

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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 March 31, 2021

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: 333-254998

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

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**8000 Jarvis Avenue, Suite 204**  
**Newark, CA**  
(Address of principal executive offices)

**82-1130967**  
(I.R.S. Employer  
Identification No.)

**94560**  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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

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

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 May 20, 2021, the registrant had 26,482,660 shares of common stock, \$0.001 par value per share, outstanding, comprised of 18,755,190 shares of voting 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 Balance Sheets**  
(In thousands)

	March 31, 2021	December 31, 2020 <sup>(1)</sup>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 53,110	\$ 58,863
Prepaid and other current assets	702	662
<b>Total current assets</b>	<b>53,812</b>	<b>59,525</b>
Property and equipment, net	113	99
Operating lease right-of-use asset	473	447
Deferred offering costs	1,282	385
Other assets	817	624
<b>Total assets</b>	<b>\$ 56,497</b>	<b>\$ 61,080</b>
<b>Liabilities, convertible preferred stock, and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,389	\$ 816
Accrued research and development	2,103	1,527
Other accrued liabilities	1,831	935
Operating lease liability, current portion	115	141
<b>Total current liabilities</b>	<b>5,438</b>	<b>3,419</b>
Operating lease liability, net of current portion	345	312
Other long-term liabilities	69	69
<b>Total liabilities</b>	<b>5,852</b>	<b>3,800</b>
Commitments and contingencies		
Series A convertible preferred stock, \$0.001 par value; 3,731,208 shares authorized, issued and outstanding as of March 31, 2021 and December 31, 2020, \$19,638 liquidation preference at March 31, 2021 and December 31, 2020	20,147	20,147
Series B convertible preferred stock, \$0.001 par value; 12,542,198 shares authorized, issued and outstanding as of March 31, 2021 and December 31, 2020; \$74,877 liquidation preference at March 31, 2021 and December 31, 2020	74,550	74,550
<b>Total convertible preferred stock</b>	<b>94,697</b>	<b>94,697</b>
Stockholders' deficit:		
Common Stock, \$0.001 par value; 24,000,000 authorized as of March 31, 2021 and December 31, 2020; 3,530,975 shares issued and outstanding as of March 31, 2021 and December 31, 2020	4	4
Additional paid-in capital	1,314	1,149
Accumulated deficit	(45,370)	(38,570)
<b>Total stockholders' deficit</b>	<b>(44,052)</b>	<b>(37,417)</b>
<b>Total liabilities, convertible preferred stock, and stockholders' deficit</b>	<b>\$ 56,497</b>	<b>\$ 61,080</b>

(1) The balance sheet at December 31, 2020 has been derived from the audited financial statements included in Rain Therapeutics Inc.'s final prospectus for its initial public offering filed on April 23, 2021.

See accompanying notes to financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Operating expenses:		
Research and development	\$ 5,328	\$ 1,762
General and administrative	1,480	668
Total operating expenses	<u>6,808</u>	<u>2,430</u>
Loss from operations	(6,808)	(2,430)
Other income (expense):		
Interest income	8	20
Interest expense, related party	—	(31)
Change in fair value of convertible promissory notes, related party	—	(128)
Total other income (expense), net	<u>8</u>	<u>(139)</u>
Net loss and comprehensive loss	<u>\$ (6,800)</u>	<u>\$ (2,569)</u>
Net loss per share, basic and diluted	<u>\$ (1.93)</u>	<u>\$ (0.82)</u>
Weighted average shares of common stock outstanding, basic and diluted	<u>3,530,975</u>	<u>3,139,695</u>

See accompanying notes to financial statements.

**Rain Therapeutics Inc.**  
**Condensed Statements of Changes in Convertible Preferred Stock and Stockholders' 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	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2020</b>	<u>3,731,208</u>	<u>\$ 20,147</u>	<u>12,542,198</u>	<u>\$ 74,550</u>	<u>3,530,975</u>	<u>\$ 4</u>	<u>\$ 1,149</u>	<u>\$ (38,570)</u>	<u>\$ (37,417)</u>
Stock-based compensation expense	—	\$ —	—	\$ —	—	\$ —	\$ 165	\$ —	\$ 165
Net loss	—	—	—	—	—	—	—	(6,800)	(6,800)
<b>Balance as of March 31, 2021</b>	<u>3,731,208</u>	<u>\$ 20,147</u>	<u>12,542,198</u>	<u>\$ 74,550</u>	<u>3,530,975</u>	<u>\$ 4</u>	<u>\$ 1,314</u>	<u>\$ (45,370)</u>	<u>\$ (44,052)</u>

  

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2019</b>	<u>3,731,208</u>	<u>\$ 20,147</u>	<u>—</u>	<u>\$ —</u>	<u>2,986,385</u>	<u>\$ 3</u>	<u>\$ 236</u>	<u>\$ (17,487)</u>	<u>\$ (17,248)</u>
Vesting of restricted shares	—	\$ —	—	\$ —	289,377	\$ —	\$ —	\$ —	\$ —
Stock-based compensation expense	—	—	—	—	—	—	199	—	199
Net loss	—	—	—	—	—	—	—	(2,569)	(2,569)
<b>Balance as of March 31, 2020</b>	<u>3,731,208</u>	<u>\$ 20,147</u>	<u>—</u>	<u>\$ —</u>	<u>3,275,762</u>	<u>\$ 3</u>	<u>\$ 435</u>	<u>\$ (20,056)</u>	<u>\$ (19,618)</u>

See accompanying notes to financial statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating activities</b>		
Net loss	\$ (6,800)	\$ (2,569)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization expense	15	15
Stock-based compensation expense	165	199
Non-cash interest expense, related party	—	31
Change in fair value of convertible promissory notes, related party	—	128
Changes in operating assets and liabilities:		
Prepaid and other current assets	(40)	60
Operating lease right-of-use asset and liability, net	(19)	8
Other assets	(193)	—
Accounts payable	573	75
Accrued research and development	576	(66)
Other accrued liabilities	857	(375)
Other long-term liabilities	—	4
Net cash used in operating activities	<u>(4,866)</u>	<u>(2,490)</u>
<b>Investing activities</b>		
Purchases of property and equipment	(29)	—
Net cash used in investing activities	<u>(29)</u>	<u>—</u>
<b>Financing Activities</b>		
Payments for deferred offering costs	(858)	—
Net cash used in financing activities	<u>(858)</u>	<u>—</u>
Net decrease in cash and cash equivalents	(5,753)	(2,490)
Cash and cash equivalents at beginning of period	58,863	5,794
Cash and cash equivalents at end of period	<u>\$ 53,110</u>	<u>\$ 3,304</u>

See accompanying notes to financial statements.

**Rain Therapeutics Inc.**  
**Notes to Condensed 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 clinical-stage precision oncology company developing therapies that target oncogenic drivers for which the Company is able to genetically select patients it believes will most likely benefit. Rain’s lead product candidate, RAIN-32, is a small molecule, oral inhibitor of MDM2, which may be oncogenic in numerous cancers. In addition to RAIN-32, 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.

***Reverse Stock Split***

On April 15, 2021 and April 16, 2021, the Company’s board of directors (the “Board of Directors”) and stockholders, respectively, approved an amended and restated certificate of incorporation of the Company to effect a 1-for-1.0799 reverse stock split of the Company’s common stock. The reverse stock split was effected on April 16, 2021. The Company’s outstanding stock options were also adjusted to reflect the 1-for-1.0799 reverse stock split of the Company’s common stock. Accordingly, all common stock and stock options and related per share amounts in these financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series A and Series B convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

***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 \$121.9 million after estimated offering costs. In connection with the IPO, the Board of Directors and stockholders approved an amended and restated certificate of incorporation, which authorized 260,000,000 shares of common stock, 200,000,000 shares of which are designated as “Voting Common Stock” and 50,000,000 shares of which are designated as “Non-Voting Common Stock” and 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company’s Board of Directors in one or more series.

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 voting common stock. Following the IPO, there were no shares of convertible preferred stock outstanding.

***Basis of Presentation***

The accompanying interim unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”) and with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”) related to a quarterly report on Form 10-Q. The year-end condensed balance sheet data was derived from the Company’s audited financial statements but does not include all disclosures required by U.S. GAAP. These condensed financial statements should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2020 included in the Company’s final prospectus for its IPO, filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the SEC on April 23, 2021 (the “Prospectus”). 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 never generated any revenue, 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 March 31, 2021, the Company has funded its operations through the issuance of convertible promissory notes and convertible preferred stock.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Substantial doubt about the Company's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. Management has prepared cash flow forecasts which indicate that based on the Company's expected operating losses, there is not substantial doubt about the Company's ability to continue as a going concern for twelve months after the date the financial statements for the three months ended March 31, 2021 are issued.

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

### ***Use of Estimates***

The preparation of the Company's financial statements in conformity with U.S. 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 financial statements and accompanying notes. The most significant estimate in the Company's 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 primarily represent funds invested in readily available checking and money market accounts.

### ***Deferred Offering Costs***

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's IPO. The deferred offering costs will be offset against the IPO proceeds upon the consummation of an offering. The Company had \$1.3 million and \$385,000 deferred offering costs as of March 31, 2021 and December 31, 2020, respectively.

### ***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 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 cost of 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 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.

### **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 was the same as its reported net loss for the periods presented.

### **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, unvested common stock and outstanding stock options 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 period 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 Accounting Pronouncements**

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 is currently evaluating the impact the standard may have on its financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which simplifies the accounting for income taxes. ASU 2019-12 is effective for the Company for the fiscal year beginning after December 15, 2021 and early adoption is permitted. The Company is currently evaluating the impact the adoption of ASU 2019-12 will have on the Company's financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*, which addresses the complexity associated with applying generally accepted accounting principles for certain financial instruments with characteristics of liabilities and equity. The guidance is effective for the Company beginning on January 1, 2024, with early adoption permitted. The Company elected to adopt this standard on January 1, 2020 under the modified retrospective transition method with no material impact on its financial statements and disclosures.

**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 Company's 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 periods ended March 31, 2021 and December 31, 2020.

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 March 31, 2021:				
Cash and cash equivalents	\$ 13,496	\$ —	\$ —	\$ 13,496
As of December 31, 2020:				
Cash and cash equivalents	\$ 19,257	\$ —	\$ —	\$ 19,257

As further described in Note 5, the Company issued convertible promissory notes in October 2019 (the "2019 Notes") and in June 2020 (the "2020 Notes") to investors. The Company elected the fair value option for the convertible promissory notes. The fair value of the convertible promissory notes was determined using a scenario-based analysis that estimated the fair value of the convertible promissory notes based on the probability-weighted present value of expected future investment returns, considering possible outcomes available to the noteholders, including conversions in subsequent equity financings. The 2019 Notes and 2020 Notes were valued upon issuance, remeasured to fair value each reporting period and remeasured immediately prior to conversion into Series B convertible preferred stock based on changes in the expected time to closing ranging from 0 to 0.67 years and the relevant discount rate of 25% during the period. In September 2020, the 2019 Notes and 2020 Notes were converted to 1,905,688 shares of Series B convertible preferred stock.

There were no liabilities measured at fair value on a recurring basis as of March 31, 2021 and December 31, 2020.

The following table provides a reconciliation of all liabilities measured at fair value using Level 3 significant unobservable inputs (in thousands):

	Convertible Promissory Notes
Fair value as of December 31, 2019	\$ 2,751
Change in fair value of convertible promissory notes (Note 5)	128
Fair value as of March 31, 2020	\$ 2,879

#### **Note 4 – Related Party Transactions**

As further described in Note 5, the Company issued the 2019 Notes in October 2019 to certain holders of convertible preferred stock, for an aggregate purchase price of \$2.5 million and the 2020 Notes in June 2020 to certain holders of convertible preferred stock, for an aggregate purchase price of \$6.4 million. In September 2020, all outstanding convertible promissory notes with a total fair value of \$11.2 million and accrued interest of \$167,000 were converted to 1,905,688 shares of Series B convertible preferred stock. The change in fair value of the convertible promissory notes for the three months ended March 31, 2020 was \$128,000.

#### **Note 5 – Convertible Promissory Notes**

In October 2019, the Company entered into a convertible note purchase agreement with certain holders of preferred stock and issued convertible promissory notes (the “2019 Notes”) for an aggregate purchase price of \$2.5 million. The 2019 Notes bore an interest rate of the lesser of (a) 5% per annum and (b) the maximum rate permissible by law. The 2019 Notes were due and payable on demand from the holders on or after 18 months after the date of issuance (“2019 Notes Maturity Date”), unless repaid in full or automatically converted per the Automatic Conversion feature. Under the Automatic Conversion feature, the 2019 Notes were to automatically convert to convertible preferred stock, upon the closing of the Company’s next issuance of preferred stock for capital-raising purposes resulting in net proceeds to the Company of at least \$10.0 million (excluding any amounts received in connection with the conversion of the 2019 Notes) (“Future Qualifying Financing”). The 2019 Notes would convert into that whole number of shares of the securities equal to the number obtained by dividing the principal plus accrued interest of the 2019 Notes by 80% of the price per share paid by cash investors in the Future Qualifying Financing. The convertible notes included other optional redemption features as follows (i) optionally converted upon a non-qualified equity financing with a conversion price of 80% of the price paid per share in such financing, (ii) any time after the 2019 Notes Maturity Date, demand immediate repayment of an amount equal to the then-outstanding loan balance, or convert the outstanding loan balance into shares of common stock of the Company in an amount equal to the ratio of the then-outstanding loan balance over the ratio of \$38.4 million divided by the number of shares of capital stock of the Company outstanding, (iii) automatically upon the occurrence of change in control or an IPO with a conversion of the loan balance into shares of common stock in an amount equal to the ratio of the then-outstanding loan balance over the ratio of \$76.8 million divided by the fully diluted capitalization prior to the change in control or IPO, or demand immediate repayment of two times the outstanding loan balance, and (iv) upon certain events of default, immediately due and payable in full.

In June 2020, the Company entered into a convertible note purchase agreement with certain holders of preferred stock and issued convertible promissory notes (the “2020 Notes”) for an aggregate purchase price of \$6.4 million. The 2020 Notes bore an interest rate of the lesser of (a) 5% per annum and (b) the maximum rate permissible by law. The 2020 Notes were due and payable on demand from the holders on or after 18 months after the date of issuance (“2020 Notes Maturity Date”), unless repaid in full or automatically converted per the Automatic Conversion feature. Under the Automatic Conversion feature, the 2020 Notes were to automatically convert to convertible preferred stock, upon the closing of the Company’s next issuance of preferred stock for capital-raising purposes resulting in net proceeds to the Company of at least \$10.0 million (excluding any amounts received in connection with the conversion of the 2020 Notes) (“Qualifying Financing”). The 2020 Notes would convert into that whole number of shares of the securities equal to the number obtained by dividing the principal plus accrued interest of the 2020 Notes by 80% of the price per share paid by cash investors in the Qualifying Financing. The convertible notes included other optional redemption features as follows (i) optionally converted upon a non-qualified equity financing with a conversion price of 80% of the price paid per share in such financing, (ii) any time after the 2020 Notes Maturity Date, demand immediate repayment of an amount equal to the then-outstanding loan balance, or convert the outstanding loan balance into shares of common stock of the Company in an amount equal to the ratio of the then-outstanding loan balance over the ratio of \$38.4 million divided by the number of shares of capital stock of the Company outstanding, (iii) automatically upon the occurrence of change in control or an IPO with a conversion of the loan balance into shares of common stock in an amount equal to the ratio of the then-outstanding loan balance over the ratio of \$76.8 million divided by the fully diluted capitalization prior to the change in control or IPO, or demand immediate repayment of two times the outstanding loan balance, (iv) automatically upon the consummation of a transaction in which the Company merges with a public company and (v) upon certain events of default, immediately due and payable in full.

For the three months ended March 31, 2020, the Company recognized interest expense of \$31,000, in connection with the 2019 Notes. In September 2020, all outstanding convertible promissory notes with a total fair value of \$11.2 million and accrued interest of \$167,000 were converted to 1,905,688 shares of Series B convertible preferred stock.

## **Note 6 – Convertible Preferred Stock and Stockholders' Deficit**

### ***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.

### ***Dividends***

Each holder of the Company's Series A and Series B convertible preferred stock is entitled to receive non-cumulative dividends, when and if declared by the Company's 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 shall be 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 is 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 are 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 are not explicitly redeemable at the option of the holder at a specified date in the future or at the option of the Company.

The Company's Series A and Series B convertible preferred stock have been classified as temporary equity on the accompanying balance sheet instead of in stockholders' deficit in accordance with authoritative guidance for the classification and measurement of redeemable securities. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock can cause its redemption. The Company has 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 events would occur.

### Common Stock, Stock Options and Liability for Restricted Stock

In 2017, the Company entered into restricted stock purchase agreements with various employees for 3,518,842 shares of common stock, which are subject to time-based vesting. The Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary separation of an employee from the Company. The shares purchased pursuant to the restricted stock purchase agreements are not deemed, for accounting purposes, to be outstanding until those shares vest. The cash received in exchange for unvested shares of the restricted stock granted is recorded as a liability on the accompanying condensed balance sheet and will be transferred into common stock and additional paid-in capital as the restricted stock vests.

In 2020, the Company amended its articles of incorporation and authorized the issuance of 24,000,000 shares of common stock.

The Company issued 532,455 shares in 2020 in connection with the vesting of the restricted stock. As of December 31, 2020, no shares remained subject to repurchase by the Company.

In August 2020, the Company's Board of Directors amended the Amended and Restated 2018 Stock Option—Stock Issuance Plan (the "Plan") to increase the maximum number of shares of common stock that may be issued over the term of the plan ("Share Reserve"). The Plan provides for the grant of stock options, non-statutory stock options, incentive stock options and stock issuances to employees, nonemployees and consultants of the Company. As of March 31, 2021, the Share Reserve was 1,465,156.

A summary of the Company's stock option activities under the Plan in the three months ending March 31, 2021 are as follows (in thousands, except share and per share amounts and years):

	Total Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	882,942	\$ 3.72	9.0	\$ 1,263
Granted	196,312	\$ 5.15		
Exercised	—			
Forfeited or cancelled	(14,854)	\$ 3.99		
Outstanding as of March 31, 2021	1,064,400	\$ 3.73	8.7	\$ 10,538
Vested and expected to vest as of March 31, 2021	1,064,400	\$ 3.73	8.7	\$ 10,538
Vested and exercisable as of March 31, 2021	413,052	\$ 3.54	8.2	\$ 4,168

The weighted-average grant date fair values of employee option grants during the three months ended March 31, 2021 and 2020 were \$4.09 and \$2.18 per share, respectively. The weighted-average grant date fair values of employee options forfeited during the three months ended March 31, 2021 was \$3.07 per share. There were no employee options forfeited during the three months ended March 31, 2020.

### Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 134	\$ 128
General and administrative	31	71
	\$ 165	\$ 199

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:

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Risk-free interest rate	0.80%	0.91% – 0.94%
Expected volatility	118.7%	96.9% – 98.0%
Expected term (in years)	6.0	5.3 – 5.6
Expected dividend yield	0%	0%

*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 options.

*Expected volatility.* Due to the Company's limited operating history and lack of company-specific historical or implied volatility as a private company, 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 of stock options represents the weighted-average period the stock options 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 options.

*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.

As of March 31, 2021, the unrecognized compensation cost related to outstanding options was \$2.1 million and is expected to be recognized as expense over approximately 3.75 years.

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

Common stock reserved for future issuance consist of the following:

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
Convertible preferred stock	15,069,330	15,069,330
Stock options issued and outstanding	1,064,400	882,942
Authorized for future stock awards or option grants	385,891	582,203
Total	<u>16,519,621</u>	<u>16,534,475</u>

#### **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.

### ***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.

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 made payments of \$19,000 under the Drexel License Agreement for the three months ended March 31, 2021. No similar payment was made for the three months ended March 31, 2020.

### ***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 RAIN-32.

Under the Daiichi Sankyo License Agreement, the Company obtained worldwide, sublicensable exclusive rights to seven families of patents with respect to milademetan. While the Company is solely responsible under the Daiichi Sankyo License Agreement for the research, development and registration of milademetan, Daiichi Sankyo has the right to continue to conduct three ongoing clinical trials and prepare final reports with respect to these clinical trials. The Company has agreed to reimburse Daiichi Sankyo certain third-party expenses incurred while conducting such trials.

The Company is obligated to use commercially reasonable efforts to develop, commercialize and manufacture

milademetan and to commercially launch milademetan as soon as reasonably practicable after receiving the requisite approvals from the authorities in any given country. The Company is also obligated to use commercially reasonable efforts to receive at least three full approvals for use in each of the following countries: France, Germany, Italy, Spain, the United Kingdom, the United States and one country outside of the United States and the European Union. 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. The Company is required to make aggregate future milestone payments of up to an aggregate of \$225.0 million on the attainment of certain development and sales milestones. None of the milestones have been achieved. Additionally, the Company is required to pay Daiichi Sankyo a high single digit royalty based on the annual net sales of milademetan, to be reduced to an agreed rate upon expiration of the licensed patent in the particular country wherein sales are made. 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).

The Company made no payments under the Daiichi Sankyo License Agreement for the three months ended March 31, 2021 and 2020.

## 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 3% 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 (“Shelter in Place Order”) 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.

The future minimum lease payments required under the operating lease as of March 31, 2021, are summarized as follows (in thousands):

2021 - remainder	\$	108
2022		167
2023		171
2024		129
Total minimum lease payments	\$	<u>575</u>
Less: amount representing interest	\$	(115)
Present value of operating lease liabilities		460
Less: operating lease liabilities, current		(115)
Operating lease liabilities, non-current	\$	<u>345</u>
Weighted-average remaining lease term (in years)		3.50
Weighted-average incremental borrowing rate		10.00%

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

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Total operating lease expense	\$ 34	\$ 47
Operating cash flows used for operating lease	40	39

### **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 – 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):

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Numerator:</b>		
Net loss	\$ (6,800)	\$ (2,569)
<b>Denominator:</b>		
Weighted-average shares of common stock outstanding, basic and diluted	3,530,975	3,518,842
Less: weighted-average unvested common stock	—	(379,147)
Weighted-average shares used to compute net loss per share, basic and diluted	<u>3,530,975</u>	<u>3,139,695</u>
Net loss per share, basic and diluted	<u>\$ (1.93)</u>	<u>\$ (0.82)</u>

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:

	<b>March 31,</b>	<b>March 31,</b>
	<b>2021</b>	<b>2020</b>
Series A convertible preferred stock	3,731,208	3,731,208
Series B convertible preferred stock	12,542,198	—
Common stock options	1,064,400	503,744
Total	<u>17,337,806</u>	<u>4,234,952</u>

### **Note 10 – Subsequent Events**

#### **Stock Options**

The Company's 2021 Equity Incentive Plan (the "2021 Plan") was approved by the Company's Board of Directors and became effective on April 15, 2021. 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 Stock Option—Stock Issuance Plan (the "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 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 Company's Board of Directors.

**2021 Employee Share Purchase Plan**

The 2021 Employee Share 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. 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.

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

*This Quarterly Report on Form 10-Q includes forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are subject to the "safe harbor" created by those sections, that involve a number of risks, uncertainties and assumptions. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Quarterly Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Quarterly Report was filed with the Securities and Exchange Commission (SEC). These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, the risk factors identified in our SEC reports, including this Quarterly Report. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements.*

### Overview

We are a clinical-stage precision oncology company developing therapies that target oncogenic drivers for which we are able to genetically select patients we believe will most likely 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, RAIN-32 (milademetan), is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. We in-licensed RAIN-32 in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors. Data from well-differentiated/de-differentiated (WD/DD) liposarcoma (LPS) patients in the Phase 1 clinical trial of RAIN-32 demonstrated median progression-free survival (mPFS) approximately three to four times greater than trabectedin or eribulin, the current standard of care (SOC). 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 RAIN-32 in a broad range of MDM2-dependent cancers. Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021, a Phase 2 tumor-agnostic basket trial in certain solid tumors in the second half of 2021 and a Phase 2 trial in intimal sarcoma by early 2022. In addition to RAIN-32, 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 March 31, 2021, we had an accumulated deficit of \$45.4 million and we incurred net losses of approximately \$6.8 million and \$2.6 million for the three months ended March 31, 2021 and 2020, 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 March 31, 2021, 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. As of March 31, 2021, we had cash and cash equivalents of \$53.1 million. 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 \$121.9 million, net of estimated offering fees and expenses. Although we believe, based on our current business plans, that our existing cash and cash equivalents 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 and cash equivalents as of March 31, 2021, together with the actual net proceeds from the IPO in April 2021, including the additional shares sold pursuant to the overallotment, will be sufficient to fund our pivotal Phase 3 trial in LPS, Phase 2 tumor-agnostic basket trial in certain solid tumors and Phase 2 trial in intimal sarcoma including continuing to advance our pipeline through additional preclinical studies and clinical trials.

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 RAIN-32 program, we will select and transfer Daiichi Sankyo Company, Limited (Daiichi Sankyo) processes to suitable 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. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and most of our employees working remotely. We will continue to monitor the rapidly 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, or that we determine are in the best interests of our employees and other third parties with whom we do 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.

### **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.

## Overview of RAIN-32

Our lead product candidate, RAIN-32, 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, pharmacokinetics and drug accumulation 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. Residual drug concentration, due to poor drug clearance or tissue accumulation during the dosing break may otherwise prevent recovery from thrombocytopenia. RAIN-32's differentiated profile, as a potent MDM2 inhibitor with rapid plasma clearance and lack of drug accumulation in tissues, 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 RAIN-32 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 RAIN-32 demonstrated mPFS approximately three to four times greater than trabectedin or eribulin, the current SOC. 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. We plan to commence a pivotal Phase 3 trial for RAIN-32 in WD/DD LPS in the second half of 2021. 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. We also plan to evaluate RAIN-32 in other MDM2-dependent cancers in an open-label Phase 2 tumor-agnostic basket trial for RAIN-32 for which there will be pre-specified MDM2 amplification levels and WT p53. This Phase 2 basket trial is expected to commence in the second half of 2021. We also intend to commence a Phase 2 trial in patients with intimal sarcoma by early 2022.

## Overview of RAD52

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. Lead candidate selection is expected in 2022.

## 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 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:

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(in thousands)</b>	
RAIN-32	\$ 2,404	\$ —
Other clinical candidate	1,078	1,762
Unallocated internal research and development costs	1,846	—
Total research and development expenses	<u>\$ 5,328</u>	<u>\$ 1,762</u>

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 determine with certainty the timing of initiation, the duration or the completion 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."

### **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**

Interest income consists of interest on our money market account.

### **Interest Expense**

Interest expense as of March 31, 2020 consisted of interest on then outstanding convertible promissory notes.

## **Results of Operations**

### **Comparison of Three Months Ended March 31, 2021 and 2020**

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020, together with the changes in those items in dollars:

	<b>Three Months Ended March 31,</b>		<b>Increase</b>
	<b>2021</b>	<b>2020</b>	<b>(Decrease)</b>
	<b>(in thousands)</b>		
Operating expenses:			
Research and development	\$ 5,328	\$ 1,762	\$ 3,566
General and administrative	1,480	668	812
Total operating expenses	6,808	2,430	4,378
Other income (expense):			
Interest income	8	20	(12)
Interest expense, related party	—	(31)	31
Change in fair value of convertible promissory notes, related party	—	(128)	128
Total other expense	8	(139)	147
Net loss	\$ 6,800	\$ 2,569	\$ 4,231

### **Research and Development Expenses**

Research and development (R&D) expenses were \$5.3 million and \$1.8 million for the three months ended March 31, 2021 and 2020, respectively. The increase in R&D expenses was primarily due to increases in R&D costs for our lead product candidate, RAIN-32, as well as personnel costs. Non-cash stock-based compensation expenses included in R&D expenses was approximately \$0.1 million in each of the first quarters of 2021 and 2020. We expect our R&D costs to continue to increase in 2021 as we initiate our proposed Phase 3 trial in LPS, as well as our Phase 2 tumor-agnostic basket trial for RAIN-32.

### **General and Administrative Expenses**

General and administrative (G&A) expenses were \$1.5 million and \$668,000 for the three months ended March 31, 2021 and 2020, respectively. The increase in G&A expenses was primarily due to increases in various third-party G&A costs as well as personnel costs. Non-cash stock-based compensation expense included in G&A expenses was approximately \$0.1 million in each of the first quarters of 2021 and 2020. We expect our general and administrative expenses to increase in 2021 as we continue to add personnel and build out systems and infrastructure to support our operations as a public company.

### **Other (Income) Expenses**

Other income was \$8,000 for the three months ended March 31, 2021 and other expenses was \$139,000 for the three months ended March 31, 2020. The decrease in other (income) expenses was primarily due to decreases in the fair value of our convertible promissory notes, interest expense on the convertible promissory notes, and interest income from our money market account.

### **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 never generated any revenue from product sales. To date, we have financed our operations through the issuance of convertible promissory notes and the issuance of convertible preferred stock. From our inception through March 31, 2021, 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. As of March 31, 2021, we had cash and cash equivalents of \$53.1 million. 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 \$121.9 million, net of estimated offering fees and expenses. Although we believe, based on our current business plans, that our existing cash and cash equivalents 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 RAIN-32 and other product candidates and programs, which are still in the early stages of development. In addition, following the IPO, 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:

- initiate clinical trials for our RAIN-32 program and incur additional preclinical research costs for our RAD52 program;
- initiate and continue research and preclinical and clinical development of our other 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, any future commercialization efforts and our transition to a public company;
- 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
- operate as a public company.

Because of the numerous risks and uncertainties associated with the development of RAIN-32 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 RAIN-32 for our current targeted indications;
- the scope, progress, results and costs of drug discovery, preclinical research and clinical trials for RAD52 and our 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, 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 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 for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in:		
Operating activities	\$ (4,866)	\$ (2,490)
Investing activities	(29)	—
Financing activities	(858)	—
Net decrease in cash and cash equivalents	\$ (5,753)	\$ (2,490)

### ***Operating Activities***

We have incurred losses since inception. Net cash used in operating activities for the three months ended March 31, 2021 was \$4.9 million, consisting primarily of net loss of \$6.8 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 \$1.8 million and non-cash adjustments of \$180,000.

Net cash used in operating activities for the three months ended March 31, 2020 was \$2.5 million, consisting primarily of net loss of \$2.6 million resulting from expenses associated with research and development activities for our product candidates and general and administrative expenses partially offset by non-cash adjustments of \$373,000 net of decrease in operating assets and liabilities of \$294,000.

### ***Investing Activities***

Net cash used in investing activities for the three months ended March 31, 2021 was \$29,000 mainly related to purchases of property and equipment. We did not have investing activities for the three months ended March 31, 2020.

### ***Financing Activities***

Net cash used in financing activities in the three months ended March 31, 2021 of \$858,000 primarily relates payments for deferred offering costs. We did not have financing activities for the three months ended March 31, 2020.

### ***Contractual Obligations and other Commitments***

During the period ended March 31, 2021, there were no material changes to our principal contractual obligations and commitments as reported in our final prospectus for IPO, filed pursuant to Rule 424(b) under the Securities Exchange Act of 1933, as amended, with the SEC on April 23, 2021 (the Prospectus).

### ***Critical Accounting Policies and Use of Estimates***

There have been no significant changes to our critical accounting policies from our disclosure reported in "Critical Accounting Policies and Estimates" in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Prospectus, except as described in Note 2 to the interim unaudited condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### ***Emerging Growth Company Status***

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards; and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest to occur of: (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, or December 31, 2026, (b) in which we have total annual gross revenues of \$1.07 billion or more, or (c) in which we are deemed to be a large accelerated filer under the rules of the SEC, which means the market value of our outstanding common stock held by non-affiliates exceeds \$700 million as of last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years.

### ***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 financial statements included elsewhere in this Quarterly Report on Form 10-Q.

### ***Off-Balance Sheet Arrangements***

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **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 Chief Executive Officer and Chief Accounting 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 that evaluation, our Chief Executive Officer and Chief Accounting Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2021.

#### ***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 March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

None.

### Item 1A. Risk Factors.

*Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed financial statements and related notes. We believe the risks described below are the risks that are material to us as of the date of this Quarterly Report on Form 10-Q. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.*

#### Risk Factor Summary

Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- We have a limited operating history, have not initiated, conducted or completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from our product candidates and may never generate revenue or become profitable.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of development programs or future commercialization efforts.
- Our future growth depends on our ability to identify and acquire or in-license products.
- We are substantially dependent on the success of our lead product candidate, RAIN-32, and our anticipated clinical trials of RAIN-32 may not be successful.
- We may find it difficult to enroll patients in our clinical trials given the relatively small patient populations with the indications for which our product candidates are being developed.
- The results of our preclinical testing and early clinical trials may not be predictive of the success of our later clinical trials, and the results of any of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.
- We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable.
- We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials.

- We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved.
- We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.
- Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.
- We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.
- We license patent rights from third-party owners and we rely on such owners to obtain, maintain and enforce the patents underlying such licenses.

#### **Risks Related to Our Limited Operating History, Business, Financial Condition, Results of Operations and Need for Additional Capital**

***We have a limited operating history, have not initiated, conducted or completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.***

We are a clinical-stage company with limited operating history. 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. We have no significant experience as a company in initiating, conducting or completing clinical trials, including global late-stage clinical trials. In particular, Daiichi Sankyo conducted the Phase 1 trial for our lead product candidate, RAIN-32, prior to our in-license of RAIN-32 in September 2020. In part because of this lack of experience, we cannot be certain that our planned clinical trials will begin or be completed on time, if at all. In addition, we have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Further, we may encounter unexpected expenses, challenges and complications from known and unknown factors such as the COVID-19 pandemic.

***We have incurred significant losses since inception, and we expect to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future. We have not generated any revenue from our product candidates and may never generate revenue or become profitable.***

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risks that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale, we have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We do not expect to generate product revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we are unable to generate sufficient revenue through the sale of our current product candidates or any future product candidates, we may be unable to continue operations without additional funding.

We have incurred significant net losses in each period since we commenced operations in April 2017. Our net losses were \$6.8 million and \$2.6 million for the three months ended March 31, 2021 and 2020, respectively. We expect to continue to incur significant losses for the foreseeable future. Our failure to become profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business and/or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of development programs or future commercialization efforts.***

Developing biopharmaceutical products is a very long, time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, RAIN-32, and advance our other product candidates and future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities to launch any such product. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Our future capital requirements depend on many factors, including factors that are not within our control. We will also incur additional costs associated with operating as a public company. Accordingly, we will require substantial additional funding to continue our operations. Based on our current operating plan, we believe that the net proceeds from the IPO, together with our existing cash, cash equivalents and short-term marketable securities, will be sufficient to fund our operations for at least the next twelve months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

We do not have any committed external sources of funds and adequate additional financing may not be available to us on acceptable terms, or at all. We may be required to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or the failure to obtain such financing may restrict our operating activities. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to future collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. 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. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

***Our future growth depends on our ability to identify and acquire or in-license products.***

We have in-licensed the rights to all of our current product candidates from third parties who conducted the initial development of each product candidate. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks. In addition, we may compete with competitors in pursuing these in-licensing opportunities and such competitors may have access to greater financial resources than us and may have greater experience in identifying and evaluating new opportunities.

***If we breach any of the agreements under which we license rights to our product candidates from others, we could lose the ability to develop and commercialize our product candidates.***

In September 2020, we entered into a worldwide, exclusive license agreement with Daiichi Sankyo relating to RAIN-32 for all human prophylactic or therapeutic uses and in July 2020 we entered into a license agreement with Drexel University relating to our RAD52 research program. Because we have in-licensed the rights to all of our product candidates from third parties, if there is any dispute between us and our licensors regarding our rights under these license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under these license agreements could result in our loss of exclusive rights to the related product candidate and may lead to a complete termination of our product development efforts for such product candidate.

***Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or the pursuit of treatments for certain indications. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We are developing therapies for patients with genetically defined cancers with unmet needs. We apply a tumor-agnostic development approach to the essential biological pathways and molecular machinery of cancer. Our lead product candidate, RAIN-32 (milademetan), is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or indications may not lead to the development of any viable commercial product and may divert resources away from better opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. For example, even if RAIN-32 receives marketing approval, it may not achieve commercial success, including as a result of the gravity of the patients' illnesses in our target market. The primary endpoint for the pivotal Phase 3 trial for RAIN-32 that we plan to commence in WD/DD LPS is progression-free survival (PFS) evaluated by Response Evaluation Criteria in Solid Tumors. Even if the primary endpoint of such trial is met and RAIN-32 demonstrates meaningful increases in PFS, there is no guarantee that such increases in PFS will lead to the market acceptance or commercial success of RAIN-32, if approved. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. We may make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in our industry.

### **Risks Related to Product Development**

***We are substantially dependent on the success of our lead product candidate, RAIN-32, and our anticipated clinical trials of RAIN-32 may not be successful.***

Our future success is substantially dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, RAIN-32, our lead product candidate. We are investing a majority of our efforts and financial resources into the research and development of RAIN-32. Our other product candidates are in earlier stages of development. We plan to commence a pivotal Phase 3 trial for RAIN-32 in WD/DD LPS in the second half of 2021. We also plan to commence an open-label Phase 2 MDM2-amplified tumor-agnostic basket trial for RAIN-32 across solid tumors in patients with pre-specified MDM2 amplification levels and WT p53 in the second half of 2021. We also intend to commence a Phase 2 trial in patients with intimal sarcoma by early 2022.

RAIN-32 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote RAIN-32, or any other product candidates, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of RAIN-32 will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of RAIN-32, even if approved. If we are not successful in commercializing RAIN-32, or are significantly delayed in doing so, our business will be materially harmed.

***We may find it difficult to enroll patients in our clinical trials given the relatively small patient populations with the indications for which our product candidates are being developed. If we experience delays or difficulties in the enrollment of patients in clinical trials, including failure to develop or use existing companion diagnostic tests, our successful completion of clinical trials or receipt of marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials. Because our product candidates are focused on indications with relatively small patient populations, our ability to enroll eligible patients in our clinical trials may be limited

or may result in slower enrollment than we anticipate. Moreover, because specific genetic mutations will be used to identify the appropriate patients for our programs and our current or future product candidates, successful enrollment of eligible patients to these trials may depend, in part, on our ability to use existing companion diagnostic tests and genetic sequencing, or to develop novel companion diagnostics in collaboration with partners. Patient enrollment may be affected by various factors, including if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients instead enroll in such other clinical trials. Our inability to enroll a sufficient number of patients or a delay in enrolling such patients, could result in significant delays in completing clinical trials, increased development costs, or a delay or inability to receive marketing approvals and may require us to abandon one or more clinical trials altogether.

***The results of our preclinical testing and early clinical trials may not be predictive of the success of our later clinical trials, and the results of any of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.***

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Demonstrations of efficacy or an acceptable safety profile in our prior preclinical studies does not mean that future clinical trials will yield the same results. For instance, we do not know whether RAIN-32 will perform in future clinical trials as RAIN-32 has performed in preclinical studies and early clinical trials conducted by Daiichi Sankyo, and, despite decades of research on p53 as a target for precision medicines, prior product development efforts have been unsuccessful. Product candidates, including RAIN-32, may fail to demonstrate in later-stage clinical trials sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety or efficacy results in preclinical studies or earlier-stage trials, which could prevent us from conducting the clinical trials we currently anticipate. For example, we plan to commence an open-label Phase 2 basket trial evaluating RAIN-32 across solid tumors in patients with pre-specified MDM2 amplification levels and WT p53 based on the efficacy results observed from ten non-LPS patients who enrolled in Daiichi Sankyo's Phase 1 trial of RAIN-32, one of which died four months into therapy due to the emergence of a pulmonary embolism. There is no guarantee that the FDA will consider the data we have obtained in non-LPS patients sufficient to allow us to initiate the planned Phase 2 basket trial within the timelines we anticipate, or at all. Even if we are able to initiate our planned clinical trials on schedule, there is no guarantee that we will be able to complete such trials on the timelines we anticipate, that such trials will produce positive results, or that positive results will result in the commercial sale of any product candidate. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population to which we may market our product candidates, if approved.

***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.***

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and a failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. In particular, we plan to initiate a pivotal Phase 3 trial for RAIN-32 in WD/DD LPS patients in the second half of 2021. We anticipate that this trial will compare RAIN-32 to trabectedin, an SOC therapeutic. Although data from WD/DD LPS patients in our Phase 1 clinical trial demonstrated median PFS approximately three to four times greater than the current SOC, the efficacy of the SOC in prior preclinical studies does not mean that future clinical trials will yield the same results. Unexpectedly favorable results of the SOC in our Phase 3 trial could lead to unfavorable comparisons to RAIN-32. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an investigational new drug application (IND) or similar application will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such

clinical trials. Events that may prevent successful or timely initiation or completion of clinical trials include: inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials; delays in reaching a consensus with regulatory authorities on study design or implementation of the clinical trials; delays or failure in obtaining regulatory authorization to commence a trial; delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; delays in identifying, recruiting and training suitable clinical investigators; delays in obtaining required institutional review board (IRB) approval at each clinical trial site; delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's good clinical practice requirements (GCPs) or applicable regulatory guidelines in other countries; changes to the clinical trial protocols; clinical sites deviating from trial protocol or dropping out of a trial; changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data; transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization (CMO) and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and third parties being unwilling or unable to satisfy their contractual obligations to us. In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, if the results of these trials are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected, and we may incur significant additional costs.

***Preliminary, "top-line" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.***

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures. Any preliminary or top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the preliminary, top-line or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

**Public health crises such as pandemics or similar outbreaks have affected and could continue to seriously and adversely affect our preclinical studies and anticipated clinical trials, business, financial condition and results of operations.**

In March 2020, the World Health Organization declared COVID-19 a global pandemic, and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, “shelter in place” orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our offices, clinical trial sites, key vendors and partners. Due to “shelter in place” orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise seriously harm our business.

As a result of the COVID-19 pandemic, or similar pandemics, and related “shelter in place” orders and other public health guidance measures, we have, and may in the future, experience disruptions that could seriously harm our business. Potential disruptions include but are not limited to: delays or difficulties in enrolling patients in, initiating or expanding our clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine; interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed; recommendations by federal, state or local governments, employers and others or interruptions of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical trial endpoints; diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors; interruption or delays in the operations of the FDA and comparable foreign regulatory authorities including delays in receiving approval from local regulatory authorities to initiate our planned clinical trials; interruption of, or delays in receiving, supplies of our product candidates from our CMOs due to staffing shortages, raw materials shortages, production slowdowns or stoppages and disruptions in delivery systems; and limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions.

The COVID-19 pandemic may also affect the ability of the FDA and other regulatory authorities to perform routine functions. 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.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

**A variety of risks associated with marketing our product candidates internationally may materially adversely affect our business.**

We plan to eventually seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries including differing regulatory requirements in foreign countries and whether regulatory approvals are possible. Risks associated with international operations may materially adversely affect our business, financial condition and results of operations.

***We face substantial competition, which may result in others discovering, developing, licensing or commercializing products before or more successfully than we do.***

We face substantial competition from major pharmaceutical companies and biotechnology companies worldwide. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

In particular, we are aware of molecules that also are being explored for p53 upregulation and activation in various stages of clinical development by Actavalon, Aprea Therapeutics, CDG Therapeutics, Cotinga Pharmaceuticals, Innovation Pharmaceuticals, PMV Pharmaceuticals and Senhwa Biosciences, among others. We are also aware of selective small molecule inhibitors that are designed to target WT p53 containing tumors through the p53-MDM2 interaction, which are in various stages of clinical development by Aileron Therapeutics, Ascentage Pharma, Boehringer Ingelheim, Kartos Therapeutics, Novartis, and Roche, including testing MDM2 inhibitors in combination with a variety of other anti-cancer agents.

We face competition with respect to our current product candidates and will face competition with respect to any future product candidates from segments of the pharmaceutical, biotechnology and other related industries that pursue targeted therapies for patients with genetically defined cancers. If RAIN-32 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. In addition, we will likely need to develop our product candidates in collaboration with companion diagnostic companies, and we will face competition from other companies in establishing these future collaborations.

Furthermore, we also face competition more broadly across the market for existing cost-effective and reimbursable cancer treatments. Our product candidates, if any are approved, may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges.

***Our product candidates may cause significant adverse events, toxicities or other undesirable side effects that may result in a safety profile that could prevent regulatory approval, marketing approval or market acceptance, or limit their commercial potential.***

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may adversely affect our business, financial condition and prospects significantly.

In general, the anticipated clinical trials of RAIN-32 will include cancer patients who are very sick and whose health is deteriorating, and we expect that additional clinical trials of RAIN-32 and our other product candidates will include similar patients with deteriorating health. A number of patients in RAIN-32 trials have experienced adverse events, including blood and lymphatic disorders and gastrointestinal disorders. See the section titled “Business—Our Lead Product Candidate, RAIN-32—Phase 1 Clinical Data—Phase 1 Study in Solid Tumors or Lymphomas (U101)” in the Prospectus.

The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients’ illnesses. For

example, it is expected that many of the patients enrolled in our RAIN-32 clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials. Such outcomes may make it more difficult for us to identify a clinical benefit in our targeted patient populations, and could ultimately prevent us from obtaining regulatory approval for RAIN-32 in such critically ill populations, including WD/DD LPS. Additionally, such adverse events or deaths in clinical trials involving our product candidates, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed and a decrease in demand for any such product candidates.

Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result. For example, regulatory authorities may suspend, limit or withdraw approvals of such product or seek an injunction against its manufacture or distribution, require additional warnings on the label, including "boxed" warnings, or issue safety alerts, require press releases or other communications containing warnings or other safety information about the product, require us to change the way the product is administered or conduct additional clinical trials or post-approval studies, require us to create a risk evaluation and mitigation strategy (REMS) which could include a medication guide outlining the risks of such side effects for distribution to patients, impose fines, injunctions or criminal penalties. We could also be sued and held liable for harm caused to patients, and our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

#### **Risks Related to Regulatory Process and Other Legal Compliance Matters**

***The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.***

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate RAIN-32, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials; the FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates; the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. For example, based on preliminary feedback from the EMA on the Phase 3 trial planned for RAIN-32 in liposarcoma, the agency may require different clinical endpoints or additional data to support a filing in the EU

than in the United States. Thus, the approval requirements for our product candidates are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired.

***If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates and we fail to obtain or face delays in obtaining FDA approval of a diagnostic device, we could be delayed or may not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.***

If safe and effective use of any of our product candidates depends on an *in vitro* diagnostic that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates, if at all. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has required premarket approval of all companion diagnostics for cancer therapies, such as those we are developing. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to develop or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time-consuming and costly. If the FDA or a comparable foreign regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of such product candidate. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

***We may seek orphan drug designation for our product candidates, but we may be unable to obtain such designation or to obtain or maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our product revenue, if any, to be reduced.***

We have obtained orphan drug designation in the United States for RAIN-32 for the treatment of LPS and we may seek additional orphan drug designations for RAIN-32 or our other product candidates; however, we may never receive such designations. See the section titled "Business—Government Regulation—Review and Approval of Drugs in the United States—*Orphan Drug Designation*" in the Prospectus.

Exclusive marketing rights in the United States may be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even

after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, is more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***Even if we receive regulatory approval of our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.***

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or comparable foreign regulatory authorities approve our product candidates, our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices (cGMPs) and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials, restrictions on the manufacturing process, warning or untitled letters, civil and criminal penalties, injunctions, product seizures, detentions or import bans, voluntary or mandatory publicity requirements and imposition of restrictions on operations, including costly new manufacturing requirements. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

***Even if we are able to commercialize any product candidates, due to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, we may not be able to offer such products at competitive prices which would seriously harm our business.***

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. See the sections titled “Business—Government Regulation—Review and Approval of Drug Products in the European Union,” “Business—Government Regulation—Review and Approval of Drug Products in the United States—New Legislation and Regulations,” “Business—Government Regulation—U.S. Pharmaceutical Coverage, Pricing and Reimbursement” and “Business—Government Regulation—U.S. Healthcare Reform” in the Prospectus.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and any infraction could subject us to liability.***

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. See the section titled “Business—Government Regulation—Review and Approval of Drugs in the United States—Post-approval Requirements” in the Prospectus. If we

cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors acting for or on our behalf may engage in misconduct or other improper activities. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these parties and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

***Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. See the section titled “Business—Government Regulation—Healthcare Laws and Regulations” in the Prospectus for a more detailed description of the laws that may affect our ability to operate.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including certain arrangements we have with physicians who are compensated in the form of stock or stock options for services provided to us, are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

#### **Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business**

***We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our managerial, scientific and medical personnel, including our Chief Executive Officer and our Chief Scientific Officer. If we do not succeed in attracting and retaining qualified personnel, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

***In order to successfully implement our plans and strategies, we will need to grow the size of our organization and we may experience difficulties in managing this growth.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical operations, regulatory affairs and, potentially, sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We are dependent on financial resources and the experience of our management team in managing a company with such anticipated growth, and we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.***

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained on our internal information technology systems and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners and/or other third parties, or from cyber-attacks by malicious third parties, which may compromise our system infrastructure or lead to the loss, destruction, alteration or dissemination of, or damage to, our data. To the extent that any disruption or security breach were to result in a loss, destruction, unavailability, alteration or dissemination of, or damage to, our data or applications, or for it to be believed or reported that any of these occurred, we could incur liability and reputational damage and the development and commercialization of our product candidates could be delayed. Further, our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in, or failure or security breach of, our systems or third-party systems where information important to our business operations or commercial development is stored.

#### **Risks Related to Reliance on Third Parties**

***We currently rely, and plan to rely in the future, on third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners, to conduct and support our preclinical studies and clinical trials under agreements with us. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates.

***We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.***

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We received a batch of our product candidate that we believe is representative of our anticipated early commercial batch requirements. However, as a clinical-stage company with no prior history of product sales or commercialization of products, representative batches of our product candidate received to date may not represent what will be required to meet our future commercial requirements or be manufactured at scale. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Moreover, if any CMOs on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates.

***We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.***

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

## Risks Related to Our Intellectual Property

***Our ability to protect our patents and other proprietary rights is uncertain, exposing us to the possible loss of competitive advantage.***

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, product candidates and their uses, as well as our ability to operate without infringing on or violating the proprietary rights of others. We own and have licensed rights to pending patent applications and expect to continue to file patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. However, we may not be able to protect our intellectual property rights throughout the world and the legal systems in certain countries may not favor enforcement or protection of patents, trade secrets and other intellectual property. Filing, prosecuting and defending patents on product candidates worldwide would be prohibitively expensive and our intellectual property rights in some foreign jurisdictions can be less extensive than those in the United States. As such, we do not have patents in all countries or all major markets and may not be able to obtain patents in all jurisdictions even if we apply for them. Our competitors may operate in countries where we do not have patent protection and can freely use our technologies and discoveries in such countries to the extent such technologies and discoveries are publicly known or disclosed in countries where we do have patent protection or pending patent applications. Our pending and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. Further, any issued patents that we may license or own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the United States Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, enforceability of our patents and/or other intellectual property. Finally, changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we own, and license may not afford us any meaningful competitive advantage.

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors and those affiliated with or controlled by state actors. In addition, while we undertake efforts to protect our

trade secrets and other confidential information from disclosure, others may independently discover trade secrets and proprietary information, and in such cases, we may not be able to assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Lastly, if our trademarks and trade names are not registered or adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.***

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we

request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

***Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act (the Leahy-Smith Act) could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.***

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent

in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may be subject to patent infringement claims or may need to file claims to protect our intellectual property, which could result in substantial costs and liability and prevent us from commercializing our potential products.***

Because the intellectual property landscape in the biotechnology industry is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on or violating third party rights. However, if certain of our product candidates are ultimately granted regulatory approval, we are currently aware of certain patent rights held by third parties that, if found to be valid and enforceable, could be alleged to render one or more of our product candidates infringing. If a third party successfully brings a claim against us, we may be required to pay substantial damages, be forced to abandon any affected product and/or seek a license from the patent holder. In addition, any intellectual property claims (e.g., patent infringement or trade secret theft) brought against us, whether or not successful, may cause us to incur significant legal expenses and divert the attention of our management and key personnel from other business concerns. We cannot be certain that patents owned or licensed by us will not be challenged by others in the course of litigation. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise funds and on the market price of our common stock.

Competitors may infringe or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In addition, in a patent infringement proceeding, a court or administrative body may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court or administrative body may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable.

Further, we may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to

invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships and we may be required to indemnify those parties for any damages they suffer as a result of these claims, which may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of such claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

***We license patent rights from third-party owners, and we rely on such owners to obtain, maintain and enforce the patents underlying such licenses.***

We are a party to certain licenses, including with our licensors Daiichi Sankyo and Drexel University, that provide us rights to intellectual property that are necessary or useful for our product candidates, RAIN-32 and RAD52, and their respective components, formulations, methods of manufacturing and methods of treatment. These license agreements require us to satisfy certain obligations and, if these agreements are terminated (e.g., as a result of our failure to satisfy such obligations), our technology and our business could be adversely affected. We also expect to enter into additional licenses to third-party intellectual property in the future; however, we may not be able to obtain such licenses on economically feasible terms or other reasonable terms and conditions, or at all.

Our licensors may not successfully prosecute the patent applications that we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Additionally, we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. For example, should Daiichi Sankyo decide it no longer wants to maintain any of the patents licensed to us, Daiichi Sankyo is required to afford us the opportunity to do so at our expense. However, we cannot be sure that Daiichi Sankyo will perform as required. If Daiichi Sankyo does not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***Our technology licensed from various third parties may be subject to retained rights.***

Our licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. Further, the U.S. government may retain certain rights under the Bayh-Dole Act for research funded by the Federal Government.

***We may not be able to effectively secure first-tier technologies when competing against other companies or investors.***

Our future success may require that we acquire patent rights and know-how to new or complimentary technologies. However, we compete with a substantial number of other companies that may also compete for technologies we desire. In addition, many venture capital firms and other institutional investors, as well as other biotechnology companies, invest in companies seeking to commercialize various types of emerging technologies. Many of these companies have greater financial, scientific and commercial resources than us. Therefore, we may not be able to secure the technologies we desire. Furthermore, should any commercial undertaking by us prove to be successful, there can be no assurance competitors with greater financial resources will not offer competitive products and/or technologies.

**Risks Related to Our Common Stock**

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q. The realization of any of these factors could have a dramatic and adverse impact on the market price of our common stock.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In particular, the trading prices for biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would materially adversely affect our business, financial condition and results of operation.

***If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us or our business, our stock price and trading volume could decline.***

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts commence coverage of us or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, our stock price could be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.***

Following the IPO, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 26.5 % of our outstanding voting common stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

**General Risk Factors**

***Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders

might consider favorable. In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. See the section titled “Description of Capital Stock—Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law” in the Prospectus for a more detailed description of these provisions.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes.***

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for certain actions, in all cases subject to the court’s having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. These exclusive forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes, which may discourage lawsuits. There is uncertainty as to whether a court would enforce such provisions. If a court were to find these types of provisions to be inapplicable or unenforceable, and if a court were to find the exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially adversely affect our business. See the section titled “Description of Capital Stock—Anti-Takeover Effects of Our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware Law—Exclusive Forum Selection Clause” in the Prospectus for a more detailed description of these choice of forums provisions.

***The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.***

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

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

### *Use of Proceeds from IPO of Common Stock*

On April 27, 2021, we completed our IPO pursuant to which we issued and sold an aggregate of 7,352,941 shares of our common stock at the public offering price of \$17.00 per share. On May 7, 2021, the underwriters exercised their option to purchase 492,070 additional shares of our common stock at the public offering price (the Overallotment) and the Overallotment closed on May 11, 2021.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to our Registration Statement on Form S-1, as amended (File No. 333-254998), which was declared effective on April 22, 2021. Goldman Sachs & Co. LLC, Citigroup, Piper, and Guggenheim Securities acted as joint book-running managers for the IPO.

We received net proceeds from our IPO of approximately \$121.9 million, after deducting underwriting discounts and commissions, and other offering fees inclusive of the Overallotment. None of the underwriting discounts and commissions or other offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

The net proceeds from the IPO (including the Overallotment) have been used and will be used, to fund a pivotal Phase 3 trial in LPS, a Phase 2 tumor-agnostic basket trial in certain solid tumors and a Phase 2 trial in intimal sarcoma for our lead product candidate, RAIN-32, fund the purchase of raw materials and drug substance and drug product manufacturing for our RAIN-32 program and fund various clinical pharmacology, biomarker and translational studies for our RAIN-32 program, and for working capital, including continuing to advance our pipeline through preclinical studies and clinical trials, and general corporate purposes. There has been no material change in our intended use of proceeds from our IPO as described in the Prospectus filed with the SEC pursuant to Rule 424(b)(4) on April 23, 2021.

## **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	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference from Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on April 27, 2021 (Commission File No. 001-40356)).</a>
3.2	<a href="#">Bylaws of the Registrant (incorporated by reference from Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on April 27, 2021 (Commission File No. 001-40356)).</a>
4.1	<a href="#">Form of Common Stock Certificate of the Registrant (incorporated by reference from Exhibit 4.1 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)).</a>
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, dated September 2, 2020, by and among the Registrant and certain of its stockholders (incorporated by reference from Exhibit 4.2 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)).</a>
10.1+	<a href="#">Form of Indemnification Agreement for directors and executive officers (incorporated by reference from Exhibit 10.1 of the Registrant's Amendment No. 1 to Registration Statement on Form S-1 filed on April 9, 2021 (Commission File No. 333-254998)).</a>
10.2+	<a href="#">2021 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)).</a>
10.3+	<a href="#">2021 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.4 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)).</a>
10.4	<a href="#">Exchange Agreement, dated April 17, 2021, by and among the Registrant and the stockholders listed therein (incorporated by reference from Exhibit 10.13 of the Registrant's Amendment No. 2 to Registration Statement on Form S-1 filed on April 19, 2021 (Commission File No. 333-254998)).</a>
31.1*	<a href="#">Certification of the principal executive officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.</a>
31.2*	<a href="#">Certification of the principal financial officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.</a>
32.1 (1)	<a href="#">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</a>
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.

+ Indicates management contract or compensatory plan.

(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: May 25, 2021

By: /s/ Avanish Vellanki

Avanish Vellanki  
*Chairman and Chief Executive Officer*  
*(principal executive officer)*

Date: May 25, 2021

By: /s/ Nelson Cabatuan

Nelson Cabatuan  
*Senior Vice President of Finance and Administration*  
*(principal financial and accounting officer)*

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

I, 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: May 25, 2021

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

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

I, 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: May 25, 2021

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

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

In connection with the Quarterly Report on Form 10-Q of Rain Therapeutics Inc. (the "Company") for the period ended March 31, 2021 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: May 25, 2021

By: /s/ Avanish Vellanki

Avanish Vellanki  
Chairman and Chief Executive Officer  
*(principal executive officer)*

Date: May 25, 2021

By: /s/ Nelson Cabatuan

Nelson Cabatuan  
Senior Vice President of Finance and Administration  
*(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.