UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended 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: 001-35005

ASSEMBLY BIOSCIENCES, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**20-8729264**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
331 Oyster Point Blvd., Fourth Floor South San Francisco, California	**94080**
(Address of principal executive offices)	(zip code)

(833) 509-4583
(Registrant's telephone number, including area code)

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	ASMB	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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer	☐
Non-accelerated Filer	☐	Smaller Reporting Company	☐
Emerging growth company	☐		

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

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

As of May 3, 2021, there were 40,158,197 shares of the registrant's common stock outstanding.

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References to Assembly Biosciences, Inc.

Throughout this Quarterly Report on Form 10-Q, the "Company," "Assembly," "we," "us," and "our," except where the context requires otherwise, refer to Assembly Biosciences, Inc. and its consolidated subsidiaries, and "our board of directors" or "the Board" refers to the board of directors of Assembly Biosciences, Inc.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that are subject to certain risks and uncertainties, including, without limitation, those set forth in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchanges Commission (SEC) on February 25, 2021 (2020 Annual Report) and Part II, Item 1A of this Quarterly Report on Form 10-Q under the heading "Risk Factors," that could cause actual results to materially differ. In addition, factors that could cause actual results to differ from those stated in the forward-looking statements in this Quarterly Report on Form 10-Q include, among other things:

- changes in our ability to initiate and complete clinical trials involving our chronic hepatitis B virus (HBV) therapeutic product candidates in the currently anticipated timeframes;
- safety and efficacy data from clinical studies may not warrant further development of our product candidates;
- clinical and nonclinical data presented at conferences may not differentiate our product candidates from other companies' candidates;
- continued development and commercialization of our HBV product candidates is dependent on, and subject to, our collaboration agreement governing our activity in the China territory;
- changes in our ability to maintain financial resources necessary to continue our clinical studies and fund business operations; and
- any impact that the COVID-19 pandemic may have on our business and operations, including initiation and continuation of our clinical studies or timing of discussions with regulatory authorities.

You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. We intend such forward-looking statements to be covered by the safe harbor provisions contained in 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). Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	March 31, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 78,253	$ 59,444
Marketable securities	136,631	156,969
Accounts receivable from collaborations	203	1,230
Prepaid expenses and other current assets	6,547	6,850
Total current assets	221,634	224,493
Property and equipment, net	1,493	1,600
Operating lease right-of-use (ROU) assets	8,104	9,131
Other assets	6,034	6,392
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 278,903**	**$ 283,254**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,562	$ 4,598
Accrued clinical expenses	4,342	4,444
Other accrued expenses	3,659	11,987
Operating lease liabilities - short-term	2,934	3,404
Total current liabilities	14,497	24,433
Deferred tax liabilities	2,531	2,531
Deferred revenue	8,987	8,987
Operating lease liabilities - long-term	5,644	6,725
Total liabilities	**31,659**	**42,676**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 40,104,684 and 34,026,680 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	40	34
Additional paid-in capital	776,248	742,387
Accumulated other comprehensive loss	(271)	(270)
Accumulated deficit	(528,773)	(501,573)
Total stockholders' equity	247,244	240,578
Total liabilities and stockholders' equity	**$ 278,903**	**$ 283,254**

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except for share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Collaboration revenue	$ —	$ 4,081
Operating expenses:		
Research and development	18,554	23,046
General and administrative	8,704	8,729
Total operating expenses	27,258	31,775
Loss from operations	**(27,258)**	**(27,694)**
Other income:		
Interest and other income, net	58	1,039
Total other income	58	1,039
Net loss	**$ (27,200)**	**$ (26,655)**
Other comprehensive (loss) income		
Unrealized (loss) gain on marketable securities	(1)	115
Comprehensive loss	**$ (27,201)**	**$ (26,540)**
Net loss per share, basic and diluted	$ (0.69)	$ (0.76)
Weighted average common shares outstanding, basic and diluted	39,679,734	35,079,756

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (27,200)	$ (26,655)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	107	115
Stock-based compensation	(286)	4,924
Net accretion and amortization of investments in marketable debt securities	92	(135)
Non-cash rent expense	1,135	1,151
Loss on disposal of fixed assets	1,611	—
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	1,027	319
Prepaid expenses and other current assets	303	795
Other assets	358	23
Accounts payable	(1,036)	373
Accrued clinical expenses	(102)	(193)
Other accrued expenses	(8,312)	(3,808)
Deferred revenue	—	(1,007)
Operating lease liabilities	(1,041)	(1,120)
Net cash used in operating activities	(33,344)	(25,218)
Cash flows from investing activities		
Purchases of property and equipment	(3,078)	(65)
Proceeds from sale of property and equipment	857	—
Purchases of marketable securities	(49,213)	(44,242)
Proceeds from maturities of marketable securities	66,450	55,000
Proceeds from sale of marketable securities	3,000	10,000
Net cash provided by investing activities	18,016	20,693
Cash flows from financing activities		
Proceeds from the exercise of stock options	—	119
Proceeds from sale of common stock, net of issuance costs	34,137	—
Net cash provided by financing activities	34,137	119
Net increase (decrease) in cash and cash equivalents	18,809	(4,406)
Cash and cash equivalents at the beginning of the period	59,444	46,732
Cash and cash equivalents at the end of the period	**$ 78,253**	**$ 42,326**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ 42	$ 362
Remeasurement of lease liabilities arising from modification of ROU assets	$ (788)	$ —

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands except for share amounts)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	**34,026,680**	**$ 34**	**$ 742,387**	**$ (270)**	**$ (501,573)**	**$ 240,578**
Issuance of common stock under at-the-market (ATM) equity offering program, net of issuance costs	5,991,858	6	34,131	—	—	34,137
Issuance of shares of common stock for settlement of restricted stock units (RSUs)	86,146	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(1)	—	(1)
Stock-based compensation	—	—	(270)	—	—	(270)
Net loss	—	—	—	—	(27,200)	(27,200)
Balance as of March 31, 2021	**40,104,684**	**$ 40**	**$ 776,248**	**$ (271)**	**$ (528,773)**	**$ 247,244**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	**32,558,307**	**$ 32**	**$ 712,807**	**$ (201)**	**$ (439,421)**	**$ 273,217**
Issuance of common stock upon exercise of stock options	16,834	—	119	—	—	119
Issuance of shares of common stock for settlement of RSUs	49,584	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	115	—	115
Stock-based compensation	—	—	4,972	—	—	4,972
Net loss	—	—	—	—	(26,655)	(26,655)
Balance as of March 31, 2020	**32,624,725**	**$ 32**	**$ 717,898**	**$ (86)**	**$ (466,076)**	**$ 251,768**

See Accompanying Notes to Condensed Consolidated Financial Statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc. (together with its subsidiaries, Assembly or the Company), incorporated in Delaware in October 2005, is a clinical-stage biotechnology company advancing a novel class of oral therapeutic candidates for the treatment of chronic hepatitis B virus (HBV) infection. The Company operates in one segment and is headquartered in South San Francisco, California, with operations in California and China. Prior to the Company's wind-down of its Microbiome program on January 31, 2021, the Company also had operations in Connecticut.

The Company's research and development programs are pursuing multiple drug candidates that inhibit the HBV replication cycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of discovering and developing finite and curative therapies for patients with HBV. Assembly has discovered several novel core inhibitors, which are small molecules that directly target and allosterically modify the HBV core (HBc) protein in a way that affects assembly and stability of HBV nucleocapsids.

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, proceeds from the exercise of warrants and stock options, issuance of debt, and upfront payments related to collaboration agreements. The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months following the date these unaudited condensed consolidated interim financial statements are issued. If the Company cannot generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, grants or other arrangements (see Note 6 for recent sales of common stock). The Company cannot assure such funding will be available on reasonable terms, if at all. Market volatility resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact the Company's ability to access capital when and as needed.

If the Company is unable to generate enough revenue from its collaborations, secure additional sources of funding or receive full and timely collections of amounts due, it may be necessary to significantly reduce the current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs, including more costly clinical trials.

Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the SEC. In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and include normal recurring adjustments necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with the Company's audited consolidated financial statements and accompanying notes for the fiscal year ended December 31, 2020, which are contained in the 2020 Annual Report. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the entire year ending December 31, 2021 or future operating periods.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Estimates inherent in the preparation of the accompanying unaudited condensed consolidated financial statements include estimates for the cost-based input of revenue recognition and standalone selling price estimates for allocation of transaction price to performance obligations, revenue recognition, estimates of costs incurred but not yet invoiced for clinical trial accruals, recoverability and useful lives of our long-lived assets, the estimated fair value of our indefinite-lived intangible assets, the estimated fair value of our reporting unit for purposes of evaluating goodwill impairment, provisions for income taxes, amounts receivable under collaboration agreements, measurement of operating lease liabilities, and the fair value of stock options, stock appreciation rights, and restricted stock units (RSUs) granted to employees, directors, and consultants.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible these external factors could have an effect on the Company's estimates and could cause actual results to differ materially from those estimates and assumptions.

Other Risks and Uncertainties

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To date, the Company's operations have not been significantly impacted by the COVID-19 pandemic. However, the Company cannot at this time predict the specific extent, duration, or full impact the COVID-19 pandemic will have on its business, operations, strategy, prospects and financial condition and results. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

Income Taxes

In March 2021, the American Rescue Plan (H.R. 1319) was signed into law. This legislation extends and enhances a number of current-law tax incentives for businesses, but also expands the definition of a "covered employee" as defined by Section 162(m)(1) of the Internal Revenue Code. The corporate tax provisions included within the bill are not expected to have a material impact on the Company.

Net Loss per Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. Since the Company has only incurred losses, basic and diluted net loss per share is the same.

In December 2019, the Company sold 6,287,878 shares of common stock as well as pre-funded warrants to purchase up to 2,424,242 shares of common stock. The pre-funded warrants are exercisable for shares of common stock at an exercise price of $0.001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing earnings per share because the shares may be issued for little or no consideration, they are fully vested, and are exercisable after the original issuance date.

A reconciliation of the numerators and the denominators of the basic and diluted net loss per common share computations is as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	$ (27,200)	$ (26,655)
Denominator:		
Weighted average common shares and pre-funded warrants outstanding - basic and diluted	39,679,734	35,079,756
Net loss per share - basic and diluted	$ (0.69)	$ (0.76)

Securities excluded from the computation of diluted loss per share because including them would have been antidilutive are as follows:

	March 31,	
	2021	2020
Warrants to purchase common stock	—	15,296
Options to purchase common stock	7,382,515	6,370,396
Common stock subject to purchase under our ESPP	44,870	32,940
Unvested RSUs	666,574	999,926
Total	8,093,959	7,418,558

Adoption of Recent Accounting Pronouncements

On January 1, 2021, the Company adopted ASU 2020-10, *Codification Improvements – Disclosures*. This ASU improves consistency by amending the codification to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the Codification by amending and adding new headings, cross referencing to other accounting standards and refining or correcting termination. The adoption of this standard had no material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the FASB) issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. In April, May and November 2019, the FASB issued additional amendments to the new guidance related to transition and clarification. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives*

and Hedging (Topic 815), and Leases (Topic 842): Effective Dates, which deferred the effective date of this standard for all entities except SEC filers that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the timing and impact of adopting this new accounting standard on its condensed consolidated financial statements and related disclosures.

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): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* (ASU 2020-06), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically, ASU 2020-06 simplifies accounting for convertible instruments by removing major separation models in ASC 470-20 that require separate accounting for embedded conversion features. The ASU also removes certain settlement conditions in ASC 815-40 that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for the scope exception and simplifies the diluted earnings per share (EPS) calculation in certain areas. The ASU is effective for interim and annual periods beginning after December 15, 2021, with early adoption permitted. Adoption of the ASU can either be on a modified retrospective or full retrospective basis. The Company is currently evaluating the impacts of ASU 2020-06 on its condensed consolidated financial statements and related disclosures.

Note 3 – Fair Value Measurements and Investments in Marketable Securities

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable, accrued expenses, lease liability-short term and deferred revenue-short term.

The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

Level 3: Significant unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Investments in marketable securities consisted of the following (in thousands):

	March 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market funds	$ 66,494	$ —	$ —	$ 66,494
Total cash equivalents	66,494	—	—	66,494
Short-term investments				
U.S. and foreign corporate debt securities	22,954	—	(6)	22,948
Asset-backed securities	16,762	2	(2)	16,762
U.S. and foreign commercial paper	96,921	—	—	96,921
Total short-term investments	136,637	2	(8)	136,631
Total cash equivalents and investments	$ 203,131	$ 2	$ (8)	$ 203,125

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gain (1)	Gross Unrealized Loss (1)	Fair Value
Cash equivalents				
Money market funds	$ 47,553	$ —	$ —	$ 47,553
U.S. and foreign commercial paper	6,498	—	—	6,498
Total cash equivalents	54,051	—	—	54,051
Short-term investments				
U.S. and foreign corporate debt securities	16,939	3	(3)	16,939
Asset-backed securities	12,674	2	(1)	12,675
U.S. treasury securities	23,997	2	—	23,999
U.S. and foreign commercial paper	103,356	—	—	103,356
Total short-term investments	156,966	7	(4)	156,969
Total cash equivalents and investments	$ 211,017	$ 7	$ (4)	$ 211,020

The contractual term to maturity of short-term marketable securities held by the Company as of March 31, 2021 is less than one year. There were no long-term marketable securities held by the Company as of March 31, 2021.

Realized gains and losses for the three months ended March 31, 2021 and 2020 were not significant. None of the Company's investments have been in a continuous unrealized loss position for more than 12 months as of March 31, 2021.

The following tables present the fair value of the Company's financial assets measured at fair value on a recurring basis (in thousands):

	March 31, 2021			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 66,494	$ —	$ —	$ 66,494
Total cash equivalents	66,494	—	—	66,494
Short-term investments				
U.S. and foreign corporate debt securities	—	22,948	—	22,948
Asset-backed securities	—	16,762	—	16,762
U.S. and foreign commercial paper	—	96,921	—	96,921
Total short-term investments	—	136,631	—	136,631
Total assets measured at fair value	$ 66,494	$ 136,631	$ —	$ 203,125

	December 31, 2020			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 47,553	$ —	$ —	$ 47,553
U.S. and foreign commercial paper	—	6,498	—	6,498
Total cash equivalents	47,553	6,498	—	54,051
Short-term investments				
U.S. and foreign corporate debt securities	—	16,939	—	16,939
Asset-backed securities	—	12,675	—	12,675
U.S. treasury securities	—	23,999	—	23,999
U.S. and foreign commercial paper	—	103,356	—	103,356
Total short-term investments	—	156,969	—	156,969
Total assets measured at fair value	$ 47,553	$ 163,467	$ —	$ 211,020

The Company estimates the fair value of its investments in marketable securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs.

There were no transfers between Level 1, Level 2 or Level 3 during the periods presented.

Note 4 – Other Accrued Expenses

Other accrued expenses consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued expenses:		
Accrued compensation	$ 1,842	$ 7,016
Accrued restructuring charges	1,246	4,164
Accrued professional fees and other	571	807
Total accrued expenses	$ 3,659	$ 11,987

Note 5 – Restructurings

Restructuring charges relate to the Company's decision to relocate its headquarters to South San Francisco, California, which was approved by the Board of Directors in November 2019 and effective January 1, 2020 and the wind-down of the Company's Microbiome program, which the Company and its Board of Directors determined in December 2020 was in the Company's best interest, enabling the Company to prioritize resources and focus on the advancement of its pipeline of novel core inhibitors for chronic HBV infection.

The following table summarizes the Company's estimates of costs to be incurred and expected to be incurred (in thousands):

	Total Restructuring Cost	Employee Severance and Related Benefits	Asset Impairment and Other Costs
Total estimated restructuring costs to be incurred	$ 6,988	$ 3,798	$ 3,190
Restructuring costs incurred for the three months ended March 31, 2021	$ (1,052)	$ (2,663) [1]	$ 1,611
Cumulative restructuring costs incurred through March 31, 2021	$ 6,726	$ 3,536	$ 3,190

(1) The reversal of $2.7 million in employee severance and related benefits recognized during the three months ended March 31, 2021 reflects the reversal of previously recognized stock-based compensation expense related to forfeited awards based on the Company's policy of recognizing stock-based awards with graded vesting schedules using an accelerated attribution method on a straight-line basis over the requisite service period for each separately vesting portion of the award and to recognize forfeitures when they occur.

The following table presents where the restructuring charges were recognized during the three months ended March 31, 2021 (in thousands):

Research and development	$ (1,329)
General and administrative	277
Total	$ (1,052)

There were no restructuring costs incurred for the three months ended March 31, 2020.

The following table presents the activity in the accrued restructuring charges during the three months ended March 31, 2021 (in thousands):

	Total Restructuring Cost	Employee Severance and Related Benefits	Asset Impairment and Other Costs
Accrued balance as of December 31, 2020	$ 4,164	$ 4,164	$ —
Costs incurred	1,611	—	1,611
Reductions for cash payments	(4,529)	(2,918)	(1,611) [1]
Accrued balance as of March 31, 2021	$ 1,246	$ 1,246	$ —

(1) Cash payments are presented net of proceeds received from the sale of assets of $0.9 million.

The asset impairment and other costs includes $1.4 million for the remaining payment obligations of leased equipment the Company purchased and sold to third parties.

The Company expects the accrued restructuring liability to be fully paid in 2021.

Note 6 – Stockholders' Equity

The Company was authorized to issue 5,000,000 shares of preferred stock as of March 31, 2021 and December 31, 2020, respectively. As of March 31, 2021 and December 31, 2020, no shares of preferred stock were issued and outstanding. The Company was authorized to issue 100,000,000 shares of common stock as of March 31, 2021 and December 31, 2020, respectively.

Sale of Common Stock

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC, File No. 333-248469, that became effective on September 4, 2020 (the 2020 Registration Statement). The Company may from time to time sell any combination of the securities described in the 2020 Registration Statement in one or more offerings up to an aggregate offering price of $300.0 million. In connection with the filing of the 2020 Registration Statement, the Company entered into a sales agreement under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $100.0 million through "at-the-market" offerings (2020 ATM), which shares are included in the $300.0 million of securities registered pursuant to the 2020 Registration Statement. During the three months ended March 31, 2021, the Company sold 5,991,858 shares of common stock under the 2020 ATM, for which the Company received net proceeds of $34.1 million, after deducting commissions, fees and expenses.

Common Stock Warrants

The following warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue date	Expiration date	Exercise Price per Share	Number of warrants outstanding
December 16, 2019	None	$ 0.001	2,424,242

There were no warrants exercised during the three months ended March 31, 2021 or 2020.

Note 7 – Stock Plans and Stock-Based Compensation

Equity Incentive Plans

In May 2018, the Company's stockholders approved (1) the Assembly Biosciences, Inc. 2018 Stock Incentive Plan (the 2018 Plan) pursuant to which the Company reserved 1,900,000 shares of its common stock for issuance in connection with equity incentive awards and (2) the Assembly Biosciences Inc. Employee Stock Purchase Plan (the 2018 ESPP) pursuant to which the Company reserved 400,000 shares of its common stock for issuance in connection with purchases by employees pursuant to this plan.

In May 2019, the Company's stockholders approved an amendment to the 2018 Plan that increased the aggregate number of shares of common stock reserved under the 2018 Plan to 3,000,000.

In June 2020, the Company's stockholders approved an amendment to the 2018 Plan that increased the aggregate number of shares of common stock reserved under the 2018 Plan to 4,600,000.

As of March 31, 2021, the Company had awards outstanding under the following shareholder-approved plans: the 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen; the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. As of March 31, 2021, the Company also had awards outstanding under the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the 2017 Plan), the Assembly Biosciences, Inc. 2019 Inducement Award Plan (the 2019 Plan) and the Assembly Biosciences, Inc. 2020 Inducement Award Plan (the 2020 Plan).

The Company issues new shares of common stock to settle options exercised and vested RSUs. The Company also issues new shares of common stock in connection with purchases of shares of common stock by eligible employees under the Company's 2018 ESPP.

Stock Plan Activity

Stock Options

A summary of the Company's option activity and related information for the three months ended March 31, 2021 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	6,696,592	$ 15.70		
Granted	1,112,250	4.40		
Forfeited	(417,127)	20.89		
Expired	(9,200)	30.00		
Outstanding as of March 31, 2021	7,382,515	$ 13.68	7.1	$ 1,393
Options vested and exercisable as of March 31, 2021	4,260,738	$ 14.81	5.5	$ 1,110

The weighted-average grant-date fair value of options granted was $3.15 and $9.74 during the three months ended March 31, 2021 and 2020, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2020 was $0.2 million. There were no options exercised during the three months ended March 31, 2021.

RSUs

A summary of the Company's RSUs and related information for the three months ended March 31, 2021 is as follows:

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2020	886,868	$ 20.35
Granted	199,875	4.33
Vested	(135,929)	19.73
Forfeited	(144,240)	17.49
Nonvested as of March 31, 2021	806,574 [(1)]	$ 16.81

(1) Includes 140,000 RSUs that have vested but are subject to deferred settlement, which have a weighted average remaining contractual term of 1.9 years.

The total fair value of RSUs vested and settled during the three months ended March 31, 2021 and 2020 was $2.5 million and $2.4 million, respectively. The total intrinsic value of RSUs vested and settled during the three months ended March 31, 2021 and 2020 was $0.6 million and $1.5 million, respectively.

In September 2019, the Company granted 100,000 RSUs with performance-based vesting conditions to its chief executive officer. On March 31, 2021, 25,000 of these awards were forfeited back to the Company due to the time period to complete one of the performance conditions expiring. The outstanding 75,000 awards with an aggregate fair value of $0.8 million vest upon performance conditions not yet deemed probable. Accordingly, no stock-based compensation expense has been recognized as of March 31, 2021.

ESPP

There were no shares purchased under the 2018 ESPP during the three months ended March 31, 2021 or 2020.

Valuation Assumptions

The fair value of the stock options granted or modified during the periods indicated was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended March 31,	
	2021	2020
Exercise price	$4.33 - $5.79	$14.45 - $19.13
Expected volatility	81.4% - 91.2%	66.4% - 82.2%
Risk-free rate	0.50% - 1.37%	0.46% - 1.44%
Expected term (years)	5.5 - 7.0	5.5 - 7.0
Expected dividend yield	0%	0%

The fair value of RSUs granted is determined based on the price of the Company's common stock on the date of grant.

The fair value of ESPP purchase rights were not material for any period presented.

Stock-Based Compensation Expense

The following table summarizes the components of total stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,			
	2021		2020	
Research and development	$ (2,091)	(1)	$ 1,945	
General and administrative	1,805		2,979	
Total stock-based compensation expense	$ (286)		$ 4,924	

(1) Includes the reversal of previously recognized stock-based compensation expense of $3.6 million related to forfeited awards of terminated employees, $2.7 million of which resulted from the wind-down of the Company's Microbiome program (see Note 5).

As of March 31, 2021, there was $18.6 million of total unrecognized stock-based compensation related to outstanding equity awards, which is expected to be recognized over a weighted average remaining amortization period of 1.8 years.

Note 8 - Collaboration Agreements

Allergan Agreement

In January 2017, the Company and Allergan Pharmaceuticals International Limited (Allergan) entered into the Research, Development, Collaboration and License Agreement (the Allergan Agreement) to develop and commercialize select microbiome gastrointestinal disease therapies. In June 2020, following its acquisition of Allergan, AbbVie Inc. (AbbVie), on behalf of Allergan, gave written notice of termination of the Allergan Agreement, which subsequently became effective on October 10, 2020. Upon termination, the licenses granted by the Company and its know-how reverted to the Company.

For the three months ended March 31, 2020, the Company recognized $4.1 million in revenue associated with the Allergan Agreement. A contract asset balance of $1.0 million was recorded as of December 31, 2020. There were no deferred revenue contract liabilities as of December 31, 2020 and no revenue, contract assets or contract liabilities recognized as of and for the three months ended March 31, 2021 due to the termination of the Allergan Agreement in 2020.

BeiGene Agreement

In July 2020, the Company and BeiGene, Ltd. (BeiGene) entered into a Collaboration Agreement (the BeiGene Agreement) to develop and commercialize the Company's novel core inhibitor product candidates VBR, ABI-H2158 and ABI-H3733 for chronic HBV infection (the Licensed Product Candidates) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory). Under the agreement, the Company and BeiGene are collaborating on certain global clinical studies and both the Company and BeiGene will independently conduct other clinical studies in their own respective territories.

BeiGene agreed to pay all development and regulatory costs for the Licensed Product Candidates in the Territory up to an aggregate of $45.0 million. Development and regulatory costs for the Licensed Product Candidates for the Territory in excess of $45.0 million will be shared equally by the Company and BeiGene. If the Company conducts certain ancillary studies outside of the plan to develop these candidates in the Territory, BeiGene may elect to obtain access to the know-how and clinical data resulting for such ancillary studies and shall reimburse the Company proportionally for the Territory costs of such studies. Activities under the BeiGene Agreement will be governed by a joint steering committee (JSC) consisting of equal representatives from each party to the agreement. All decisions of the JSC are to be made by consensus with final decision-making authority granted to each party based on key areas of the collaboration for which they are responsible. During the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory. The Company will be responsible for manufacturing and supply of the candidates to be used in and outside of the Territory, although the parties may approve BeiGene to take on some or all of the commercial supply activities of the applicable Licensed Products in the Territory.

The Company is not obligated to perform pre-Phase 3 clinical study development work outside the Territory on ABI-H2158 and ABI-H3733 but must provide BeiGene pre-Phase 3 clinical study know-how and development results if and when such development efforts are completed. If, after ABI-H2158 and ABI-H3733 reach the end of Phase 2 clinical studies, the Company and BeiGene are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the BeiGene Agreement solely as it relates to that compound, as applicable. Such a termination would result in Assembly regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the BeiGene Agreement for convenience at any time upon 90 days' advance written notice to Assembly. The BeiGene Agreement also contains customary provisions for termination by either party, including in the event of breach of the BeiGene Agreement, subject to cure.

Pursuant to the terms of the BeiGene Agreement, the Company received an upfront cash payment of $40.0 million from BeiGene for the delivery of exclusive, royalty-bearing licenses to develop and commercialize the Licensed Product Candidates in the Territory, and the Company is eligible to receive up to approximately $500.0 million in cash milestone payments, comprised of up to $113.8 million for development and regulatory milestones and up to $385.0 million in net sales milestones. In addition, the Company is eligible to receive tiered royalties at percentages ranging from the mid-teens to the low thirties of net sales.

The BeiGene Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of commercializing the Licensed Product Candidates in the Territory but that the unit of account related to the delivery of Licensed Product Candidates is within the scope of the contract with customers guidance. The remaining units of account related to participation on the JSC and subcommittees, clinical supply and other in Territory and global development activities (the Collaboration Activities) are within the scope of the collaborative arrangements guidance. Commercial supply will be evaluated as a separate contract when the agreement is executed and a purchase order is received from BeiGene.

The Company identified the following material promises related to the contract with customers unit of account under the BeiGene Agreement: (1) the transfer of the VBR License; (2) the transfer of the ABI-H2158 License; and (3) the transfer of the ABI-H3733 License. The Company concluded each of these licenses to be functional as they have significant standalone functionality and grants BeiGene the right to use the Company's intellectual property as it exists on the effective date of the license. The ABI-H2158 and ABI-H3733 Licenses have a continuing technology transfer obligation that is considered to be an attribute of these licenses. The agreed upon prices for the clinical and

commercial supply of the Licensed Product Candidates to BeiGene do not represent material rights, and therefore are not performance obligations, and such pricing on an aggregate basis represents the standalone selling price an entity would typically pay for such a product in that region or market. There are also no minimum purchase commitments.

The Company estimated the standalone selling price (SSP) of the Licenses using an income-based valuation approach for the estimated value a licensor of the compounds would receive considering the stage of the compound's development. The Company believes a change in the assumptions used to determine its best estimate of SSP would not have a significant value on the allocation of consideration received.

The transaction price at the inception of the agreement was limited to the $40.0 million upfront payment. The variable consideration related to the remaining development and commercialization milestone payments has not been included in the transaction price as these were fully constrained as of March 31, 2021. As part of the Company's evaluation of the development and commercialization milestones constraint, the Company determined the achievement of such milestones are contingent upon success in future clinical studies and regulatory approvals which are not within its control and uncertain at this stage. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the Licensed Product Candidates granted to BeiGene. The Company will reevaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

Upon entering into the BeiGene Agreement in July 2020, the Company recognized $31.0 million as collaboration revenue for the amount allocated to the VBR License as substantial completion of the license technology transfer had occurred. The remaining transaction price allocated to the ABI-H2158 and ABI-H3733 Licenses of $9.0 million was recorded as a long-term deferred revenue contract liability on the unaudited condensed consolidated balance sheet as of March 31, 2021 and December 31, 2020. Revenue for these performance obligations will be recognized when the Company provides pre-Phase 3 clinical study know-how and development results for these compounds to BeiGene or a termination of the BeiGene Agreement for the respective compound.

Payments to, or reimbursements from, BeiGene related to the Collaboration Activities will be accounted for as an increase to or reduction of research and development expenses when incurred or realized, respectively. During the three months ended March 31, 2021, the Company did not recognize any increase or reduction of research and development expense under the BeiGene Agreement.

The Company incurred $3.5 million in incremental costs of obtaining the BeiGene Agreement. These contract costs have been capitalized and are being recognized consistent with the pattern of recognition of revenue associated with the Licensed Product Candidates. As of March 31, 2021 and December 31, 2020, $0.8 million remains unamortized and is included in other assets on the condensed consolidated balance sheet.

Arbutus Agreement

In August 2020, the Company and Arbutus Biopharma Corporation (Arbutus) entered into a Clinical Trial Collaboration Agreement (the Arbutus Agreement) to conduct a randomized, multi-center, open-label Phase 2 clinical study to explore the safety, PK and antiviral activity of the triple combination of VBR, AB-729 and a nucleos(t)ide reverse transcriptase inhibitor (NrtI) compared to the double combinations of VBR plus NrtI and AB-729 plus NrtI. Assembly and Arbutus will share responsibility for the costs of the study equally, excluding manufacturing supply which will be the burden of each company to supply their respective drugs VBR and AB-729.

The Arbutus Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of the collaborative activity. Arbutus is not a customer as it does not obtain an output from the collaborative activities as they were not provided an exclusive license to VBR or the ability to manufacture VBR, and the Company does not consider performing such collaborative activities to be a part of its ongoing activities.

The revenue from contracts with customers guidance was considered by analogy in determining the unit of account, and the recognition and measurement of such unit of account for collaborative activities under the Arbutus Agreement and concluded there is one activity, to run an open-label Phase 2 clinical study, which is akin to performance obligation related to collaborative activities. Reimbursements and cost-sharing portions of this

performance obligation will be reflected as a reduction of research and development expense when realized in the Company's condensed consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations. During the three months ended March 31, 2021, the Company recognized a reduction of research and development expenses of $0.5 million under the Arbutus Agreement.

Contract Liabilities

The following table presents changes in the Company's contract liabilities (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months Ended March 31, 2021				
Contract liabilities:				
Deferred revenue	$ 8,987	$ —	$ —	$ 8,987

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months Ended March 31, 2020				
Contract liabilities:				
Deferred revenue	$ 37,048	$ —	$ (1,007)	$ 36,041

Note 9 - Milestones and Research Agreements

HBV Research Agreement with Indiana University

Since September 2013, the Company has been party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it has licensed aspects of the Company's HBV program held by IURTC. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, should all milestones through development be met, is $0.8 million, with a portion related to the first performance milestone having been paid. The Company is obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly receives. The Company is also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than such fees for that year. No amounts were paid in the three months ended March 31, 2021. Amounts paid in the three months ended March 31, 2020 were insignificant.

Microbiome Targeted Colonic Delivery Platform

In November 2013, the Company entered into a License and Collaboration Agreement with Therabiome, LLC (Therabiome), for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release capsule-in-capsule technology. The Company was solely responsible for all research and development activities with respect to any product it developed under the license.

The Company was obligated to pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. In addition, the Company was obligated to pay Therabiome lesser amounts for foreign regulatory milestones, which varied by country and region. The Company was also required to pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceeded certain thresholds, a one-time cash payment upon reaching such thresholds.

Therabiome was obligated to pay the Company royalties on annual net sales of any product Therabiome was permitted to develop using the intellectual property in the low double to mid-double-digit percentages, depending on the level of development or involvement the Company had in the product.

No amounts were accrued for this agreement as of and for the three months ended March 31, 2021 or 2020. In connection with the wind-down of the Microbiome program, the License and Collaboration Agreement with Therabiome was terminated in January 2021, and the termination became effective on April 21, 2021.

Door Agreement

In November 2020, the Company and Door Pharmaceuticals, LLC (Door) entered into an exclusive, two-year Collaboration Agreement and Sublicense Agreement (collectively, the Door Agreement) focused on the development of a novel class of HBV inhibitors. Under the terms of the agreement, Door will build upon its previous efforts to lead and conduct new discovery research, which the Company will fund. In return for an up-front payment of $1.8 million, success-based milestones up to $35.0 million, exercise and annual fees ranging from $0.1 million to $2.0 million and royalties in the low to mid-single digits, the Company will be granted an exclusive option to license compounds arising from the collaboration and will be responsible for the continued development and commercialization of optioned compounds. For the three months ended March 31, 2021, the Company incurred $0.4 million of research and development funding.

Under the consolidation accounting standard, the Company determined that Door is a variable interest entity. The Company does not have the power to direct the activities that most significantly affect the economic performance of Door and as such the Company is not the primary beneficiary and consolidation is not required. As of March 31, 2021, the Company has not provided financial or other support to Door that was not contractually required.

Note 10 - Leases

The Company leases office and laboratory space in South San Francisco, California under a sub-sublease that expires in December 2023. The sub-sublease contains scheduled rent increases over the lease term. The Company also leases office space in Carmel, Indiana under a lease agreement that expires in August 2023. In February 2021, the Company subleased substantially all of the office space under the Carmel, Indiana lease. The Company also leases office and laboratory space in Groton, Connecticut that supported the Microbiome program under a lease that expires in June 2021. Due to the wind-down of the Microbiome program, the lease will not be renewed. The Company's China subsidiary leased office space and lab space in Shanghai, which the Company let expire in March 2021 and December 2020, respectively. Additionally, the Company's China subsidiary leases office space in Beijing under a lease agreement that expires in December 2021. Certain lease contracts contain renewal clauses that the Company assesses on a case-by-case basis. The Company also leases certain laboratory equipment accounted for as operating leases expiring at various dates, with the final lease expiring in 2023. In February 2021, the Company purchased substantially all of the leased equipment used for the Microbiome program from its leasing agency and sold them to third parties (see Note 5).

When the Company cannot determine the implicit rate in its leasing arrangements, the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment.

At March 31, 2021, the Company had operating lease liabilities of $8.6 million and ROU assets of $8.1 million.

The following summarizes quantitative information about the Company's operating leases (in thousands):

	Three Months Ended March 31,	
	2021	2020
Lease cost		
Operating lease cost	$ 1,135	$ 1,151
Short-term lease cost	103	100
Variable lease cost	343	284
Sublease income	(27)	—
Total lease cost	$ 1,554	$ 1,535

	Three Months Ended March 31,	
	2021	2020
Operating cash flows from operating leases	$ 1,041	$ 1,120
ROU assets exchanged for new operating lease liabilities	$ 42	$ 362

As of both March 31, 2021 and December 31, 2020, the weighted-average remaining lease term for operating leases was 2.7 years. As of March 31, 2021 and December 31, 2020, the weighted-average discount rate for operating leases was 9.7% and 9.2%, respectively.

As of March 31, 2021, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Nine months ending December 31, 2021	$ 2,724
Year Ending December 31, 2022	3,612
Year Ending December 31, 2023	3,460
Total	9,796
Less: present value discount	(1,218)
Operating lease liabilities	$ 8,578

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

The interim condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission on February 25, 2021 (2020 Annual Report). In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under "Part I. Item 1A. Risk Factors" in our 2020 Annual Report and "Part II. Item 1A. Risk Factors" in this report.

Overview

We are a clinical-stage biotechnology company advancing a novel class of oral therapeutic candidates for the treatment of chronic hepatitis B virus (HBV) infection. According to the World Health Organization (WHO), approximately 270 million people worldwide are chronically infected with HBV. Our research and development programs are pursuing multiple drug candidates designed to inhibit the HBV replication cycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of discovering and developing finite and curative therapies for patients with chronic HBV infection. We have discovered several novel core inhibitors, which are small molecules that directly target and allosterically modulate the HBV core (HBc) protein in a way that affects assembly and stability of HBV nucleocapsids.

The ongoing COVID-19 pandemic has affected certain aspects of our business. As further detailed below, those effects have been primarily limited to where and how our employees work in our labs and offices. To date, our current and future planned clinical and nonclinical studies have not been subject to significant impact as a result of the COVID-19 pandemic.

As previously announced, in January 2021, we wound down our Microbiome program to prioritize and focus our resources on discovering and developing finite and curative therapies for chronic HBV infection.

Our Primary Focus: Targeting HBV Core Protein to Achieve a Cure

HBV is a DNA virus that infects hepatocytes and establishes a reservoir of cccDNA, a unique viral DNA species that resides in the nucleus of HBV-infected hepatocytes and is associated with viral persistence and chronic infection. No currently approved oral therapies target cccDNA activity directly, which makes molecules that can modulate cccDNA generation or disrupt its function highly sought in the HBV field. As a result, most of our research and development efforts to date have focused on discovering and developing compounds targeting the core protein, a viral protein involved in numerous aspects of the HBV replication cycle, including the generation of HBV cccDNA. Through our research efforts, we have discovered several chemically distinct series of small molecule core inhibitors that directly target and allosterically inhibit core protein functions.

Vebicorvir

Vebicorvir (VBR), our lead core inhibitor product candidate, is licensed from Indiana University. The conduct of our initial Phase 2 studies, Study 201 and 202, is complete. Our open-label extension study, Study 211, involved treating patients with VBR plus nucelos(t)ide analog reverse transcriptase inhibitors (NrtIs) and ultimately transitioning patients who met the requisite stopping criteria, as determined with our lead investigators and the U.S. Food and Drug Administration (FDA), off of therapy to test for sustained virologic response (SVR). SVR refers to sustained viral suppression (more than six months) of HBV DNA below the lower limit of quantification (LLOQ) and would be consistent with a successful finite treatment for chronic HBV infection. In November 2020, it became clear that patients who stopped therapy in Study 211 had not achieved meaningful SVR rates, as 39 of 41 patients relapsed, meaning they had detectable HBV, and that dual combination therapy of VBR plus NrtIs is insufficient to cure chronic HBV infection. Based on these results, we terminated Study 211 in the fourth quarter of 2020. We plan to present additional follow-up from Study 211 related to virologic response, safety and resistance following treatment discontinuation, at the European Association for the Study of the Liver's (EASL) International Liver Congress™ in June 2021 (EASL 2021).

Based on discussions with leading viral hepatitis experts, global regulatory discussions and feedback and, with respect to the China territory, discussions and agreement with our collaboration partner, BeiGene, Ltd. (BeiGene),

we recently decided to not move forward with the global registrational studies for VBR as a chronic suppressive treatment (CST) with NrtIs. The decision was made to focus on the greatest unmet medical need of patients, which lies predominantly in cure, rather than CST. In connection with focusing our efforts with VBR moving forward in combination with NrtIs and additional mechanisms targeting finite and curative combination therapy, we terminated Study 205 in the first quarter of 2021. Study 205 had been initiated to evaluate treatment intensification with VBR in patients with chronic HBV infection who are only partially virologically suppressed on NrtI.

ABI-H2158

Our second-generation core inhibitor product candidate, ABI-H2158 (2158), was internally discovered and developed and is chemically distinct from VBR.

We reported the final data from dose-ranging cohorts of the Phase 1b portion of the Phase 1a/1b dose-ranging clinical study at EASL in August 2020. Based on data from the Phase 1b dose-ranging study, we initiated a Phase 2 clinical study in June 2020 using a 300 mg daily dose of 2158. This study is being conducted in approximately ten countries in Asia, North America and Europe. We expect interim data from this study in the second half of 2021. While we will continue to monitor the situation closely, we do not currently expect our timelines for this study to be significantly impacted by the COVID-19 pandemic.

ABI-H3733

Our third core inhibitor product candidate, ABI-H3733 (3733), has completed Investigational New Drug (IND) enabling studies. 3733 has a novel chemical scaffold separate from both VBR and 2158. We presented a preclinical profile of this candidate in the first quarter of 2019.

In the first quarter of 2020, we initiated a Phase 1a clinical study to evaluate safety, tolerability and pharmacokinetics (PK) following single ascending dose and multiple ascending dose administration of 3733 in healthy subjects in New Zealand. Conduct for the study was completed in the fourth quarter of 2020 and preliminary data indicate that 3733 was generally well-tolerated and had favorable PK.

We expect to present observations on the enhanced potency and target coverage for both antiviral inhibition and inhibition of cccDNA generation for our next generation core inhibitors 2158 and 3733 at EASL 2021.

Additional Product Candidates

In addition to our three clinical-stage product candidates, our research discovery team is actively focused on identifying and selecting a fourth core inhibitor candidate, which we anticipate in the first half of 2021.

Multi-Drug Combination Studies

We believe that core inhibitors and NrtIs will be central to finite and curative therapies for chronic HBV infection. Therefore, as we continue to develop and advance our current and future core inhibitors through clinical studies, we have begun to conduct multi-drug combination studies in parallel that add additional drugs (or compounds) with non-overlapping mechanisms of action to the core inhibitor + NrtI antiviral backbone. Specifically, we plan to only incorporate our current and future core inhibitors that have demonstrated they are well-tolerated and effective in clinical studies in dual combination with NrtI. As the 300 mg daily dose of VBR has been observed to be well-tolerated in all studies conducted to date, with no serious adverse effects or dose-limiting toxicities identified and no pattern of treatment-emergent clinical or laboratory abnormalities observed, we are exploring the 300mg VBR + NrtI antiviral backbone in two triple combination studies.

Our first triple combination study is being conducted pursuant to a Clinical Trial Collaboration Agreement with Arbutus Biopharma Corporation (Arbutus Biopharma) and consists of a randomized, multi-center, open-label Phase 2 clinical study to explore the safety, PK and antiviral activity of the triple combination of VBR, NrtI and AB-729 (Arbutus Biopharma's investigational RNAi candidate) compared to the dual combinations of VBR + NrtI and AB-729 + NrtI in virologically suppressed subjects. Our second triple combination study evaluates VBR and NrtI in combination with pegylated interferon alfa in treatment-naïve HBeAg positive subjects. Both studies initiated in the first quarter of 2021.

In addition to the above studies, we expect to pursue additional multi-drug combinations that include other or additional non-overlapping mechanisms of action to the core inhibitor + NrtI antiviral backbone.

Beyond Core Inhibitors

In addition to the development and advancement of our core inhibitor portfolio and our current and future multi-drug combination studies, our research and development team is working on discovering and developing a potent fourth core inhibitor, cccDNA disruptors and small molecules targeting novel undisclosed targets to add to the core inhibitor + NrtI antiviral backbone to achieve finite and curative therapies. In November 2020, we entered into an exclusive, two-year collaboration and option agreement with Door Pharmaceuticals (Door Pharma) focused on the development of a novel class of HBV inhibitors. Door Pharma's discovery platform targets functions of HBV core protein distinct from viral assembly and has the potential to interfere with viral nucleic acid, including intra-nuclear cccDNA. Together with Door Pharma, we are working on identifying cccDNA disruptors, which will be aimed at inhibiting different intra-nuclear steps in the viral replication cycle that complement the activity of our core inhibitors.

Under the terms of the agreement, Door Pharma will build upon its previous efforts to lead and conduct new discovery research, which we will fund. In return for an up-front payment and success-based milestones and royalties, we received an exclusive option to license compounds arising from the collaboration and will be responsible for the continued development and commercialization of optioned compounds.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California and a small office in China. Until the lease expires in June 2021, we also have administrative office and laboratory space in Groton, Connecticut that was used by our Microbiome program prior to the program being wound down.

Since our inception, we have had no revenue from product sales and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings and collaborations since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovering and developing our product candidates, maintaining and improving our patent portfolio and raising capital.

We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of March 31, 2021, we had an accumulated deficit of $528.8 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In mid-March 2020, as a result of the COVID-19 pandemic, six San Francisco Bay Area counties announced a shelter-in-place order, restricting all residents to their homes, with few exceptions. Within a week, California issued a statewide stay-at-home order. As a biotechnology company, we were exempt from such orders. While California has begun reopening on a tiered county-by-county basis, with counties assigned to tiers based on positivity rate, adjusted case rate and a health equity metric, both the statewide and local orders remain in place.

Because of the exemptions described above, there has not been any significant interruption to date of essential activities at our offices, including work in our laboratories with proper protections and procedures in place. While we have experienced some shipping delays or shortages of personal protective equipment (PPE) that are important to maintaining normal workflows in our laboratories, we have been able to continue our critical research activities through schedule shifts, use of PPE on-hand and reallocation of certain resources that allow our employees to practice "social distancing" and comply with applicable laws. Substantially all of our U.S.-based non-research employees have been working from their homes since mid-March 2020. Clinical study-related impacts of the COVID-19 pandemic to date have been limited to short enrollment delays for our Phase 1 study of 3733. We continually work with our contract research organizations (CROs) and other vendors to ensure, to the extent possible, that services are provided in a timely manner while also identifying alternative vendors and strategies to utilize in the event that COVID or third party-related delays threaten our ability to meet our timelines. We cannot currently predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our ongoing and planned research efforts, clinical studies and other business operations. We continue to monitor the situation regularly for additional potential delays, or modifications to our ongoing and planned studies and, if circumstances warrant, we may adjust our budget and operating plan.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses.

We evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation, on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and significant estimates are detailed in our 2020 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2020 Annual Report, except for those accounting subjects discussed in the section of Note 2 to the unaudited condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements included in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

Collaboration Revenue

The following table summarizes the period-over-period changes in our collaboration revenue (in thousands, except for percentages):

	Three Months Ended March 31,		$ Change	% Change
	2021	2020	2021 vs. 2020	2021 vs. 2020
Collaboration revenue	$ —	$ 4,081	$ (4,081)	-100%

Collaboration revenue for the three months ended March 31, 2020 includes the recognition of deferred revenue and reimbursements incurred under Research, Development, Collaboration and License Agreement (the Allergan Agreement) that we entered into with Allergan Pharmaceuticals Limited (Allergan). Following its acquisition of Allergan, AbbVie, Inc. (AbbVie) gave written notice of termination of the Allergan Agreement in June 2020 which became effective October 2020.

Research and Development Expense

The following table summarizes the period-over-period changes in our research and development expenses (in thousands, except for percentages):

	Three Months Ended March 31,		$ Change	% Change
Program/Description	2021	2020	2021 vs. 2020	2021 vs. 2020
HBV Cure program	$ 19,358	$ 15,636	$ 3,722	24%
Microbiome program	(804)	7,410	(8,214)	-111%
Total research and development expenses	$ 18,554	$ 23,046	$ (4,492)	-19%

Research and development expenses were $18.6 million for the three months ended March 31, 2021 compared to $23.0 million for the same period in 2020. The decrease was due to a decrease of $8.2 million in research and development expenses related to the Microbiome program due to the wind-down of the Microbiome program and includes the reversal of $2.4 million of previously recognized stock-based compensation expense related to forfeited awards of terminated employees. This decrease was partially offset by an increase of $3.7 million in research and development expenses related to the HBV program, which were primarily due to increases in clinical activities, chemistry and manufacturing control activities to support our clinical studies and increased salary and benefits due to additional employees. Research and development expenses include $2.1 million in a net reversal of non-cash

stock-based compensation expense as a result of forfeited awards for the three months ended March 31, 2021 compared to $1.9 million of non-cash stock-based compensation expense for the same period in 2020.

General and Administrative Expense

The following table summarizes the period-over-period changes in our general and administrative expenses (in thousands, except for percentages):

	Three Months Ended March 31,		$ Change	% Change
	2021	2020	2021 vs. 2020	2021 vs. 2020
General and administrative expenses	$ 8,704	$ 8,729	$ (25)	0%

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services, accounting and tax services, insurance and travel expenses, as well as stock-based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expenses were $8.7 million for both the three months ended March 31, 2021 and 2020. General and administrative expenses include non-cash stock-based compensation expenses of $1.8 million for the three months ended March 31, 2021 and $3.0 million for the same period in 2020. The decrease in stock-based compensation expense of $1.2 million was in part due to the reversal of $0.5 million of previously recognized expense related to forfeited awards from terminated employees as well as a decrease in the grant-date fair value of recent option grants. This decrease in stock-based compensation expense was offset by increases of $0.2 million in salary and benefits and $0.2 million in recruitment expenses due to additional employees and $0.7 million in lease-related costs largely attributable to asset impairment and other charges in connection with restructurings.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through March 31, 2021 principally through equity financings, raising an aggregate of $586.0 million in net proceeds, and strategic collaborations, raising an aggregate of $90.0 million through upfront payments.

Cash Flows for the Three Months Ended March 31, 2021 and 2020

The following table summarizes our cash flow activities (in thousands):

	Three Months Ended March 31,	
Cash provided by (used in):	2021	2020
Operating activities	$ (33,344)	$ (25,218)
Investing activities	18,016	20,693
Financing activities	34,137	119

Net Cash from Operating Activities

Net cash used in operating activities was $33.3 million for the three months ended March 31, 2021. This was primarily due to a $27.2 million net loss, $0.1 million of accretion of discount of marketable securities and a decrease of $8.8 million of operating assets and liabilities. These decreases were partially offset by $1.1 million amortization of operating lease right-of-use (ROU) assets, $0.3 million net reversal of non-cash stock-based compensation recognized as a result of forfeited awards from terminated employees, $0.1 million depreciation and amortization expense and a $1.6 million loss on the sale of purchased leased equipment in connection with the wind-down of the Microbiome program.

Net cash used in operating activities was $25.2 million for the three months ended March 31, 2020. This was primarily due to a $26.7 million net loss, $0.1 million accretion of discount of marketable securities and a decrease of $4.6 million of operating assets and liabilities, which were offset by $4.9 million non-cash stock-based

compensation expense, $1.2 million amortization of operating lease ROU assets and $0.1 million depreciation and amortization expense.

Net Cash from Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2021 was $18.0 million due to $66.5 million of redemptions of marketable securities and $3.0 million of sale of marketable securities, which were partially offset by the purchase of $49.2 million of marketable securities. Additionally, the Company purchased leased equipment for $3.1 million that it sold for $0.9 million in connection with the wind-down of the Microbiome program.

Net cash provided by investing activities for the three months ended March 31, 2020 was $20.7 million due to $55.0 million of redemptions of marketable securities and $10.0 million of sale of marketable securities, which were partially offset by the purchase of $44.2 million of marketable securities and $0.1 million of property and equipment.

Net Cash from Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 was $34.1 million resulting from sale of 6.0 million shares of our common stock through “at-the-market” offerings, net of commissions and fees.

Net cash provided by financing activities for the three months ended March 31, 2020 was $0.1 million resulting from the exercise of stock options to purchase 16,834 shares of common stock.

Funding Requirements

We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so numerous times since our initial public offering by issuing equity securities, most recently in March 2021. We expect to continue to raise capital when and as needed and at the time and in the manner most advantageous to us.

We expect that our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- the extent to which we further acquire or in-license other product candidates and technologies;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting nonclinical testing and clinical studies 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 and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt 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 additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. 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 or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

There were no material changes in our commitments under contractual obligations as disclosed in our 2020 Annual Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our 2020 Annual Report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that is designed to provide reasonable assurance that information that is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in 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

We are not a party to any material legal proceedings. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

You should carefully consider the following risk factors, together with all other information in this report, including our consolidated financial statements and notes thereto, and in our other filings with the SEC. If any of the following risks, or other risks not presently known to us or that we currently believe to not be material, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and depend on the future success of our HBV program. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from our current pipeline or any other product candidates that we may subsequently identify, license or otherwise acquire.

We and our collaborators are not permitted to market or promote any product candidates in the United States, Europe, China or other countries before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted a new drug application (NDA) to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so in the near future.

All of our product candidates are in clinical development or in varying stages of nonclinical development. Data supporting our drug discovery and nonclinical and clinical development programs are derived from laboratory studies, nonclinical studies and Phase 1 and Phase 2 clinical studies. It may be years before the larger, pivotal studies necessary to support regulatory approval of our current product candidates are completed, if ever.

In addition to our current product pipeline, we may identify, license or otherwise acquire rights to other technologies or product candidates. Any such transactions would involve numerous risks, and we may be unsuccessful in entering into any such transactions or developing any such technologies or product candidates.

For these reasons, our drug discovery and development may not be successful, and we may be unable to continue clinical development of our product candidates and may not generate product approvals or product revenue, any of which could have a material adverse impact on our business, results of operations and financial condition.

The COVID-19 pandemic may materially and adversely affect our business.

The continued spread of COVID-19 could adversely impact our research and development through delay, modification or suspension of our clinical and/or nonclinical studies. Other clinical-stage biotechnology companies, like us, have had their clinical and nonclinical studies affected by the COVID-19 pandemic.

The COVID-19 pandemic has and may continue to: (1) impact patient enrollment, retention or compliance with clinical study protocols; (2) require modifications to, or deviations from, study protocols and procedures, such as the use of telehealth and home health visits instead of on-site monitoring and treatment, which could increase the cost of, and time for, conducting clinical studies; (3) disrupt or suspend the business operations of our third-party CROs, manufacturers of our drug candidates and the clinical sites conducting our clinical studies; (4) delay regulatory meetings and filings with regulatory agencies in the United States and other countries; and (5) disrupt supply chains and cause delays of shipments of critical reagents, PPE and disinfectants, each of which are necessary for our laboratories and our CROs' laboratories to maintain normal workflows. Even if we are able to timely collect clinical data while the pandemic is ongoing, COVID-19 may negatively affect the quality, completeness, integrity, interpretability and cost of obtaining such clinical study data.

The full extent of the pandemic's impact on our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and severity of the pandemic and the effectiveness of actions for containment, treatment and prevention of COVID-19. However, any COVID-19-related business interruptions or delays could materially and adversely affect our ability to conduct our research and development activities in the manner and on the timelines presently planned as well as negatively affect the accuracy of our estimates regarding capital requirements, needs for additional financing and our ability to produce accurate and timely financial statements. Any of these disruptions could have a material adverse impact on our business, results of operations, financial condition and share price.

As a result of the COVID-19 pandemic, governments around the world implemented significant measures to control the spread of the virus, including quarantines, travel restrictions, stay-at-home orders and business shutdowns. While governments have relaxed these measures as cases numbers go down, periodic surges in COVID-19 cases have, and may in the future, prompted many governments to reimplement these restrictions, including in Europe and the United States. We continue to take precautionary measures intended to minimize our employees' potential exposure to the virus, including temporarily requiring all employees who are able to do so to work remotely and suspending all non-essential business travel worldwide for our employees. Requiring our employees to work remotely may disrupt our operations, increase the risk of a cybersecurity incident or otherwise negatively affect our business.

In addition to the risks related to the COVID-19 pandemic discussed above, the uncertainty surrounding, and risks created by, the pandemic may have the effect of heightening many of the other risks discussed in this section impacting our operations.

We are not currently profitable and might never become profitable, and we will need additional financing to complete the development of any product candidates and fund our activities into the future.

We do not have any approved products, and we have a history of losses. We expect to continue to incur substantial operating and capital expenditures to advance our current product candidates through clinical development, continue research and discovery efforts to identify potential additional product candidates and seek regulatory approvals for our current and future product candidates. All operations and capital expenditures will be funded from cash on hand, securities offerings or debt financings and payments we may receive from out-licensing, collaborations or other strategic arrangements. However, there is no assurance that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If we are unable to develop and commercialize any product candidates and generate sufficient revenue or raise capital, we could be forced to delay, scale back or discontinue product development and clinical studies, sacrifice attractive business opportunities, cease operations entirely and sell, or otherwise transfer, all or substantially all of our remaining assets, which would likely have a material adverse impact on our business, results of operations, financial condition and share price.

Nonclinical and clinical studies required for our product candidates are expensive and time-consuming and may fail to demonstrate the level of safety and efficacy necessary for product approval.

Before we or any commercial partners can obtain FDA approval (or other foreign approvals) necessary to sell any of our product candidates, we must show that each potential product is safe and effective. To meet these requirements, we must conduct extensive nonclinical and sufficient, well-controlled clinical studies.

The results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of our clinical studies. In addition, the results of early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies.

Conducting nonclinical and clinical studies is a lengthy, time consuming and expensive process. The length of time varies substantially according to the type, complexity, novelty and intended use of the product candidate and often can be several years or more. In addition, failure or delays can occur at any time during the nonclinical and clinical study process, resulting in additional operating expenses or harm to our business.

The commencement and rate of completion of clinical studies might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on study design;

- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- failure to demonstrate efficacy or the emergence of unforeseen safety issues;
- insufficient quantities of qualified materials under current good manufacturing practice (cGMP) for use in clinical studies due to manufacturing challenges, delays or interruptions in the supply chain;
- slower than expected rates of patient recruitment or failure to recruit a sufficient number of eligible patients, which may be due to a number of reasons, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, and other potential drug candidates being studied;
- delays in patients completing participation in a study or return for post-treatment follow-up for any reason, including, product side effects or disease progression;
- modification of clinical study protocols;
- delays, suspension, or termination of clinical studies by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government or other regulatory agency delays or clinical holds requiring suspension or termination of our clinical studies due to safety, tolerability or other issues related to our product candidates.

The failure of nonclinical and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications, whether conducted by us or by a CRO, would harm the development of that product candidate and potentially other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or failure of, our nonclinical studies or clinical studies could delay, or preclude, the filing of our NDAs and comparable applications with the FDA and foreign regulatory agencies, as applicable, and materially harm our business, prospects, financial condition and results of operations.

We rely on CROs to conduct some of our nonclinical and clinical studies due to our lack of suitable facilities and resources.

We do not have sufficient facilities or resources to conduct all of our anticipated nonclinical and clinical studies internally. As a result, we contract with CROs to conduct a significant portion of the nonclinical and clinical studies required for regulatory approval for our product candidates. Our reliance on CROs reduces our control over these activities but does not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, including, in the case of clinical studies, good clinical practices, even if the study is conducted by a CRO. In the event CROs fail to perform their duties in such a fashion or we are unable to retain or continue with CROs on acceptable terms, we may not be able to complete our clinical studies and may fail to obtain regulatory approval for our product candidates.

Furthermore, these CROs may also have relationships with other entities, some of which may be our competitors. CRO personnel are not 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 clinical and nonclinical studies. If the CROs 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, regulatory requirements or for other reasons, our research, nonclinical studies or clinical studies may be extended, delayed or terminated, and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, any of which could materially harm our business, prospects, financial condition and results of operations.

Top-line or preliminary data may not accurately reflect the final results of a particular study.

We may publicly disclose top-line or preliminary data based on analysis of then-available efficacy, tolerability, pharmacokinetics and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimates, calculations and conclusions as part of our data analyses, and we may not have received or had the

opportunity to fully and carefully evaluate all data prior to release. As a result, the top-line or preliminary results that we report may differ from final results of the same studies or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remains subject to audit and verification procedures that may result in the final data differing materially from previously published preliminary data. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

In addition to top-line or preliminary results, the information we may publicly disclose regarding a particular nonclinical or clinical study is based on extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. In addition, any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with, or do not accept, the data or conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

We rely on third parties to formulate and manufacture our product candidates and products that we study in combination with our product candidates. Our use of third parties may increase the risk that we will not have sufficient quantities of our product candidates or other products on time or at an acceptable cost.

We rely on third-party manufacturers to supply the quantities of VBR, 2158 and 3733 used in our clinical and nonclinical studies. If any product candidate we develop or acquire in the future receives FDA or other regulatory approval, we expect to continue our reliance on one or more third-party contractors to manufacture our products. If, for any reason, we are unable to rely on any third-party sources we have identified to manufacture our product candidates, we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substances and drug products for nonclinical, clinical and commercial purposes. We may be unsuccessful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity, the development and sales of our products and our financial performance may be materially and adversely affected.

We are exposed to the following risks with respect to the manufacture of our product candidates:

- We will need to identify manufacturers for commercial supply on acceptable terms, which we may be unable to do because the number of potential manufacturers is limited, and the FDA must evaluate and approve any new or replacement contractor.
- Any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and quality required to meet our clinical and, if approved, commercial needs in a timely manner.
- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our products.
- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.
- We do not have complete control over, and cannot ensure, any third-party manufacturers' compliance with cGMP and other government regulations and corresponding foreign requirements, including periodic FDA and state regulatory inspections.
- We may be required to obtain intellectual property rights from third parties to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to the innovation.

- We may be required to share our trade secrets and know-how with third parties, increasing risk of misappropriation or disclosure of our intellectual property by or to third parties.

- When contracting with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than we are given.

Each of these risks could delay our development efforts, nonclinical studies and clinical studies or the approval, if any, of our product candidates by the FDA or applicable non-U.S. regulatory authorities and the commercialization of our product candidates. This could result in higher costs or deprive us of potential product revenues and materially harm our business, financial condition and results of operations.

If we lose key management personnel and cannot recruit and retain similarly qualified replacements, our business may materially suffer.

We are highly dependent on the services of our executive officers. Our employment agreements with our executive officers do not ensure their retention. We do not currently maintain, nor do we intend to obtain in the future, "key person" life insurance that would compensate us in the event of the death or disability of any of the members of our management team. Our executive officers are critical to our success, and loss of any of these key employees could have a material adverse impact on our business, financial condition and results of operations.

Fast Track designations for VBR and 2158 may not result in faster development, regulatory review or approval.

If nonclinical or clinical data demonstrate potential to address unmet medical needs for a serious or life-threatening condition, the sponsor may apply for FDA Fast Track designation. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during nonclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Both VBR and 2158 have received Fast Track designation for the treatment of patients with chronic HBV infection. However, even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our product development program. Any such withdrawal could adversely affect our business.

We are dependent on an in-license relationship for VBR.

Our license agreement with Indiana University Research and Technology Corporation (IURTC) imposes diligence requirements on us and requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to VBR, royalty payments if VBR is approved and diligence maintenance fees. These payments will make it less profitable for us to develop VBR than if we owned the technology outright. In addition, if we breach any of our obligations under our license agreement, IURTC may have a right to terminate the license, in which event we could lose our rights to VBR.

Our collaboration partners might delay, prevent, or undermine the success of our product candidates.

Our operating and financial strategy for the development, nonclinical and clinical testing, manufacture, and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish or maintain these collaborations. If a collaboration is terminated, replacement collaborators might not be available on attractive terms, or at all.

The activities of any collaborator will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration is unsuccessful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, a lack of development and marketing collaborations might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We rely on data provided by third parties that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, investigators and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical studies, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Significant disruptions of information technology systems or breaches of data security could materially and adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form and are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have outsourced elements of our information technology infrastructure and, as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, has escalated as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and our efforts to address these problems may not be successful. If unsuccessful, these problems could cause interruptions, delays, cessation of service and other harm to our business and our competitive position, including material disruption of our product development programs. For example, any loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

If a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and non-U.S. privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state breach notification law and the European Union’s General Data Protection Regulation (GDPR). We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Research, development and commercialization goals may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expectations, regarding the timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the clinical development and regulatory approval process. As a result, there can be no assurance that we or any collaborators will initiate or complete clinical development activities, make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, our business could be materially adversely affected, and the price of our common stock could decline.

Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscape for HBV is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We compete with organizations, some with significantly more resources, who are developing competitive product candidates. If our competitors develop effective treatments for HBV or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects could be materially harmed.

Other companies with core inhibitor products may produce negative clinical data, which would adversely affect public and clinical communities' perceptions of our product candidates and may negatively impact regulatory approval of, or demand for, our potential products.

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with core inhibitors. Negative data from clinical studies using a competitor's core inhibitors could adversely impact the perception of the therapeutic use of our product candidates and our ability to enroll patients in clinical studies.

The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of core inhibitors, a novel class of product candidates. Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of core inhibitor product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which more clinical data may be available. Adverse events in our nonclinical or clinical studies or those of our competitors or of academic researchers utilizing core inhibitor therapies, even if not ultimately attributable to our product candidates, and any resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

Risks Related to Our Regulatory and Legal Environment

We are and will be subject to extensive and costly government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Our product candidates are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. Both before and after approval of any product, we and our collaborators, suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary or mandatory product recall; product seizure; interruption of manufacturing or clinical studies; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business.

If we or our collaborators obtain regulatory approval for a particular product, the approval might limit the intended medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in delays in the approval of applications or supplements to approved applications, refusal by a regulatory authority (including the FDA) to review pending market approval applications or supplements to approved applications, untitled letters or warning letters, fines, import and export restrictions, product recalls or seizures, injunctions, total or partial suspension of production, civil

penalties, withdrawals of previously approved marketing applications, recommendations by the FDA or other regulatory authorities against governmental contracts, and/or criminal prosecutions.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We, or any current or future collaborators, cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. To obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe and effective for its intended use. This requires significant research, nonclinical studies, and clinical studies. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe and effective for their indicated uses. The FDA has substantial discretion in the approval process and might require us to conduct additional nonclinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any approval we obtain.

The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might: delay commercialization of, and our ability to derive product revenues from, our product candidates; impose costly procedures on us; and diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory approval and commercialize any of our current or future product candidates. In foreign jurisdictions, we are subject to regulatory approval processes and risks similar to those associated with the FDA described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. If we fail to comply with any applicable federal, state or foreign legal requirement, we could be subject to penalties.

Regulators globally are imposing greater monetary fines for privacy violations. The GDPR applies to any company established in the European Union (EU) as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as

implemented by individual countries. Compliance with the GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products or even prevent us from offering certain products in jurisdictions that we may operate in.

The California Consumer Privacy Act (CCPA) also created new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical study regulations, as currently written, the CCPA may impact our business activities. The uncertainty surrounding the implementation of the CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in drug development. If the use of one or more of our product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical study insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we maintain might not be adequate to cover all liabilities we might incur. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products, our liability could exceed our total assets and our ability to pay. Any successful product liability claims brought against us would decrease our cash and may adversely affect our business, stock price and financial condition.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, comply with federal, state and local laws and regulations for using, storing, handling and disposing of these materials, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially and adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially and adversely affect our business, financial condition and results of operations. We do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future, if necessary, but cannot give assurance that we will obtain such coverage.

Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct, including failure to:

- comply with applicable regulations of, and provide accurate information to, the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the United States Foreign Corrupt Practices Act (the FCPA), the U.K. Bribery Act 2010, the PRC Criminal Law, the PRC Anti-unfair Competition Law and other anti-bribery and trade laws;
- report financial information and data accurately; or
- disclose unauthorized activities.

Misconduct could also involve the improper use or misrepresentation of information obtained during clinical studies, creating fraudulent data in our nonclinical studies or clinical studies or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical studies, or serious harm to our reputation.

It is not always possible to identify and deter misconduct. 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 such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

We have international operations, including in China, and conduct clinical studies outside of the United States. A number of risks associated with international operations could materially and adversely affect our business.

We expect to be subject to a number of risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indication for which our product candidates are being developed;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with the FCPA and other anti-corruption and anti-bribery laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations and compliance with foreign currency exchange rules, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and

- business interruptions resulting from geopolitical actions, including tariffs, war and terrorism, natural disasters or outbreaks of disease.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we and our licensors do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. We cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming, and we may be unable to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We could also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection or before our competitors secure patents covering such discoveries. The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents.

Composition-of-matter patents relating to the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products. Such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s) and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions. Any patent applications that we own or license may fail to result in issued patents. In addition, the U.S. Patent and Trademark Office (the USPTO) and patent offices in other jurisdictions often require that patent applications concerning pharmaceutical and/or biotechnology-related inventions are limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors obtain patents, the patents might be substantially narrower than anticipated.

If patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. The legal systems of certain countries, including China, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights.

Beyond the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors, collaborators, contractors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

We may incur substantial costs as a result of litigation or other proceedings relating to our patents and other intellectual property rights.

We may in the future be involved in legal or administrative proceedings involving our intellectual property, including infringement of our intellectual property by third parties. These lawsuits or proceedings likely would be expensive, consume time and resources and divert the attention of managerial and scientific personnel, even if we were successful in stopping the infringement of such patents. There is a risk that these proceedings will decide that such patents or other intellectual property rights are not valid and that we do not have the right to stop the other party from using our inventions. There is also the risk that, even if the validity of such patents is upheld, the court or administrative agency will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of any product candidates that we develop will not infringe third-party patents.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial costs and monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

The cost of maintaining our patent protection globally is high and requires continuous review and compliance. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees, payments and continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of patents or patent applications and a partial or complete loss of patent rights in the relevant jurisdiction. Such a loss could reduce royalty payments for lack of patent coverage from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing the costs and the potential protections afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in

and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and may infringe our patents in territories which provide inadequate enforcement mechanisms. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Such competition could materially and adversely affect our business and financial condition.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as, or similar to, our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, because of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may damage our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products, often are of lower cost and lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product.

If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. In addition, counterfeit products could be used in nonclinical studies or clinical studies or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims.

In China, although the government has recently increased the lower and upper limits on penalties on producers of counterfeit and substandard pharmaceuticals, these penalties have not eliminated counterfeit pharmaceuticals. As a result, we may be unable to prevent third parties from selling or purporting to sell our products in China. The existence of, and any increase in, the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Our Common Stock

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that, with certain limited exceptions, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or to our stockholders; (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, or our certificate of incorporation or bylaws (as each may be amended from time to time); or (4) any action asserting a claim governed by the internal affairs doctrine. Alternatively, if such court does not have jurisdiction, the Superior Court of Delaware, or, if such other court does not have jurisdiction, the United States District Court for the District of Delaware, will be the sole and exclusive forum for such actions and proceedings. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse impact on our business. The choice of forum provision in our amended and restated bylaws will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the federal securities laws, including the Exchange Act or the Securities Act, or the respective rules and regulations promulgated thereunder.

The price of our common stock might fluctuate significantly, and you could lose all or part of your investment.

The price of our common stock fluctuates widely. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock may continue to be volatile and subject to wide price fluctuations in response to various factors, many of which are beyond our control, such as the progress, results and timing of our clinical studies and nonclinical studies and other studies involving our product candidates, the success or failure of our product candidates, the receipt or loss of required regulatory approvals for our product candidates, the availability of capital or the other risks discussed in this "Risk Factors" section.

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

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

(a) *Exhibits.* The following exhibits are filed as part of this quarterly report on Form 10-Q:

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
3.1	Amended and Restated Bylaws of Assembly Biosciences, Inc, effective January 22, 2021.		8-K	01/27/2021	3.1
10.1#	Assembly Biosciences, Inc. 2021 Corporate Bonus Plan.		8-K	02/17/2021	10.1
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).	X			

Represents management contracts or compensatory plans or arrangements.

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Assembly Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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

Assembly Biosciences, Inc.

Date: May 6, 2021

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: May 6, 2021

By: /s/ Thomas J. Russo, CFA
Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, John G. McHutchison, A.O., M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: May 6, 2021

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Thomas J. Russo, CFA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: May 6, 2021

By: /s/ Thomas J. Russo, CFA
Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, John G. McHutchison, A.O., M.D., Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: May 6, 2021

EXHIBIT 32.2

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 Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Thomas J. Russo, CFA, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Thomas J. Russo, CFA

Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer)

Date: May 6, 2021