed to evaluate the safety and efficacy of milademetan in patients with advanced or metastatic solid tumors refractory or intolerant to standard-of-care therapy and that exhibit wild-type p53 and a prespecified minimum MDM2 gene copy number. Approximately 65 patients are expected to be enrolled to receive milademetan. The primary endpoint of the trial is objective response rate as measured by RECIST criteria. Secondary endpoints include duration of response, disease control rate progression-free survival by investigator assessment, overall survival, and growth modulation index. As discussed under the Recent Development section above, on November 4, 2022, we announced preliminary interim data in our MANTRA-2 clinical trial.

In January 2022, we announced a clinical supply agreement with Roche for the supply of the anti-Programmed Death Ligand-1 (PD-L1) monoclonal antibody, atezolizumab. Clinical trials are planned to evaluate milademetan in combination with atezolizumab for the treatment of patients in genetically selected populations. Under this agreement, we are the sponsor of the anticipated clinical trial, and Roche will supply atezolizumab. An initial Phase 1/2 clinical trial is planned to evaluate the safety, tolerability and efficacy of milademetan in combination with atezolizumab in patients with loss of CDKN2A and wildtype p53 advanced solid tumors who have previously progressed on ICI. We anticipate the start of the Phase 1/2 clinical trial in the first quarter of 2023. Subsequent Phase 2 clinical trials evaluating the combination of milademetan and atezolizumab may span various additional tumor types.

In November 2022, in order to rationalize use of financial resources, we deprioritized the MANTRA-3 Phase 2 trial of milademetan in Merkel cell carcinoma, which was planned to commence in the fourth quarter of 2022.

***Milademetan and p53 Overview***

Milademetan reactivates p53, known as the “guardian of the genome,” by inhibiting MDM2. p53 is present in every cell and acts as a key regulator of a variety of cellular processes including cell cycle, DNA repair and apoptosis. In a normal cell, the activity of p53 is controlled and regulated by the inhibitory protein MDM2. MDM2 binds to p53, thereby inducing degradation and allowing normal cells to function properly. In response to cell damage and other stress conditions, p53 is activated and prevents the formation of cancerous cells by inducing apoptosis.

In contrast to normal cells, in tumor cells, the two primary mechanisms by which p53 can be inactivated in tumor cells are mutations in p53 and activation or overexpression of MDM2. Approximately half of all tumors are characterized by mutations of the p53 gene. The remaining cancer patients have a p53 gene that is not mutated, and is otherwise known as WT p53, but can be functionally suppressed through the activation or overexpression of MDM2. We have identified MDM2 dependence in several solid tumors. This dependence is caused by overexpression of MDM2 through gene amplification or other mechanisms, loss of a negative regulator of MDM2 or other causes. Overexpression of MDM2 promotes the degradation of p53 and also eliminates p53’s ability to activate transcription. Milademetan, by binding MDM2 at the p53 interaction site, prevents the formation of the MDM2-p53 complex, allowing p53 reactivation and subsequent transcription of genes, such as MIC1, that trigger cancer cell cycle arrest or apoptosis, among others.

***RAD52 Overview***

We are also developing a preclinical program focused on targeting RAD52 in the DNA damage repair pathway. While our RAD52 program is in an early stage of development, we expect to develop this program for patients with a molecularly diagnosed HRD+, such as mutations and loss-of-function in BRCA1/2 or others that utilize RAD52 as an alternative DNA repair pathway, as well as for patients that may have relapsed to poly (ADP ribose) polymerase (PARP) inhibitor therapy. There are currently no approved therapies or clinical programs in development targeting RAD52.

Targeting RAD52 represents a novel strategy for tumors exhibiting tumor HRD+ or a loss of function, of several pathway constituents, including BRCA1/2 or others in tumor types frequently characterized by these deficiencies. These tumors include breast, prostate, pancreatic, ovarian and possibly other cancers. Developmental paths for RAD52 inhibitors include as a monotherapy in HRD+ patients relapsing on PARP inhibitor therapy, or in front-line combinations with PARP inhibitors in HRD+ tumors.

Our RAD52 program is currently in lead optimization stage. We anticipate evaluating identified RAD52 inhibitor candidates in animal models of patient tumors with HRD+ that have relapsed on PARP inhibitors and in HRD+ tumors with a loss-of-function mutation of BRCA1/2 in combination with PARP inhibitors.

**Collaboration and License Agreements**

We are party to a number of license agreements for the in-license of our product candidates and development programs. See Note 7 to the Condensed Consolidated Financial Statements.

**Components of Our Results of Operations**

***Revenue***

To date, we have not generated any revenue from product sales, licenses or collaborations and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue from future product sales. If we enter into license or collaboration agreements for any of our product candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates or from license or collaboration agreements. We may never succeed in obtaining regulatory approval for any of our product candidates.

***Operating Expenses***

Our operating expenses since inception have consisted solely of research and development costs, including acquisition of in-process research and development, and general and administrative costs.

***Research and Development Expenses***

To date, our research and development expenses have related to the discovery and clinical development of our product candidates, including acquisition of in-process research and development. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits and stock-based compensation charges for those individuals involved in research and development efforts;
- expenses incurred in connection with research, laboratory consumables and preclinical studies;
- external research and development expenses incurred under agreements with CROs and consultants to conduct and support our planned clinical trials of our product candidates;

- the cost of consultants engaged in research and development-related services and the cost to manufacture drug product for use in our preclinical studies and clinical trials;
- costs related to regulatory compliance;
- the cost of annual license fees and the cost of acquiring in-process research and development, including upfront license payments; and
- any development milestone payments that we may make under our license agreements.

We track external development costs by product candidate or development program, but we do not allocate personnel costs or other internal costs to specific development programs or product candidates as our personnel works across multiple development programs and product candidates. These costs are included in unallocated research and development expenses in the table below.

The following table summarizes our research and development expenses by product candidate or development program:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| | (in thousands) | | (in thousands) | |
| Milademetan | $ 7,639 | $ 10,366 | $ 23,766 | $ 16,603 |
| Other research and clinical candidates | 158 | 209 | 569 | 1,546 |
| Unallocated internal research and development costs | 6,713 | 4,709 | 17,987 | 7,952 |
| Total research and development expenses | $ 14,510 | $ 15,284 | $ 42,322 | $ 26,101 |

We plan to substantially increase our research and development expenses for the foreseeable future as we continue to expand the development of our product candidates. We cannot predict with certainty the timing for initiation or completion of, the duration of, or the costs of current or future clinical trials and nonclinical studies of any of our product candidates due to the inherently unpredictable nature of clinical and preclinical development. The clinical development timeline, probability of success of clinical trials and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly. See the section titled “Risk Factors—Risks Related to Product Development—Preclinical and clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future clinical trial results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidates” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021.

***General and Administrative Expenses***

General and administrative expenses consist of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and facility-related costs. We anticipate that our general and administrative expenses will continue to increase in the future to support our continued research and development activities, pre-commercial preparation activities for our product candidates and, if any product candidate receives marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

***Interest Income***

For the three and nine months ended September 30, 2022 and 2021, interest income consists of interest on our money market accounts and short-term investments.

**Results of Operations**

***Comparison of Three and Nine Months Ended September 30, 2022***

The following table summarizes our results of operations for the three and nine months ended September 30, 2022 and 2021, together with the changes in those items in dollars:

| | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2022 | 2021 | Change | 2022 | 2021 | Change |
| | (in thousands) | | | (in thousands) | | |
| Operating expenses: | | | | | | |
| Research and development | $ 14,510 | $ 15,284 | $ (774) | $ 42,322 | $ 26,101 | $ 16,221 |
| General and administrative | 3,901 | 3,154 | 747 | 11,257 | 7,334 | 3,923 |
| Total operating expenses | 18,411 | 18,438 | (27) | 53,579 | 33,435 | 20,144 |
| Loss from operations | (18,411) | (18,438) | 27 | (53,579) | (33,435) | (20,144) |
| Other income: | | | | | | |
| Interest income | 370 | 11 | 359 | 533 | 25 | 508 |
| Other income | — | 1 | (1) | — | 1 | (1) |
| Total other income, net | 370 | 12 | 358 | 533 | 26 | 507 |
| Net loss | $ (18,041) | $ (18,426) | $ 385 | $ (53,046) | $ (33,409) | $ (19,637) |

***Research and Development Expenses***

Research and development (R&D) expenses were $14.5 million and $15.3 million for the three months ended September 30, 2022 and 2021, respectively. The decrease in R&D expenses was primarily due to the milestone fees to Daiichi Sankyo of $5.5 million incurred during the three months ended September 30, 2021, partially offset by higher payroll-related costs for our R&D personnel, clinical trial costs, and various other R&D costs for milademetan. Non-cash stock-based compensation expenses, included as part of personnel costs, were $0.7 million for each of the three months ended September 30, 2022 and 2021.

R&D expenses were $42.3 million and $26.1 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in R&D expenses was primarily related to clinical trial costs, higher payroll-related costs for our R&D personnel, and various other R&D costs for milademetan. Non-cash stock-based compensation expenses, included as part of personnel costs, were $2.8 million and $1.4 million for the nine months ended September 30, 2022 and 2021, respectively. We expect our R&D costs to continue to increase for the remainder of 2022 as we continue our Phase 3 trial in LPS and our Phase 2 tumor-agnostic basket trial for milademetan.

***General and Administrative Expenses***

General and administrative (G&A) expenses were $3.9 million and $3.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase in G&A expenses was primarily due to payroll-related costs of $0.3 million, professional services costs of $0.3 million, and legal costs of $0.1 million. Non-cash stock-based compensation expense included in G&A expenses was approximately $0.2 million for each of the three months ended September 30, 2022 and 2021. We have incurred and expect to continue incur additional expenses as a result of being a public company following the completion of our IPO in April 2021, including costs associated with maintaining compliance with exchange listing and SEC requirements.

G&A expenses were $11.3 million and $7.3 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in G&A expenses was primarily due to payroll-related costs of $1.5 million, professional services costs of $0.6 million, legal costs of $0.3 million, directors and officers' insurance of $0.2 million, and various third-party G&A costs of $0.2 million. Non-cash stock-based compensation expense included in G&A expenses was approximately $0.8

million and $0.4 million for the nine months ended September 30, 2022 and 2021, respectively. We expect our general and administrative expenses to continue to increase for the remainder of 2022 as we continue to build out systems and infrastructure to support our operations.

***Other Income***

Other income for the three and nine months ended September 30, 2022 and 2021 represents interest income from money market or short-term investments.

**Liquidity and Capital Resources**

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our research programs and product candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have not generated any revenue from product sales since inception. To date, we have financed our operations through the issuance of convertible promissory notes and the issuance of convertible preferred stock and common stock. From our inception through September 30, 2022, we have raised aggregate gross proceeds of $9.9 million from the issuance of convertible promissory notes and $81.9 million from the issuance of convertible preferred stock.

In November 2022, we entered into the Underwriting Agreement with Guggenheim Securities, LLC, as representative of the Underwriters, relating to the Offering of 5,961,080 shares of our common stock and 2,615,250 shares of our non-voting common stock. The offering price per share was $5.83, for gross proceeds from the Offering of approximately $50 million, before deducting customary underwriting discounts and offering expenses. In addition, we granted the Underwriters a 30-day option to purchase up to an additional 1,286,449 shares of our common stock on the same terms and conditions as the common stock sold in the Offering.

In May 2022, we entered into a sales agreement (the “Sales Agreement”) with Oppenheimer & Co. Inc. (the “Sales Agent”) pursuant to which we may offer and sell up to $50.0 million of shares of our common stock, from time to time, in “at-the-market” offerings (the “ATM Facility”). The Sales Agent is entitled to compensation at a commission equal to 3.0% of the aggregate gross sales price per share sold under the Sales Agreement. For the three months ended September 30, 2022, there were no sales pursuant to the ATM Facility.

On April 27, 2021, we completed our IPO in which we issued and sold 7,352,941 shares of common stock at a public offering price of $17.00 per share. On May 11, 2021, we issued an additional 492,070 shares of common stock in connection with the exercise of the underwriters’ option to purchase additional shares at the public offering price. Our net proceeds from the sale of shares in the IPO, including the sale of shares pursuant to the exercise of the underwriters’ option to purchase additional shares, was $121.5 million, net of underwriting discounts and commissions, and other offering fees.

As of September 30, 2022, we had cash, cash equivalents and short-term investments of $90.7 million. Although we believe, based on our current business plans, that our existing cash, cash equivalents and short-term investments will be sufficient to meet our obligations for at least the next twelve months, we anticipate that we will require additional capital in the future in order to continue the research and development of our drug candidates. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

***Future Funding Requirements***

We expect our expenses to increase substantially in connection with our ongoing development activities related to milademetan and other product candidates and programs, which are still in the early stages of development. In addition, we

expect to incur additional costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- continue our on-going clinical trials, initiate new clinical trials for our milademetan program and incur additional preclinical research costs for our RAD52 program;
- initiate and continue research and preclinical and clinical development of our product candidates;
- seek to identify and develop additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing, manufacturing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our product candidates for clinical development and potentially commercialization;
- maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license other drugs and technologies;
- defend against any claims of infringement, misappropriation or other violation of third-party intellectual property;
- hire and retain additional clinical, quality control and scientific personnel;
- build out new facilities or expand existing facilities to support our ongoing development activity;
- add operational, financial and management information systems and personnel, including personnel to support our drug development, and any future commercialization efforts; and
- potentially experience the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the ongoing COVID-19 pandemic and the geopolitical environment.

Because of the numerous risks and uncertainties associated with the development of milademetan 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 and programs. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our current and future clinical trials of milademetan for our current targeted indications;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for RAD52 and other product candidates;
- the number of future product candidates that we pursue and their development requirements;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we acquire or invest in businesses, products and technologies, including entering into or maintaining licensing or collaboration arrangements for product candidates on favorable terms, although we currently have no commitments or agreements to complete any such transactions;
- the costs of preparing, filing and prosecuting patent applications, maintaining, protecting and enforcing our intellectual property rights and defending intellectual property-related claims;

- our headcount growth and associated costs as we expand our business operations and our research and development activities;
- our ability to successfully acquire or in-license other drugs and technologies;
- the costs and timing of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of operating as a public company.

Developing drug 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 drugs that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Until such time, if ever, as we can generate product revenues to support our cost structure, we expect to finance our cash needs through public or private equity offerings, including our ATM Facility, debt financings or other capital sources which may include strategic collaborations, licensing arrangements or other arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing and equity financing, if available, 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 raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and geopolitical events or otherwise. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

***Cash Flows***

The following table summarizes our sources and uses of cash and cash equivalents:

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2022** | **2021** |
| | **(in thousands)** | |
| Net cash provided by (used in): | | |
| Operating activities | $ (49,905) | $ (27,704) |
| Investing activities | 64,386 | (139,480) |
| Financing activities | 573 | 121,579 |
| Net increase (decrease) in cash and cash equivalents | $ 15,054 | $ (45,605) |

*Operating Activities*

We have incurred losses since inception. Net cash used in operating activities for the nine months ended September 30, 2022 was $49.9 million, consisting primarily of net loss of $53.0 million resulting from expenses associated with research and development activities for our lead product candidate and general and administrative expenses. A net decrease in changes in operating assets and liabilities of $0.5 million also contributed to the use of cash. Partially offsetting the cash use was non-cash adjustments of $2.6 million.

Net cash used in operating activities for the nine months ended September 30, 2021 was $27.7 million, consisting primarily of net loss of $33.4 million, resulting from expenses associated with research and development activities for our lead product candidate and general and administrative expenses, partially offset by changes in operating assets and liabilities of $1.7 million and non-cash adjustments of $7.4 million.

*Investing Activities*

Net cash provided by investing activities for the nine months ended September 30, 2022 was $64.4 million, which related to $99.2 million of proceeds received from available for sale securities maturities, offset by purchases of available for sale securities of $34.8 million.

Net cash used in investing activities for the nine months ended September 30, 2021 was $139.5 million, which primarily related to purchases of available for sale securities of $136.9 million and payment of $2.5 million to Daiichi Sankyo for in-process research and development expense.

*Financing Activities*

Net cash provided by financing activities in the nine months ended September 30, 2022 was $0.6 million, which related to the net proceeds from option exercises.

Net cash provided by financing activities in the nine months ended September 30, 2021 was $121.6 million, which primarily related to the net proceeds from the IPO, after deducting underwriting discounts and commissions, and other offering fees.

**Obligations and other Commitments**

As discussed in Note 8 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we are party to agreements to license intellectual property. The license agreements may require us to pay future milestones if certain developmental, regulatory and commercial milestones are achieved, as well as to pay royalties on net sales of products applicable to the license agreements. We cannot estimate if milestone and/or royalty payments will occur in future periods and the agreements are cancelable by us at any time upon prior written notice to the licensor.

In the normal course of business, we enter into contracts with CROs and other vendors for preclinical studies and clinical trials, research and development supplies and other testing and manufacturing services. These contracts generally do not contain minimum purchase commitments and are cancelable by either party at any time upon prior written notice.

Our incurred and accrued research and development obligations as of September 30, 2022 and December 31, 2021 were $4.4 million and $4.3 million, respectively.

There were no material changes outside of the ordinary course of business to our specific contractual obligations during the three and nine months ended September 30, 2022.

**Critical Accounting Policies and Use of Estimates**

There have been no significant changes to our critical accounting policies and use of estimate from our disclosure reported in “Critical Accounting Estimates” in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Form 10-K for the year ended December 31, 2021, except as described in

Note 2 to the interim unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

***Accrued Liabilities***

We are required to estimate our expenses resulting from our obligations under contracts with vendors, consultants, CROs and clinical site agreements in connection with conducting preclinical activities and clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. 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. However, some payments are made in arrears and expenditures are accrued for the time periods which services are performed on a pre-determined schedule or when contractual milestones are met. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones.

This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred when we have not yet been invoiced or otherwise notified of actual costs. During the course of a preclinical study or clinical trial, we adjust our prepaid and expense recognition if actual results differ from our estimates. To date, we have not experienced any material differences between accrued costs and actual costs incurred. The accrued research and development balances were $4.4 million and $4.3 million as of September 30, 2022 and December 31, 2021, respectively. The other accrued liabilities balances were $4.4 million and $5.7 million as of September 30, 2022 and December 31, 2021, respectively.

***Stock-Based Compensation***

We follow the provision of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718, “Compensation – Stock Compensation” (ASC 718), which requires the measurement and recognition of compensation expense for all stock-based payment awards.

We estimate the fair value of our stock options using the Black-Scholes option pricing model, which requires us to develop estimates to be used in calculating the fair value of stock options. The use of the model requires us to make estimates of assumptions, such as expected stock price volatility and the estimated expected term of each award. The fair value of RSUs granted is based on the Company’s closing stock price on the date of grant.

Stock-based compensation expense based on the fair value estimated is recognized over the requisite service period of the awards (generally the vesting period) on a straight-line basis. Prior to the IPO, the estimated fair value of the underlying common stock as determined on the date of grant by our board of directors. For each of the three months ended September 30, 2022 and 2021, stock-based compensation expense was $0.9 million. The following table summarizes unvested equity compensation costs not yet recognized as of September 30, 2022 and December 31, 2021.

| | As of September 30, 2022 | As of December 31, 2021 |
|---|---|---|
| Unvested equity compensation costs not yet recognized (in millions) | $ 12.5 | $ 9.8 |
| Weighted average period over which the unvested awards are expected to be recognized (in years) | 2.8 | 3.1 |

**Recent Accounting Pronouncements**

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

**Item 4. Controls and Procedures.**

***Limitations on Effectiveness of Controls and Procedures***

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2022.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2022, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures.

## PART II—OTHER INFORMATION

**Item 1. Legal Proceedings.**

None.

**Item 1A. Risk Factors.**

Our business is subject to various risks, including those described in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021. Except as disclosed below, there have been no material changes from the risk factors disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021.

***Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.***

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (“IRA”), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rulemaking 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.

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

None.

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

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The exhibits file or furnished as part of this Quarterly Report on Form 10-Q are set forth below.

| Exhibit Number | Description of Exhibit |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Company (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K filed on April 27, 2021 (Commission File No. 001-40356)). |
| 3.2 | Amended and Restated Bylaws of the Company (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K filed on April 27, 2021 (Commission File No. 001-40356)). |
| 4.1 | Form of Common Stock Certificate of the Company (incorporated by reference from Exhibit 4.1 of the Company's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)). |
| 4.2 | Amended and Restated Investors' Rights Agreement, dated September 2, 2020, by and among the Company and certain of its stockholders (incorporated by reference from Exhibit 4.2 of the Company's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)). |
| 31.1* | Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934. |
| 31.2* | Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934. |
| 32.1 (1) | Certification of the principal executive officer and principal financial officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(b) under the Securities Exchange Act of 1934. |
| 101.INS* | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

* Filed herewith.

(1) The certifications on Exhibit 32 hereto are deemed not "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

**SIGNATURES**

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

**Rain Therapeutics Inc.**

Date: November 10, 2022

By: /s/ Avanish Vellanki
Avanish Vellanki
*Chairman and Chief Executive Officer*
*(principal executive officer)*

Date: November 10, 2022

By: /s/ Nelson Cabatuan
Nelson Cabatuan
*Senior Vice President of Finance and Operations*
*(principal financial and accounting officer)*

**Exhibit 31.1**

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

I, Avanish Vellanki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rain Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: /s/ Avanish Vellanki
Avanish Vellanki
Chairman and Chief Executive Officer
*(principal executive officer)*

**Exhibit 31.2**

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

I, Nelson Cabatuan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rain Therapeutics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2022

By: /s/ Nelson Cabatuan
Nelson Cabatuan
Senior Vice President of Finance and Operations
*(principal financial and accounting officer)*

**Exhibit 32.1**

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

In connection with the Quarterly Report on Form 10-Q of Rain Therapeutics Inc. (the "Company") for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §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 Section 15(d) of the Exchange Act, 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: November 10, 2022

By: /s/ Avanish Vellanki
Avanish Vellanki
Chairman and Chief Executive Officer
*(principal executive officer)*

Date: November 10, 2022

By: /s/ Nelson Cabatuan
Nelson Cabatuan
Senior Vice President of Finance and Operations
*(principal financial and accounting officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Rain Therapeutics Inc. and will be retained by Rain Therapeutics Inc. and furnished to the Securities and Exchange Commission or its staff upon request.