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, 2020

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 definition 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 4, 2020, there were 32,722,365 shares of the registrant's common stock outstanding.

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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, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 42,326	$ 46,732
Marketable securities	206,803	227,311
Accounts receivable from collaboration	3,055	3,374
Prepaid expenses and other current assets	4,568	5,363
Total current assets	256,752	282,780
Property and equipment, net	1,780	1,830
Operating lease right-of-use (ROU) assets	11,479	11,975
Other assets	1,661	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 313,310**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,104	$ 1,731
Accrued clinical expenses	4,633	4,826
Other accrued expenses	4,430	8,286
Deferred revenue - short-term	6,715	6,411
Operating lease liabilities - short-term	3,264	3,186
Total current liabilities	21,146	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	29,326	30,637
Operating lease liabilities - long-term	8,539	9,082
Total liabilities	**61,542**	**66,690**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2020 and December 31, 2019; 32,624,725 and 32,558,307 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	32	32
Additional paid-in capital	717,898	712,807
Accumulated other comprehensive loss	(86)	(201)
Accumulated deficit	(466,076)	(439,421)
Total stockholders' equity	251,768	273,217
Total liabilities and stockholders' equity	**$ 313,310**	**$ 339,907**

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,	
	2020	**2019**
Collaboration revenue	$ 4,081	$ 3,885
Operating expenses:		
Research and development	23,046	22,704
General and administrative	8,729	9,517
Total operating expenses	31,775	32,221
Loss from operations	**(27,694)**	**(28,336)**
Other income		
Interest and other income, net	1,039	1,277
Total other income	1,039	1,277
Loss before income taxes	**(26,655)**	**(27,059)**
Income tax benefit	-	7
Net loss	**$ (26,655)**	**$ (27,052)**
Other comprehensive (loss) income		
Unrealized gain on marketable securities, net of tax	115	108
Comprehensive loss	**$ (26,540)**	**$ (26,944)**
Net loss per share, basic and diluted	$ (0.76)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	35,079,756	25,668,798

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,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (26,655)	$ (27,052)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	115	135
Stock-based compensation	4,924	6,577
Net accretion and amortization of investments in marketable securities	(135)	(592)
Non-cash rent expense	1,151	1,091
Deferred income tax benefit	—	(7)
Loss on disposal of fixed assets	—	102
Other	—	(1)
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	319	(557)
Prepaid expenses and other current assets	795	(2,558)
Other assets	23	1,687
Accounts payable	373	(1,266)
Accrued clinical expenses	(193)	3,077
Other accrued expenses	(3,808)	(2,679)
Deferred revenue	(1,007)	(859)
Operating lease liabilities	(1,120)	(1,037)
Net cash used in operating activities	(25,218)	(23,939)
Cash flows from investing activities		
Purchases of property and equipment	(65)	(1,488)
Purchases of marketable securities	(44,242)	(49,030)
Proceeds from maturities of marketable securities	55,000	61,453
Proceeds from sale of marketable securities	10,000	500
Net cash provided by investing activities	20,693	11,435
Cash flows from financing activities		
Proceeds from the exercise of stock options	119	140
Net cash provided by financing activities	119	140
Net decrease in cash and cash equivalents	(4,406)	(12,364)
Cash and cash equivalents at the beginning of the period	46,732	41,471
Cash and cash equivalents at the end of the period	**$ 42,326**	**$ 29,107**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ 362	$ 13,933

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 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 restricted stock units (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**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2018	**25,495,425**	**$ 25**	**$ 552,762**	**$ (347)**	**$ (341,787)**	**$ 210,653**
Issuance of common stock upon exercise of stock options	21,000	—	140	—	—	140
Issuance of shares of common stock for settlement of RSUs	33,332	1	(1)	—	—	—
Settlement of RSUs for cash	—	—	(4)	—	—	(4)
Unrealized gain on marketable securities, net of tax	—	—	—	108	—	108
Stock-based compensation	—	—	6,556	—	—	6,556
Net loss	—	—	—	—	(27,052)	(27,052)
Balance as of March 31, 2019	**25,549,757**	**$ 26**	**$ 559,453**	**$ (239)**	**$ (368,839)**	**$ 190,401**

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 two innovative programs: a novel class of oral therapeutic candidates targeting chronic hepatitis B virus (HBV) infection and a novel class of oral live microbial biotherapeutic candidates, which are designed to treat disorders associated with the microbiome. The Company operates in one segment and is headquartered in South San Francisco, California, with operations in South San Francisco, California and Groton, Connecticut. Prior to January 1, 2020, the Company was headquartered in Carmel, Indiana, and the Company expects to continue maintaining this office for a period of time.

The Company's HBV Cure program is pursuing multiple drug candidates that inhibit the HBV lifecycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rates for patients with chronic HBV infection. Assembly has discovered several novel core inhibitors, which are small molecules that directly target and allosterically modify the HBV core protein.

The Company's Microbiome program is centered on a fully integrated platform that includes a biological function-based strain isolation, identification, characterization and selection process, methods for strain purification and growth under conditions compliant with current Good Manufacturing Practice (cGMP) requirements. That platform is complemented by a licensed patented delivery system that the Company calls GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. Using the Company's microbiome platform, the Company is exploring product candidates for multiple disease indications, including ulcerative colitis (UC), Crohn's disease and irritable bowel syndrome (IBS) with Allergan Pharmaceuticals International Limited (Allergan) in connection with its Research, Development, Collaboration and License Agreement (the Collaboration Agreement). Assembly is also exploring the microbiome in connection with immune-mediated and metabolic disorders and oncology, which indications the Company will either pursue internally or in collaboration with other parties.

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 an upfront payment related to the Collaboration Agreement. 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 12 months following the date that 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 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 sufficient revenue from the Collaboration Agreement, 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 U.S. Securities and Exchange Commission (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, 2019, which are contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 4, 2020. The results for the three months ended March 31, 2020 are not necessarily indicative of results to be expected for the entire year ending December 31, 2020 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.

Significant estimates inherent in the preparation of the accompanying unaudited condensed consolidated financial statements include revenue recognition, clinical trial accruals, recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, provisions for income taxes, amounts receivable and recognized as revenue under the Collaboration Agreement, 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 that these external factors could have an effect on the Company's estimates and could cause actual results to differ from those estimates and assumptions.

Other Risks and Uncertainties

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. To date, the Company's operations have not been significantly impacted by the COVID-19 outbreak. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its condensed consolidated financial condition and operations. The impact of the COVID-19 coronavirus outbreak on the financial performance of the Company 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 COVID-19 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

On March 18, 2020, the Families First Coronavirus Response Act ("FFCR Act"), and on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The FFCR Act and CARES Act did not

have a material impact on the Company's condensed consolidated financial statements as of March 31, 2020; however, the Company continues to examine the impacts the FFCR Act and CARES Act may have on its business, results of operations, financial condition and liquidity.

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 (see Note 6). The pre-funded warrants are exercisable for shares of common stock at a 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,	
	2020	2019
Numerator:		
Net loss	(26,655)	(27,052)
Denominator:		
Weighted average common shares outstanding for diluted net (loss) income per share	35,079,756	25,668,798
Net (loss) income per share:		
Basic	(0.76)	(1.05)
Diluted	(0.76)	(1.05)

Securities that could potentially dilute loss per share in the future that were not included in the computation of diluted loss per share because including them would have been antidilutive are as follows:

	Three Months Ended March 31,	
	2020	2019
Warrants to purchase common stock	15,296	15,296
Options to purchase common stock	6,370,396	5,111,590
Common stock subject to purchase under our ESPP	32,940	22,432
Unvested RSUs	999,926	607,656
Total	7,418,558	5,756,974

Adoption of Recent Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Under the amendments in ASU 2017-04, an entity should recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The updated guidance requires a prospective adoption. 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* (ASU 2019-10), 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 for goodwill impairment tests performed on testing dates after January 1, 2017. The Company early adopted ASU 2017-04 effective January 1, 2020. The adoption of this standard had no impact on the Company's condensed consolidated financial statements.

On January 1, 2020, the Company adopted ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. The adoption of this standard had no impact on the Company's condensed consolidated financial statements and related disclosures.

On January 1, 2020, the Company adopted ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606 and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in Topic 808 retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The adoption of this standard had no impact on the Company's condensed consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* (ASU 2019-12). The ASU eliminates certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted in an interim or annual period. Entities that elect to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, entities that elect early adoption must adopt all the amendments in the same period. Entities will apply the guidance prospectively, except for certain amendments. The Company early adopted ASU 2019-12 effective January 1, 2020. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In June 2016, 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, 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 this new accounting standard but currently does not expect the adoption of this standard to have a material impact on its condensed consolidated financial statements and related disclosures.

Note 3 – 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, 2020			
	Amortized Cost	Gross Unrealized Gain (1)	Gross Unrealized Loss (1)	Fair Value
Cash equivalents				
Money market funds	$ 39,010	$ —	$ —	$ 39,010
Total cash equivalents	39,010	—	—	39,010
Short-term investments				
U.S. and foreign corporate debt securities	63,354	10	(121)	63,243
Asset-backed securities	34,893	9	(44)	34,858
U.S. treasury securities	44,637	368	—	45,005
U.S. and foreign commercial paper	63,697	—	—	63,697
Total short-term investments	206,581	387	(165)	206,803
Total cash equivalents and investments	$ 245,591	$ 387	$ (165)	$ 245,813

(1) Gross unrealized gain (loss) is pre-tax.

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain (1)	Gross Unrealized Loss (1)	Fair Value
Cash equivalents				
Money market funds	$ 33,095	$ —	$ —	$ 33,095
U.S. and foreign corporate debt securities	5,000	—	(1)	4,999
U.S. and foreign commercial paper	4,484	—	—	4,484
Total cash equivalents	42,579	—	(1)	42,578
Short-term investments				
U.S. and foreign corporate debt securities	72,452	38	(4)	72,486
Asset-backed securities	34,008	17	—	34,025
U.S. treasury securities	44,692	24	(2)	44,714
U.S. and foreign commercial paper	76,086	—	—	76,086
Total short-term investments	227,238	79	(6)	227,311
Total cash equivalents and investments	$ 269,817	$ 79	$ (7)	$ 269,889

(1) Gross unrealized gain (loss) is pre-tax.

The contractual term to maturity of short-term marketable securities held by the Company as of March 31, 2020 is less than one year. There were no long-term marketable securities held by the Company as of March 31, 2020.

Realized gains and losses for the three months ended March 31, 2020 and 2019 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, 2020.

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, 2020			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 39,010	$ —	$ —	$ 39,010
Total cash equivalents	39,010	—	—	39,010
Short-term investments				
U.S. and foreign corporate debt securities	—	63,243	—	63,243
Asset-backed securities	—	34,858	—	34,858
U.S. treasury securities	—	45,005	—	45,005
U.S. and foreign commercial paper	—	63,697	—	63,697
Total short-term investments	—	206,803	—	206,803
Total assets measured at fair value	$ 39,010	$ 206,803	$ —	$ 245,813

	December 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	33,095	—	—	33,095
U.S and foreign corporate debt securities	—	4,999	—	4,999
U.S and foreign commercial paper	—	4,484	—	4,484
Total cash equivalents	33,095	9,483	—	42,578
Short-term investments				
U.S. and foreign corporate debt securities	—	72,486	—	72,486
Asset-backed securities	—	34,025	—	34,025
U.S. treasury securities	—	44,714	—	44,714
U.S. and foreign commercial paper	—	76,086	—	76,086
Total short-term investments	—	227,311	—	227,311
Total assets measured at fair value	$ 33,095	$ 236,794	$ —	$ 269,889

The Company estimates the fair value of its U.S. and foreign corporate debt securities, asset-backed securities, U.S. treasury securities and U.S. and foreign commercial paper 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 - Property and Equipment, Net

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

	Useful life (Years)	March 31, 2020	December 31, 2019
Lab equipment	3 to 5	$ 286	$ 247
Office equipment	7	699	699
Leasehold improvement	1 to 5	2,084	2,084
Total property and equipment		3,069	3,030
Less: Accumulated depreciation and amortization		(1,315)	(1,200)
Construction in progress	N/A	26	-
Property and equipment, net		$ 1,780	$ 1,830

Depreciation expense was $0.1 million for both the three months ended March 31, 2020 and 2019 and was recorded in both research and development expense and general and administrative expense in the unaudited condensed consolidated statements of operations and comprehensive loss. Primarily all of property and equipment of the Company is located in the U.S.

Note 5 – Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Accrued expenses:		
Accrued compensation	$ 2,144	$ 5,312
Accrued restructuring charges	1,627	2,094
Accrued professional fees and other	659	880
Total accrued expenses	$ 4,430	$ 8,286

Accrued restructuring charges relate to the Company's decision to relocate its headquarters and key personnel to South San Francisco, California as approved by the Board of Directors in November 2019 and effective January 1, 2020. The Company accrued restructuring charges of $2.1 million in 2019 related to one-time severance payments and other employee-related costs associated with the relocation plan. This represents the total amount expected to be incurred in connection with the relocation and is expected to be fully paid in 2020.

Note 6 – Stockholders' Equity

The Company is authorized to issue 5,000,000 shares of preferred stock as of March 31, 2020 and December 31, 2019, respectively. As of March 31, 2020 and December 31, 2019, no shares of preferred stock were issued and outstanding. The Company is authorized to issue 100,000,000 shares of common stock as of March 31, 2020 and December 31, 2019, respectively.

Sale of Common Stock and Pre-Funded Warrants

In December 2017, the Company filed a registration statement on Form S-3 with the SEC using a "shelf" registration statement, file No. 333-222366, which became effective January 10, 2018 (the Registration Statement). Under this shelf registration process, the Company may from time to time sell any combination of the securities described in the Registration Statement in one or more offerings up to an aggregate offering price of $250.0 million. In connection with the filing of this 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 $75.0 million through "at the market offerings" (ATM). As of March 31, 2020, no shares have been sold under the ATM program and $21.4 million remains available for sale under this Registration Statement.

In December 2019, the Company sold to various investors an aggregate of 6,287,878 shares of common stock at a public offering price of $16.50 per share, which included the exercise in full by the underwriters of their option to purchase 1,136,363 additional shares of common stock, and pre-funded warrants to purchase 2,424,242 shares of common stock at a public offering price of $16.499 per warrant. The Company received aggregate net proceeds of $134.7 million from the offering and the option exercise, after deducting underwriting discounts and commissions and offering expenses payable by the Company. The pre-funded warrants are exercisable immediately upon issuance at an exercise price of $0.001 per share. Per their terms, the outstanding pre-funded warrants to purchase shares of the Company's common stock generally may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99% following such exercise. The exercise price and number of shares of common stock issuable upon the exercise of the pre-funded warrants (Warrant Shares) are subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the pre-funded warrant agreements. Under certain circumstances, the pre-funded warrants may be exercisable on a "cashless" basis. Both the pre-funded warrants and the Warrant Shares are registered securities.

The pre-funded warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants of which $37.5 million was allocated to the pre-funded warrants and recorded as a component of additional paid-in-capital.

Common Stock Warrants

As of, March 31, 2020 and December 31, 2019 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
September 10, 2010	September 10, 2020	$ 30.000	15,296
December 16, 2019	None	$ 0.001	2,424,242
			2,439,538

There were no warrants exercised during the three months ended March 31, 2020 or 2019.

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 shares of common stock reserved under the 2018 Plan to 3,000,000.

As of March 31, 2020, the Company had awards outstanding under the following shareholder-approved plans: 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, 2020, 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, 2020 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, 2019	5,613,353	$ 15.90		
Granted	833,140	14.76		
Exercised	(16,834)	7.05		
Forfeited	(59,263)	26.35		
Outstanding as of March 31, 2020	6,370,396	$ 15.67	7.4	$ 21,547
Options vested and exercisable as of March 31, 2020	3,302,792	$ 13.87	5.6	$ 18,722

The weighted-average grant-date fair value of options granted was $9.74 and $13.71 during the three months ended March 31, 2020 and 2019, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2020 and 2019 was $0.2 million and $0.3 million, respectively.

RSUs

A summary of the Company's RSUs and related information for the three months ended March 31, 2020 is as follows:

	Number of RSU's	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2019	758,718	$ 25.47
Granted	485,664	15.91
Vested	(94,224)	34.55
Forfeited	(23,982)	26.50
Nonvested as of March 31, 2020	1,126,176 [(1)]	$ 20.56

(1) Includes 126,250 RSUs that have vested but are subject to deferred settlement, which have a weighted average remaining contractual term of 2.3 years.

The total fair value of RSUs vested and settled during the three months ended March 31, 2020 and 2019 as $2.4 million and $2.2 million, respectively. The total intrinsic value of RSUs vested and settled during the three months ended March 31, 2020 and 2019 was $1.5 million and $1.3 million, respectively.

As of March 31, 2020, RSUs outstanding include 45,000 RSUs granted in December 2017 and 100,000 RSUs granted in September 2019 to executives of the Company, each with performance-based conditions. The total fair value of these awards is $0.7 million and $1.2 million, respectively. The performance conditions upon which these awards will vest are not yet deemed probable of being met, and accordingly no compensation expense has been recognized as of March 31, 2020 for these awards.

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,	
	2020	2019
Exercise price	$14.45 - $19.13	$19.69 - $23.04
Expected volatility	66.38% - 82.23%	75.0% - 83.2%
Risk-free rate	0.46% - 1.44%	2.24% - 2.65%
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,	
	2020	2019
Research and development	$ 1,945	$ 2,728
General and administrative	2,979	3,849
Total stock-based compensation expense	$ 4,924	$ 6,577

As of March 31, 2020, there was $34.5 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 Agreement

Allergan

In January 2017, the Company entered into the Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal disease therapies. Pursuant to the Collaboration Agreement, the Company granted to Allergan an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the Collaboration Agreement, to develop and commercialize licensed compounds for UC, Crohn's disease, and two compounds for IBS. Allergan and the Company also agreed to collaborate on research and development activities with respect to the licensed compounds in accordance with a mutually agreed upon research and development plan. Per the terms of the Collaboration Agreement, Allergan can select backups and additional target indications to add to the licenses granted for additional consideration and also has the ability to enter into a contract manufacturing agreement with the Company for compound supply at cost plus an agreed upon margin. In addition, the Company will participate on a Joint Development Committee (JDC) and Joint Patent Committee (JPC).

Allergan paid the Company an upfront non-refundable payment of $50.0 million, which was received in 2017. Additionally, the Company is eligible to receive variable consideration in the form of research and development cost reimbursements, up to $631.0 million related to seven development milestones and up to $2.14 billion related to 12 commercial development and sales milestones in connection with the successful development and commercialization of licensed compounds. In addition, the Company is eligible to receive tiered royalties at rates ranging from the mid-single digits to the mid-teens based on net sales.

Allergan and the Company have agreed to share research and development costs up to an aggregate of $75.0 million through proof-of-concept (POC) studies on a ⅔, ⅓ basis, respectively, and Allergan has agreed to assume all post-POC development costs. In the event any pre-POC development costs exceed $75.0 million in the aggregate, the Company may elect either (a) to fund ⅓ of such costs in excess of $75.0 million or (b) to allow Allergan to deduct from future development milestone payments ⅓ of the development costs funded by Allergan in excess of $75.0 million plus a premium of 25%. The Company has an option to co-promote the licensed programs in the U.S. and China, subject to certain conditions set forth in the Collaboration Agreement.

Allergan may terminate the Collaboration Agreement at any time upon 90 days' (prior to the initiation of the first POC trial of a licensed product) or 120 days' (after the initiation of the first POC trial of a licensed product), as applicable, advance written notice to the Company. Unless terminated early, the Collaboration Agreement has a term that ends on the earlier of the (i) the period when POC studies have been completed and no further licensed compounds or licensed products are in development, and (ii) expiration of the last to exist valid claim covering the manufacture, use and sale of the licensed products. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure. Upon termination for convenience, the licenses granted by the Company and its know-how all revert to the Company.

The Company concluded that Allergan is a customer, and the contract is not subject to accounting literature on collaborative arrangements. This is because the Company granted to Allergan licenses to its intellectual property and research and development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Company identified the following material promises under the Collaboration Agreement: (1) grant of licenses to intellectual property for the four initial indications, inclusive of the related technology know-how (Licenses) and (2) the obligation to perform research development services through POC (Development Services). The Company's participation on the JDC and JPC were considered to be immaterial in the context of the contract. The Company's co-promotion option was not considered to be a performance obligation. Allergan's selection of backups or additional target indications to add to the licenses granted for additional consideration and ability to enter into a contract manufacturing agreement with the Company for compound supply at cost plus an agreed upon margin were not considered to be performance obligations as the Company concluded the options were not offered at a discount that exceeds discounts available to other customers, and therefore were not material rights. The grant of additional licensing rights upon option exercises and contract manufacturing agreements will be accounted for as separate contracts when they occur.

The Company concluded the Licenses each were considered to be functional as they have significant standalone functionality and were capable of being distinct. However, the Company determined that each of the Licenses individually were not distinct from the Development Services within the context of the agreement. This is because Allergan is dependent on the Company to execute the Development Services, which it is uniquely able to perform, in order for Allergan to benefit from the Licenses. As such, the Company determined that it has four performance obligations under the Collaboration Agreement associated with the grant of the four compound Licenses combined with the performance of the Development Services for each of the four compound indications. The Company determined that the four performance obligations will be performed over the duration of the contract, which began in February 2017 and ends upon completion of the Development Services which is currently estimated to occur in 2025. The Company is using a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Allergan. In applying the cost-based input method of revenue recognition, the Company measures costs incurred relative to budgeted costs to fulfill the four performance obligations. These costs consist primarily of third-party contract costs and internal labor costs. Revenue will be recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligations.

To allocate transaction price among the four performance obligations, the Company estimated their standalone selling price (SSP) using an income-based valuation approach for the estimated value a licensor of the compounds would receive considering the stage of the compounds' development. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the four performance obligations would not have a significant effect on the allocation of consideration received to the four performance obligations.

The transaction price at the inception of the agreement and upon adoption of ASC 606 was limited to $50.0 million upfront payment. Of this amount, the Company allocated $12.5 million to each of the four performance obligations. Research and development cost reimbursement payments are included in the transaction price in the reporting period that the Company concludes that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. 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 at September 30, 2019. As part of the Company's evaluation of the development and commercialization milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials 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 license granted to Allergan. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The Company did not incur any significant incremental costs of obtaining the Allergan contract.

For the three months ended March 31, 2020 and 2019, the Company recognized $4.1 million and $3.9 million, respectively, in revenue associated with the Collaboration Agreement. Short-term and long-term deferred revenue contract liabilities related to the Collaboration Agreement were $6.7 million and $29.3 million at March 31, 2020 and $6.4 million and $30.6 million at December 31, 2019.

On the unaudited condensed consolidated balance sheets, contract asset balances of $3.1 million and $3.4 million were recorded as accounts receivable from collaboration as of March 31, 2020 and December 31, 2019, respectively.

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, 2020				
Contract liabilities:				
Deferred revenue	$ 37,048	$ —	$ (1,007)	$ 36,041

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Three Months Ended March 31, 2019				
Contract liabilities:				
Deferred revenue	$ 40,660	$ —	$ (859)	$ 39,801

	Three Months Ended March 31,	
	2020	2019
Collaboration revenue recognized in the period from		
Amounts included in deferred revenue at the beginning of the period	$ 1,007	$ 859
Performance obligations satisfied in previous period	—	—

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. 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. Amounts paid in the three months ended March 31, 2020 and 2019 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 will be solely responsible for all research and development activities with respect to any product it develops under the license.

The Company must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. In addition, the Company must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. The Company is 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 exceed certain thresholds, a one-time cash payment upon reaching such thresholds.

Therabiome must pay the Company royalties on annual net sales of any product Therabiome is 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, 2020. A regulatory milestone was determined to have occurred and $0.1 million was paid under this agreement as of and during the three months ended March 31, 2019.

Note 10 - Leases

Operating Leases

The Company leases office space for corporate, administrative and laboratory functions in South San Francisco, California under a sub-sublease that expires in December 2023. The Company also leases office space in Carmel, Indiana under a lease agreement that expires in August 2023 as well as office and laboratory space in Groton, Connecticut under a lease that expires in March 2021. The Company's China subsidiary leases office space in Shanghai that expires in May 2021 and rents lab space in Shanghai under a lease agreement that expires in December 2020. Additionally, the Company's China subsidiary leases office space in Beijing under a lease agreement that expires in December 2020. 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. Certain equipment leases continue to expire in 2020, with the final lease expiring in 2022.

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, 2020, the Company had operating lease liabilities of $11.8 million and ROU assets of $11.5 million, which were included in the condensed consolidated balance sheet.

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

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Lease cost		
Operating lease cost	$ 1,151	$ 1,091
Short-term lease cost	100	321
Variable lease cost	284	299
Total lease cost	$ 1,535	$ 1,711

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
Operating cash flows from operating leases	$ 1,120	$ 1,037
ROU assets exchanged for new operating lease liabilities	$ 362	$ 13,933

As of March 31, 2020 and December 31, 2019, the weighted-average remaining lease term for operating leases was 3.4 years and 2.7 years, respectively. As of both March 31, 2020 and December 31, 2019, the weighted-average discount rate for operating leases was 9.4%.

As of March 31, 2020, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Nine months ended December 31, 2020	$ 3,510
Year Ended December 31, 2021	3,924
Year Ended December 31, 2022	3,560
Year Ended December 31, 2023	3,303
Total	14,297
Less: present value discount	(2,494)
Operating lease liabilities	$ 11,803

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, 2019 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, 2019 filed with the U.S. Securities and Exchange Commission on March 4, 2020 (2019 Annual Report). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2019 Annual Report, "Part II. Item 1A. Risk Factors" in this report, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical-stage biotechnology company developing innovative therapeutics targeting chronic hepatitis B virus (HBV) infection and disorders associated with the microbiome. Our HBV Cure program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. Our Microbiome program is developing novel oral live microbial biotherapeutic candidates with our fully integrated platform, including a robust process for strain identification and selection, current Good Manufacturing Practice (cGMP) manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology.

Like most companies, the spread of the novel coronavirus, SARS-CoV-2, which causes coronavirus disease (COVID-19), and 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 trials have not been subject to significant impact.

Business Highlights

During the first quarter of 2020, we continued to grow our business and advance our development pipeline of product candidates in both our HBV Cure and Microbiome programs. Key highlights and accomplishments during the quarter and upcoming milestones include:

HBV Cure Program

- ABI-H0731 (H0731), our lead core inhibitor product candidate in the HBV Cure program:
    - Continuation of our ongoing open-label extension study, ABI-H0731-211 (Study 211), with subjects reaching 12-18 months of treatment with H0731+nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy.
    - Determination of the stopping criteria by which we will begin transitioning patients off therapy in Study 211 after discussions regarding such criteria with our lead investigators and review and agreement with the U.S. Food and Drug Administration (FDA). When we make this transition later this year, we expect this will be the first clinical trial with a core inhibitor to stop therapy and monitor patients for sustained virologic response.
    - Submission of an End of Phase 2 meeting request and briefing document for review with the Chinese regulatory authority, which details the proposed registrational studies of H0731+NrtI for chronic suppressive therapy in China.
    - Upcoming reporting of additional data from our Phase 2 studies, ABI-H0731-201 (Study 201), and Study 211 at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress™ in an oral presentation and late-breaker poster presentation. EASL's 2020 meeting

had been scheduled to occur in April 2020, but it was rescheduled to August 27 to 29, 2020 as a digital meeting due to the COVID-19 pandemic.

- ABI-H2158 (H2158), our second-generation core inhibitor product candidate in the HBV Cure program:
  - Upcoming reporting of data on the final dose-ranging cohorts of the Phase 1b portion of the Phase 1a/1b clinical study of H2158 at EASL 2020 in a late-breaker poster presentation.
  - Upcoming initiation of a Phase 2 clinical study using a 300 mg dose of H2158.
- ABI-H3733 (H3733), our third core inhibitor product candidate in the HBV Cure program:
  - Continuation of a Phase 1 clinical study to evaluate safety, tolerability, and pharmacokinetics of H3733 in healthy subjects.

Microbiome Program

- Selection of the ABI-M201 (M201) ulcerative colitis (UC) program for presentation as a poster at the Digestive Disease Week's (DDW) 2020 Virtual Meeting.
- Selection of preclinical data from our immuno-oncology microbiome program for presentation as an e-poster at the American Association for Cancer Research (AACR) 2020 Virtual Annual Meeting II to be held on June 22 to 24, 2020.

Corporate Highlights

- Strengthening of our leadership team with the addition of Jason Okazaki as Chief Legal and Business Officer and Carl Henrik Enell as Senior Vice President, Corporate Development.

HBV Cure Program

Over 250 million people worldwide are chronically infected with HBV. Our HBV Cure program is pursuing multiple drug candidates that inhibit the HBV lifecycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rate for patients with HBV. We have discovered several novel core inhibitors, which are small molecules that directly target and allosterically modulate the HBV core protein.

ABI-H0731

H0731, our lead core inhibitor product candidate in the HBV Cure program, is licensed from Indiana University. In the fourth quarter of 2019, we presented final 24-week data from HBeAg positive patients enrolled in our Phase 2 studies of H0731, Study 201, which enrolled NrtI-treated patients, and ABI-H0731-202 (Study 202), which enrolled treatment-naïve patients. In addition, we presented interim data from Study 211. The conduct of Study 201 and 202 is now complete, and Study 211 is ongoing. Most currently enrolled patients are continuing with normal study visits. For those patients unable to come to the clinic as a result of COVID-19, study drug is being shipped to their homes, and sites are conducting telehealth visits.

We presented certain top-line information and other updates regarding Study 201 and Study 211 in May 2020, and we expect to report additional data from Study 201 as well as further interim data from Study 211 at EASL 2020 in August 2020.

In addition, we recently determined the stopping criteria by which we will begin transitioning patients off therapy in Study 211. These criteria have been discussed with our lead investigators and reviewed and agreed upon by the FDA. Later this year, we expect to begin transitioning patients off treatment to observe for sustained virologic response. At this time, the ongoing COVID-19 pandemic has not impacted our timeline for the upcoming transition of patients off treatment or completion of Study 211, but we will continue to monitor the situation closely.

ABI-H2158

H2158, our second-generation core inhibitor product candidate in the HBV Cure program, was internally discovered and developed and is chemically distinct from H0731.

In the second quarter of 2019, we presented final data from the Phase 1a portion of a Phase 1a/1b dose-ranging clinical study. The Phase 1a study assessed safety, tolerability and pharmacokinetics (PK) in 48 healthy volunteers. In the fourth quarter of 2019, we reported interim data from the first, low-dose cohort of the Phase 1b portion of the Phase 1a/1b dose-ranging clinical study, which enrolled HBeAg positive patients.

We presented additional top-line data from the dose-ranging cohorts of the Phase 1b portion of the Phase 1a/1b dose-ranging clinical study in May 2020, and we expect to report the final data from these cohorts at EASL 2020.

Based on data from the Phase 1b dose-ranging study, we expect to initiate a Phase 2 clinical study in the second quarter of 2020 using a 300 mg dose of H2158. This study will be conducted in approximately ten countries in Asia, North America and Europe. While we will continue to monitor the situation closely, at this time, we do not expect our timelines for this study to be significantly impacted by the COVID-19 pandemic.

ABI-H3733

H3733, our third core inhibitor product candidate in the HBV Cure program, has completed Investigational New Drug (IND) enabling studies. H3733 has a novel chemical scaffold separate from both H0731 and H2158. We presented a preclinical profile of this candidate in the first quarter of 2019.

In the first quarter of 2020, we initiated a Phase 1 clinical study to evaluate safety, tolerability and PK following single ascending dose and multiple ascending dose administration of H3733 in healthy subjects in New Zealand. Enrollment of the study has been delayed as a result of the government mandated shutdown of all clinical studies unrelated to COVID-19. We expect to resume enrollment in the second quarter of this year and do not expect this delay to have a significant impact on our clinical development timelines for H3733.

Other Product Candidates

In addition to our three clinical-stage product candidates, our research discovery team is actively focused on identifying and creating additional product candidates for our HBV Cure program.

Microbiome Program

In recent years, there has been increasing scientific evidence suggesting the therapeutic potential of the human microbiome—the billions of microbes living in and on people—to impact health and disease. Our Microbiome program builds upon experience reported in the literature of successfully treating various disease indications with fecal microbiota transplants (FMT) and seeks to provide a pharmacologically relevant therapy using a “drug like” approach that delivers targeted and specific microbiome therapies in an oral capsule.

Our Microbiome program consists of a fully integrated platform that includes a biological-function-based strain isolation, identification, characterization and selection process, methods for strain purification and growth under conditions compliant with cGMP requirements, and a licensed patented delivery system that we call GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower GI tract.

ABI-M201

Our Microbiome program’s lead candidate, M201, is in a multi-center, randomized, double-blind, placebo-controlled Phase 1b clinical trial to evaluate its safety and efficacy in patients with mildly to moderately active UC who are being treated with mesalamine. The study’s primary objective is safety and tolerability, and its secondary objectives focus on the effect of M201 treatment on disease activity measures in patients with UC.

This Phase 1b study is ongoing; however, continued enrollment has been delayed as a result of the COVID-19 pandemic and the limitations placed on some trial sites to conduct certain procedures as part of the patient screening

process. We expect enrollment activities to resume in mid-2020, and we continue to monitor the situation closely. For currently enrolled patients who are unable to come to the clinic, study drug or placebo is being shipped to their homes and sites are conducting telehealth monitoring and home health nurse visits.

M201 is being developed as part of the Research, Development, Collaboration and License Agreement (the Collaboration Agreement) with Allergan. The Collaboration Agreement provides for the development and commercialization of microbiome gastrointestinal programs.

Preclinical data from the M201 program was selected for presentation as a poster at DDW 2020.

Additional Product Candidates

Using our microbiome platform capabilities, we are also exploring additional product candidates for other disease indications, including Crohn's disease (CD) and IBS in connection with the Collaboration Agreement, as well as immune-mediated and metabolic disorders and oncology, which indications we will pursue either internally or in collaboration with other third parties. Preclinical data from our immuno-oncology microbiome program have been selected for presentation as a poster at AACR.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California, research, development and small-scale manufacturing activities in Groton, Connecticut and administrative offices in Carmel, Indiana. We also currently have an administrative office and research laboratory space in Shanghai, China and a regulatory office in Beijing, China.

Since our inception, we have had no revenue from product sales and have funded our operations principally through equity financings and collaborations. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovering and developing our product candidates, establishing small-scale manufacturing capabilities for certain of 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 continue to develop our product candidates. As of March 31, 2020, we had an accumulated deficit of $466.1 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.

While our employees in the United States are currently under stay-at-home or shelter-in-place orders under state and local laws in response to the COVID-19 pandemic, as a biotechnology company, we qualify as a Healthcare Operation and are exempted under such orders. This exemption allows our employees to perform essential activities at our offices, including work in our laboratories in both South San Francisco and Groton 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. In addition, substantially all of our 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 enrollment delays for both our Phase 1 study of H3733 and our Phase 1b study of M201, which are the only studies that are currently enrolling. 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 trials and other business operations. We continue to monitor the situation regularly for additional potential delays, or modifications to our ongoing and planned trials 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 2019 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2019 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, 2020 and 2019

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
	2020	2019	2020 vs. 2019	2020 vs. 2019
Collaboration revenue	$ 4,081	$ 3,885	$ 196	5%

Collaboration revenue includes the recognition of deferred revenue and reimbursements incurred under the Collaboration Agreement. Revenue for the three months ended March 31, 2020 as compared to the same period in 2019 increased as a result of increased reimbursement activities associated with our development activities under the Collaboration Agreement.

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	2020	2019	2020 vs. 2019	2020 vs. 2019
HBV Cure program	$ 15,636	$ 15,712	$ (76)	0%
Microbiome program	7,410	6,992	418	6%
Total research and development expenses	$ 23,046	$ 22,704	$ 342	2%

Research and development expense were $23.0 million for the three months ended March 31, 2020 compared to $22.7 million for the same period in 2019. The increase was primarily due to an increase of $0.4 million in gross research and development expenses related to the Microbiome programs and a decrease of $0.1 million in research and development expenses related to the HBV programs. Research and development expenses include non-cash stock-based compensation expenses of $1.9 million for the three months ended March 31, 2020 and $ 2.7 million for the same period in 2019.

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
	2020	2019	2020 vs. 2019	2020 vs. 2019
General and administrative expenses	$ 8,729	$ 9,517	$ (788)	-8%

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 the stock-based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expenses were $8.7 million for the three months ended March 31, 2020 compared to $9.5 million for the same period in 2019. An increase in employee-related expenses of $0.5 million was largely offset due to a decrease of $0.2 million in professional fees and a decrease of $0.3 million in rent expense due to the move of our leased office and laboratory space from San Francisco to South San Francisco in February 2019. General and administrative expenses include non-cash stock-based compensation expenses of $3.0 million for the three months ended March 31, 2020 and $3.8 million for the same period in 2019.

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, 2020 principally through equity financings, raising an aggregate of $546.4 million in net proceeds, and a strategic collaboration raising an aggregate of $50.0 million through an upfront payment.

Cash Flows for the Three Months Ended March 31, 2020 and 2019

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

	Three Months Ended March 31,	
Cash provided by (used in):	2020	2019
Operating activities	$ (25,218)	$ (23,939)
Investing activities	20,693	11,435
Financing activities	$ 119	$ 140

Net Cash from Operating Activities

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 of 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 expense recorded for stock-based compensation, $1.2 million of amortization of operating lease right-of-use (ROU) assets and $0.1 million of depreciation and amortization expense.

Net cash used in operating activities was $23.9 million for the three months ended March 31, 2019. This was primarily due to a $27.1 million net loss, $0.6 million of accretion of discount of marketable securities and a decrease of $4.2 million of operating assets and liabilities, which were offset by $6.6 million non-cash expense recorded for stock-based compensation, $1.1 million of amortization of operating lease ROU assets and $0.1 million of depreciation and amortization expense.

Net Cash from Investing Activities

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 provided by investing activities for the three months ended March 31, 2019 was $11.4 million primarily due to the purchase of $49.0 million of marketable securities and $1.5 million of property and equipment, which were offset by $61.5 million of redemptions of marketable securities and $0.5 million of sale of marketable securities.

Net Cash from Financing Activities

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.

Net cash provided by financing activities for the three months ended March 31, 2019 was $0.1 million resulting from the exercise of stock options to purchase 21,000 shares of common stock.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical studies of our product candidates and pursue our intellectual property strategy. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, 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 would 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 by issuing equity securities, most recently in December 2019. We intend to continue to raise capital when and as needed and at the time and in the manner most advantageous to us. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed.

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 12 months. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, 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 and timing of recruiting additional employees to support the growth of our business;
- 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 many 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 2019 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 2019 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, 2020 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 might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

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 Securities and Exchange Commission. If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, 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 currently are dependent on the future success of our HBV Cure and Microbiome programs.

To date, we have no approved products on the market and have generated no product revenues. Our prospects are substantially dependent on our ability to develop and commercialize our HBV and microbiome product candidates. Unless and until we receive approval from the FDA or other regulatory authorities for our product candidates, we cannot sell our product candidates and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any future securities offerings or debt financings and any fees we may generate from out-licensing, collaborations or other strategic arrangements. If we are unable to develop and commercialize any product candidates from our HBV Cure and Microbiome programs, we will be unable to generate revenues from the sale of products or build a sustainable or profitable business.

In addition, all of our product candidates are currently in early clinical development or in varying stages of nonclinical development and their risk of failure is high. The data supporting our drug discovery and nonclinical and clinical development programs are derived from either laboratory, nonclinical studies, Phase 1 and Phase 2 clinical data. With respect to our ongoing Phase 2 trials, as we begin transitioning patients off of therapy in Study 211 later this year, we may not observe sustained virologic response and such patients may need to resume NrtI therapy. In addition, there is no guarantee that Phase 3 clinical studies, if and when completed, will result in data consistent with that observed in prior studies. As a result, we cannot predict when or if any one of our product candidates will prove safe and effective in humans or will receive regulatory approval.

The scientific evidence to support the feasibility of our product candidates and therapeutic approaches is limited, and many companies, some with more resources than we have, are and may be developing competitive product candidates. For these and other reasons, our drug discovery and development may not be successful, and we may not generate viable products or revenue.

The spread of the coronavirus and resulting COVID-19 pandemic may materially and adversely affect our business.

The recent outbreak of COVID-19 began in December 2019 and has since spread globally, reaching pandemic status. The continued spread of the coronavirus that causes 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 already had their clinical and nonclinical studies affected by the COVID-19 pandemic.

The COVID-19 pandemic has and may continue to (i) impact patient enrollment, retention or compliance with clinical study protocols; (ii) 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, that could increase the cost of conducting clinical studies; (iii) disrupt or suspend the business operations of our third-party contract research organizations (CROs), manufacturers of our drug candidates and the clinical sites conducting our clinical studies; (iv) delay regulatory meetings and filings with regulatory agencies in the United States and other countries; and (v) disrupt supply chains and cause delays of shipments of critical reagents, personal protective equipment and disinfectants, each of which are necessary for our laboratories and the laboratories of our CROs to maintain normal workflows. For example, in our Phase 1 trial of H3733 in New Zealand, which we initiated in the first quarter of this year, patient enrollment has been delayed as a result of the New Zealand government's mandated shutdown of all clinical studies other than those for clinical candidates for COVID-19.

We cannot provide any assurances about when any of our clinical studies that have delayed enrollment as a result of COVID-19 might reinitiate enrollment or that their enrollment will be reinitiated at all. For those clinical studies that are currently ongoing, we cannot provide any assurances that the measures that we have taken to date, or may in the future take, will continue to allow us to mitigate and manage results of negative impacts to site initiation, participant recruitment and enrollment, participant randomization and dosing, distribution of clinical study materials, study monitoring or data analysis. Even if we are able to collect clinical data while the outbreak is ongoing, COVID-19 may negatively affect the quality, completeness, integrity, interpretability and cost of such clinical study data. Any of these effects could adversely affect our ability to advance our product candidates in the manner and on the timelines presently planned, obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, results of operations, financial results and our share price.

As a result of the COVID-19 pandemic, governments around the world continue implementing significant measures to control the spread of the virus, including quarantines, travel restrictions, stay-at-home orders and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees who are able to do so to work remotely and suspending all non-essential travel worldwide for our employees. These measures could negatively affect our business. For instance, requiring all employees to work remotely may disrupt our operations or increase the risk of a cybersecurity incident.

The extent to which the COVID-19 pandemic may impact 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 and treatment of COVID-19. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, including to our ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned as well as negatively affect the accuracy of our estimates regarding capital requirements and needs for additional financing or our ability to produce accurate and timely financial statements. We may incur additional liabilities related to business disruptions caused by the COVID-19 pandemic, including those related to our employees, our agreements with third parties, and our interactions with governmental authorities. Any of these disruptions could have a material adverse impact on our business, results of operation, financial condition and share price.

The COVID-19 pandemic has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. In addition, a recession, depression, or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

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 depend entirely on the success of product candidates from our HBV Cure program and our Microbiome program. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from either of our current programs or any other product candidates we may subsequently identify.

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 biologic license application (BLA) or 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 foreseeable future.

All of our product candidates are currently in early clinical development or in varying stages of nonclinical development. It may be years before the larger, pivotal trials necessary to support regulatory approval of our product candidates are initiated, if ever. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must successfully meet a number of critical developmental milestones, including:

- developing dosages that will be tolerated, safe and effective;
- reaching agreement with the FDA or comparable foreign regulatory authorities regarding the scope, design and data necessary to support regulatory approval for the product candidate;
- demonstrating through clinical studies that the product candidate is safe and effective in patients for the intended indication;
- determining the appropriate delivery mechanism;
- demonstrating that the product candidate formulation will be stable for commercially reasonable time periods; and
- completing the development and scale-up to permit manufacture of our product candidates in quantities sufficient to execute on our clinical development plans and, eventually, in commercial quantities with sufficient quality and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for our HBV and microbiome therapies or any other product candidates that we may develop. We have not yet completed and may never complete the development of any products. If we are unable to complete clinical development of our HBV or microbiome therapies, or any other product candidates that we may identify, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

Nonclinical studies may not be representative of disease behavior in clinical studies. The outcomes of nonclinical testing and clinical studies are uncertain, and results of nonclinical studies and earlier clinical studies may not be predictive of future clinical study results.

The results of nonclinical studies may not be representative of disease behavior in a clinical setting and thus may not be predictive of the outcomes of our clinical studies. In addition, the results of nonclinical studies and early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies, and the results of any study or trial for any of our product candidates may not be as favorable as the results for any prior studies or trials, if at all.

Nonclinical studies and clinical testing are expensive, can take many years to complete and their outcomes are highly uncertain. Failure can occur at any time during the nonclinical study and clinical study processes due to inadequate performance of a drug candidate or inadequate adherence by patients or investigators to clinical study protocols. Further, clinical studies might not provide statistically significant data supporting a product candidate’s

safety and effectiveness to obtain the requisite regulatory approvals. In addition, there is a high failure rate for drugs and biologics proceeding through clinical studies. Our failure to replicate earlier positive results in later-stage clinical studies or otherwise demonstrate the required characteristics to support marketing approval for any of our product candidates would substantially harm our business, prospects, financial condition and results of operations.

Top-line or initial data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose top-line or initial data from time to time, which is based on a preliminary analysis of then-available efficacy, tolerability, PK and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate fully and carefully all data. As a result, the top-line or initial results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the initial or preliminary data we previously published. As a result, top-line and initial data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or biotherapeutic and our company in general. In addition, the information we may publicly disclose regarding a particular nonclinical or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line or initial data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

Nonclinical and clinical testing required for our product candidates is expensive and time-consuming and may result in delays or may fail to demonstrate safety and efficacy for desired indications. Such delays or failures could delay or prevent our receipt of licensing, sales and/or milestone revenue.

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 through nonclinical studies and human testing in clinical studies that each potential product is safe and effective in humans. To meet these requirements, we must conduct extensive nonclinical testing and sufficient and well-controlled clinical studies. Conducting clinical studies is a lengthy, time consuming, and expensive process. The length of time might vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with product candidates for which we are directly conducting nonclinical studies or clinical studies might cause us to incur additional operating expenses. 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 trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- failure to demonstrate efficacy;
- the emergence of unforeseen safety issues;
- insufficient quantities of qualified materials under cGMP for use in clinical studies due to manufacturing challenges or delays;
- slower than expected rates of patient recruitment;

- 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 having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects, disease progression or other reasons;
- clinical sites dropping out of a trial to the detriment of enrollment;
- modification of clinical study protocols;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements for clinical studies;
- impacts in trial initiation, enrollment, completion and similar activities due to the impact of COVID-19;
- 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.

We have used and intend to continue to rely on one or more CROs to conduct our nonclinical studies and clinical studies. We are highly dependent on these CROs to conduct our studies and trials in accordance with the requirements of the FDA, applicable local laws and good clinical and scientific practice. In the event the CROs fail to perform their duties in such a fashion, we may not be able to complete our clinical studies and may fail to obtain regulatory approval for any of our product candidates.

The failure of nonclinical studies and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications could harm the development of that product candidate or 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 termination of, our nonclinical studies or clinical studies would delay the filing of our NDAs or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical studies could materially harm our business, financial condition, and results of operations.

Any product candidates that we may discover and develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

In our industry, many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development. Undesirable side effects caused by any product candidates that we may discover or develop, or safety, tolerability or toxicity issues that may occur in our nonclinical studies, clinical studies or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical studies. Such results could also cause us to, or regulatory authorities to require us to, cease further development of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects, financial condition and results of operations.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a Risk Evaluation Mitigation Strategy (REMS) plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is administered, conduct additional clinical studies or change the labeling of a product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

If we are unable to hire and retain additional qualified personnel, our ability to grow our business might be harmed.

As of March 31, 2020, we had 120 employees and contracts with a number of temporary contractors, consultants and CROs. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, formulation and manufacturing and sales and marketing to commercialize our HBV drug candidates and our microbiome biotherapeutic candidates or any other product candidate we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success, and any failure to do so could have a material adverse impact on our business, financial condition and results of operations.

If we lose key management or scientific personnel, cannot recruit and retain qualified employees, officers, or other significant personnel or experience increases in our compensation costs, our business might materially suffer.

We are highly dependent on the services of our executive officers and senior management team. Our employment agreements with our executive officers and senior management team members do not ensure their retention. We do not currently maintain, nor do we intend to obtain in the future, “key man” life insurance that would compensate us in the event of the death or disability of any of the members of our management team. Our key management and scientific personnel 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.

We are not currently profitable and might never become profitable.

We have a history of losses and expect to incur significant operating and capital expenditures and resultant substantial losses and negative operating cash flow for the next several years and beyond if we do not successfully launch and commercialize any product candidates from our HBV Cure or Microbiome programs. We might never achieve or maintain profitability. We anticipate that our expenses will continue to be substantial in the foreseeable future as we:

- advance H0731, H2158 and H3733, our first three HBV product candidates through clinical development;
- advance M201, our first candidate from our Microbiome program, through Phase 1b clinical development;
- continue to undertake research and discovery efforts to identify potential additional product candidates in both our HBV Cure and Microbiome programs;
- seek regulatory approvals for our product candidates; and
- pursue our intellectual property strategy.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical studies or the development of any of our product candidates.

As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Our ability to generate revenue from the sale of products and achieve profitability will depend on, among other things:

- successful completion of research, nonclinical studies and clinical studies for our product candidates;
- obtaining necessary regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- maintaining patent protection for our products, methods, processes and technologies and/or obtaining regulatory exclusivity;
- establishing manufacturing, sales, and marketing arrangements internally and/or with third parties for any approved products; and
- raising sufficient funds to finance our activities, if and when needed.

We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations might be materially adversely affected.

We are an early stage company and might not be able to commercialize any product candidates.

We are an early stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake research and development and nonclinical studies and clinical studies;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

We currently do not have the infrastructure to manufacture, market and sell our product candidates. If we partner with one or more third-party entities, those commercial partners may demand and receive rights to control product development and commercialization. As a result, these commercial partners may conduct these programs and activities more slowly or in a different manner than expected. If any of these events were to occur, the development of any product candidate could be significantly delayed, more expensive or less lucrative to us than anticipated, any of which would have a significant adverse effect on our business.

Our failure to successfully commercialize our product candidates would negatively impact the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, or continue our operations.

There are substantial risks inherent in attempting to commercialize new drugs and biologics, and, as a result, we may not be able to successfully develop products for commercial use.

Scientific research and development require significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. To date, our research and development projects have not produced commercially approved drugs or biologics and may never do so. During the research and development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs are not fully proven.

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with core inhibitors. The development of our core inhibitor technology is in early stages, and the commercial feasibility and acceptance of our core inhibitor technology is unknown. More specifically, while there may be initial indications of decreasing cccDNA levels in some treated patients, the theory that treatment with core inhibitors may result in more rapid loss of cccDNA compared to conventional (standard of care) therapies is unproven. It is also unknown if the biomarkers assumed to be indicators of cccDNA pool levels (such as serum pgRNA, HBeAG, HBcrAg and, to a lesser extent, HBsAg in HBV patients) will be meaningfully altered in patients on treatment with core inhibitors. Additionally, even if core inhibitor technology is successful at targeting the HBV core protein and treatment is successful at reducing cccDNA levels in HBV patients, it may not result in a commercially approved drug if there is not a corresponding medical benefit related to the underlying HBV infection.

Similarly, our Microbiome program is based on a novel therapeutic approach designed to treat disorders associated with the microbiome. To our knowledge, no companies have received regulatory approval for, or manufactured on a commercial scale, any microbiome-based therapeutics. Our microbiome therapy candidates are in nonclinical and early clinical development, and our GEMICEL® dual-targeted release capsule formulation is novel and has not yet shown to successfully deliver live bacteria in patients. The ability to deliver bacteria effectively and reliably to the GI tract is unproven, and, even if it can be proven, it may be difficult or impossible to provide the treatment economically. Because of these uncertainties, it is possible that no commercial products will be successfully developed. If we are unable to successfully develop commercial products, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for FDA Fast Track designation. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. In 2018, the FDA granted Fast Track designation to H0731 for the treatment of patients with chronic HBV infection. We may seek Fast Track designation for other product candidates, but there is no assurance that it will be granted. 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.

A breakthrough therapy designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the designation.

We will need additional financing to complete the development of any product candidate and fund our activities in the future.

We anticipate that we will incur operating losses for the next several years as we continue to develop our product candidates and our Microbiome platform as well as initiate development of any other product candidates and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations for at least the next twelve months. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change or if clinical study timelines are accelerated. If that happens, we may need additional financing to continue the development of our HBV and microbiome product candidates, which we might seek and receive from the public financial markets, third-party commercial partners, private placements, debt financings or other sources. There is no assurance that we will be able to generate sufficient revenue from our Collaboration Agreement with Allergan or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. If such events or other unforeseen circumstances occurred and we were unable to generate sufficient revenue or raise capital, we could be forced to delay, scale back or discontinue product development, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

In addition, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If another prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or our ability to raise capital through the public financial markets, either of which could have a material adverse effect on our business.

Our Microbiome program is substantially dependent on our Collaboration Agreement with Allergan, which may be terminated or may not be successful due to a number of factors, which could have a material adverse effect on our business and operating results.

In January 2017, we entered into the Collaboration Agreement for the development and commercialization of select microbiome gastrointestinal programs in ulcerative colitis, Crohn's disease and irritable bowel syndrome. Our collaboration with Allergan may be terminated, or may not be successful, due to a number of factors. In particular, Allergan may terminate the Collaboration Agreement at any time upon either 90 days' (prior to the initiation of the first POC trial of a licensed product) or 120 days' (after the initiation of the first POC trial of a licensed product), as applicable, advance written notice to us. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure. In addition, if we are unable to identify product candidates for the licensed indications or we are unable to protect our products by obtaining and defending patents, the collaboration could fail. If the collaboration is unsuccessful for these or other reasons, or is otherwise terminated for any reason, we may not receive all or any of the research program funding, milestone payments or royalties under the agreement. Any of the foregoing could result in a material adverse effect on our business, results of operations and prospects and may cause our stock price to decline. In June 2019, Allergan and AbbVie Inc. (AbbVie) announced that they had entered into a definitive transaction agreement under which AbbVie will acquire Allergan. Assuming the conditions to close are satisfied, the acquisition was originally expected to close in early 2020. AbbVie and Allergan recently received approvals from both the Federal Trade Commission and the High Court of Ireland, and the acquisition is expected to close in May 2020. We do not know what, if any, impact this transaction will have on the Collaboration Agreement when it closes.

We are dependent on a license relationship for each of our HBV Cure program and our Microbiome program.

Our license agreement with IURTC from whom we have licensed H0731 and certain other HBV therapies, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to H0731 and certain other HBV therapies and royalty payments and diligence fees. If we breach any of our obligations under our license agreement, we could lose our rights to H0731.

Our license with Therabiome, from whom we have licensed a delivery platform for our Microbiome program, also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to the targeted delivery mechanism of our Microbiome program.

If we fail to comply with our obligations to our licensors, then they may have the right to terminate the license, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. In addition, the milestone and other payments associated with licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

Corporate and academic collaborators might take actions to 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. In addition, should a collaboration be 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 not successful, 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 our collaborators and others 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 adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we 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 established physical, electronic and organizational measures to safeguard and secure our systems to prevent this data from being compromised, and we rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also 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, including by computer hackers, foreign governments and cyberterrorists, has generally increased 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 while we have implemented security measures to protect our data and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a 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.

Moreover, 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 (HITECH), 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, without limitation, 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.

We lack suitable facilities for certain nonclinical and clinical testing and expect to rely on third parties to conduct some of our research and nonclinical testing and our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research, testing or trials.

We do not have sufficient facilities to conduct all of our anticipated nonclinical and clinical testing. As a result, we expect to contract with third parties to conduct a significant portion of our nonclinical and clinical testing required for regulatory approval for our product candidates. We rely on the services of third parties to conduct studies on our behalf. If we are unable to retain or continue with third parties for these purposes on acceptable terms, we may be unable to successfully develop our product candidates. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our product candidates for regulatory approval, which would impair our financial condition and business prospects.

Our reliance on these third parties for research and development activities also reduces our control over these activities but will 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, and our reliance on third parties does not relieve us of our regulatory responsibilities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, 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. As a result, our results of operations and business prospects would be harmed, our costs could increase and our ability to generate revenues from the sale of products could be delayed.

We will need to either establish our own clinical and commercial manufacturing capabilities or rely on third parties to formulate and manufacture our product candidates. We rely on third parties to manufacture products that we study in combination with our product candidates. Our use of third parties to manufacture these materials may increase the risk that we will not have sufficient quantities of our product candidates or other products, or necessary quantities of such materials on time or at an acceptable cost.

We currently rely on third-party manufacturers to supply the quantities of H0731, H2158 and H3733 used in our clinical and nonclinical studies and the drug substance for our Microbiome program. We currently manufacture our microbiome drug product for use in our planned nonclinical studies and early-stage clinical studies; however, we may require third-party manufacturers for subsequent clinical studies or other microbiome drug products. In addition, if any product candidate we might develop or acquire in the future receives FDA or other regulatory approval, we will need to either manufacture commercial quantities of the product on our own or rely on one or more third-party contractors to manufacture our products. The establishment of internal manufacturing capabilities is difficult and costly, and we may not be successful in doing so. If, for any reason, we are unable to establish our own manufacturing capabilities and we are unable to rely on any third-party sources we have identified to manufacture our product candidates, either for clinical studies or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substance and drug products for nonclinical, clinical and commercial purposes. We

might not be successful 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 either on our own or through third parties, the development and sales of our products and our financial performance will be materially and adversely affected.

In addition, before we or any of our collaborators can begin to commercially manufacture our product candidates, each manufacturing facility and process is subject to regulatory review. Manufacturing of drugs for clinical and commercial purposes must comply with the FDA's and applicable non-U.S. regulatory requirements, including cGMPs. The cGMP requirements govern compliance and documentation policies and procedures. Complying with FDA and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and compliance to assure that the product meets applicable specifications and other requirements. Any manufacturing facility must also pass a pre-approval inspection prior to regulatory approval. Failure to pass a pre-approval inspection might significantly delay regulatory approval of our product candidates. If we or any of our future collaborators fails to comply with these requirements with respect to the manufacture of any of our product candidates, regulatory action could limit the jurisdictions in which we are permitted to sell our products, if approved. As a result, our business, financial condition, and results of operations might be materially harmed.

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

- If we are unable to establish our own manufacturing capabilities, we will need to identify manufacturers for commercial supply on acceptable terms, which we may not be able to do because the number of potential manufacturers is limited, and the FDA must evaluate any new or replacement contractor. This evaluation would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory approval, if any.

- We or any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and of the 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 clinical studies or to produce, store and successfully distribute 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.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. Any internal manufacturing facilities we establish may fail to comply, and we would not have complete control over any third-party manufacturers' compliance, with these regulations and requirements.

- We may be required to obtain additional intellectual property rights from third parties in order to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.

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

- If we contract 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 us.

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 or the commercialization of our product candidates and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

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, UC, inflammatory bowel disease (IBD), including Crohn's disease, IBS, immune-mediated and metabolic disorders and oncology is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, UC, IBD, IBS, immune-mediated and metabolic disorders and oncology or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

Companies with core inhibitor products or microbiome products may produce negative clinical data, which would adversely affect public perception of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Negative data from clinical trials using core inhibitors or microbiome-based therapies (e.g., fecal transplant) could negatively impact the perception of the therapeutic use of our HBV or microbiome product candidates, respectively. This could negatively impact our ability to enroll patients in clinical trials. The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of the use of core inhibitor product candidates and oral live microbial biotherapeutic products (LBPs). Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of core inhibitor product candidates or LBPs 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 preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing core inhibitor therapies or microbiome 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.

We might not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our current and future management and other administrative and operational resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We might seek to develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the acquired technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;
- maintaining or obtaining the necessary regulatory approvals or complying with regulatory requirements; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions would depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to integrate efficiently any acquired business, technology or product into our business, our business and financial condition might be adversely affected.

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.

Product candidates employing our technology 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. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our product candidates. The regulatory review and approval process, which includes nonclinical testing and clinical studies of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical studies and approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product’s safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product.

Even if we or our collaborators are able to 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. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. 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, among other things, 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 the applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA, in the case of our HBV Cure program, or a BLA, in the case of our product candidates in our Microbiome program, demonstrating that the product candidate is safe for humans and effective for its intended use (for biological products, this standard is referred to as safe, pure and potent). This demonstration 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 or biological products that the FDA considers safe for humans 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 or BLAs. We cannot be sure that we will ever obtain regulatory approval for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate could be developed or obtained. There is no guarantee that we will ever be able to develop an existing, or acquire another, product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any product candidates. The risks associated with foreign regulatory approval processes are similar to the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

Even if our product candidates are approved, we and our collaborators will be subject to extensive post-approval regulation, including ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, our product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Once a product candidate is approved, numerous post-approval requirements apply. Among other things, we and our collaborators will be subject to requirements regarding testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. The holder of an approved NDA or BLA is subject to ongoing FDA oversight, monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA or BLA. Application holders must submit new or

supplemental applications and obtain FDA approval for changes to the approved product, product labeling, or manufacturing process, depending on the nature of the change. Application holders also must submit advertising and other promotional material to the FDA and report on ongoing clinical studies. The FDA also has the authority to require changes in the labeling of approved drug products and to require post-marketing studies. The FDA can also impose distribution and use restrictions under a REMS.

Advertising and promotional materials must comply with FDA rules in addition to other applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Sales, marketing, and scientific/educational grant programs, among other activities, must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, license revocation or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval or revise product labeling.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we or our collaborators are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

We have never commercialized a product, and even if any product candidate of ours is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians may be reluctant to take their patients off their current medications and switch their treatment regimen. Further, patients often acclimate to the treatment regime that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to lack of coverage and adequate reimbursement. In addition, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain promptly coverage and profitable payment rates from both government-funded and private payors for any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

In the United States and in other countries, there have been, and we expect there will continue to be, a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the ACA.

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices (which was increased to 70% as of January 1, 2019 under the Bipartisan Budget Act of 2018 (BBA));
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been many judicial, Presidential, and Congressional challenges to numerous aspects of the ACA, and the long ranging effects of these challenges on reimbursement by third-party payors, the viability of the ACA marketplace, providers, and potentially, our business are unknown at this time. In addition, the full impact of the ACA, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Further, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues from the sale of products, and to achieve and maintain profitability.

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, without limitation, 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. There are ambiguities as to what is required to comply with these requirements, and 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, which went into effect on May 25, 2018, 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 where such processing is subject to the GDPR, 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 and services or even prevent us from offering certain products in jurisdictions that we may operate in. Given the limited enforcement of the GDPR to date, particularly in the pharmaceutical space, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

California recently enacted the CCPA, which creates 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 will require 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, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. The uncertainty surrounding the implementation of 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. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse 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.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

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.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to refine our disclosure controls and other procedures that are designed to ensure that the information that we are required to disclose in the reports that we will file with the SEC is properly recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal control over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting.

Our current controls and any new controls that we develop in the future may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will be required to include in our periodic reports that will be filed with the SEC. If we were to have ineffective disclosure controls and procedures or internal control over financial reporting, our investors could lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

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 the development of drugs and biotherapeutics. 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. We intend to expand our insurance coverage to include product liability insurance covering the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we might be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 the liability. Any successful product liability claims or series of claims brought against us would decrease our cash and could cause the value of our common stock to decrease.

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, for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, 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 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 adversely affect our business, financial condition and results of operations. We currently do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future, if necessary, but cannot give assurance that we could obtain such coverage.

Our employees, independent contractors, consultants, collaborators and contract research organizations 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 intentional failure to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- 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 laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Misconduct could also involve the improper use or misrepresentation of information obtained in the course of 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. We have adopted a code of conduct for our directors, officers and employees (the Code of Conduct), but it is not always possible to identify and deter employee 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 be in compliance 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 are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws). We can face serious consequences for violations.

Among other matters, Trade Laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities, particularly in China, to increase in time. We engage third parties for clinical studies and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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, such as the spread of the novel strain of coronavirus and the resulting COVID-19 pandemic impacting all countries, including China.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we and our licensors, IURTC and Therabiome, 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 seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and chemical and biological compositions that are important to our business. To date, we and our licensors have filed patent applications intended to cover our products candidates and their methods of use. Although we co-own and have in-licensed two issued patents in the U.S. directed to compositions of matter that includes H0731, which are expected to expire in 2035 and 2036, and we have in-licensed issued U.S. patents related to delivery technology for our Microbiome program, which are expected to expire in 2034, we do not own or have any rights to any issued patents that cover any of our other product candidates, and 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 not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

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. These risks and uncertainties include the following:

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful; and
- Countries other than the United States might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the U.S. Patent and Trademark Office (the USPTO) and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be 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 are able to obtain patents, the patents might be substantially narrower than anticipated.

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. Our business and prospects will be harmed if we fail to obtain these protections or they prove insufficient.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates and technologies through intellectual property license agreements with third parties, including IURTC and Therabiome. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

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

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would 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 the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court 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 rely on trade secret protections through confidentiality agreements with our employees, collaborators and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality, invention, and nondisclosure agreements with our employees, scientific advisors, consultants, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

If our employees or consultants breach their confidentiality obligations, to be able to enforce these confidentiality provisions, we would need to know of the breach and have sufficient funds to enforce the provisions. We cannot assure you that we would know of or be able to afford enforcement of any breach. In addition, such provisions are subject to state law and interpretation by courts, which could limit the scope and duration of these provisions. Any limitation on or non-enforcement of these confidentiality provisions could have an adverse effect on our business.

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.

A third party may claim that we are using inventions covered by the third party’s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. Patent litigation is costly and time consuming. We may not have sufficient resources to address these actions, and such actions could affect our results of operations and divert the attention of managerial and scientific personnel.

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 in order 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 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.

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

Any disclosure to or misappropriation by third parties of our patents, trade secrets or confidential information could compromise our competitive position. 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. The legal systems of certain countries, particularly countries such as 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.

We may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted and could provoke third parties to assert claims against us.

We may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products.

Composition-of-matter patents relating to the active pharmaceutical ingredient (API) 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. Even 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. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the United States and other countries are typically not published until 18 months after filing, and in some cases are never published. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the United States, the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The United States moved to a “first to file” system under the Leahy-Smith America Invents Act (AIA), effective March 16, 2013. The effects of this change and other elements of the AIA are currently unclear, as the USPTO is still implementing associated regulations, and the applicability of the AIA and associated regulations to our patents and patent applications have not been fully determined. This new system also includes new procedures for challenging issued patents and pending patent applications, which creates additional uncertainty. We may become involved in any variety of proceedings challenging our patents and patent applications or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of, invalidate, and/or find our patent rights unenforceable, allowing third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others. In addition to ongoing changes with the AIA and USPTO regulations, recent decisions of the Supreme Court of the United States, and the possibility of statutory change to patent subject matter eligibility law advocated by such groups as the Intellectual Property Owners Association and the American Intellectual Property Law Association, provide additional uncertainty.

In addition to 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 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. Furthermore, the laws of some foreign countries, in particular China, where we anticipate increasing our activity and commercializing our product candidates, do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. 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.

Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, some of our collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations in place with our collaboration partners. Despite our efforts to protect our trade secrets and other confidential information, a competitor’s discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business.

We are developing an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. 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 and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction 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 costs and the potential protection 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 throughout the world, 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, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. 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.

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, as a result 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, often are of 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. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. 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. With respect to China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system in China. As a result, we may not be able 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

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 might be volatile and subject to wide price fluctuations in response to various factors, including:

- the progress, results and timing of our clinical studies and nonclinical studies and other studies involving our product candidates;
- success or failure of our product candidates;
- the receipt or loss of required regulatory approvals for our product candidates;
- availability of capital;
- future issuances by us of our common stock or securities exercisable for or convertible into common stock;
- sale of shares of our common stock by our significant stockholders or members of our management;
- additions or departures of key personnel;
- investor perceptions of us and the pharmaceutical industry;
- issuance of new or changed securities analysts' reports or recommendations, or the announcement of any changes to our credit rating;
- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- threatened or actual litigation and government investigations;
- legislative, political or regulatory developments;
- the overall performance of the equity markets;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- general economic conditions;
- changes in interest rates; and
- changes in accounting standards, policies, guidance, interpretations or principles.

These and other factors might cause the market price of our common stock to fluctuate substantially, which might limit or prevent investors from readily selling their shares of our common stock and might otherwise negatively affect the liquidity of our common stock. In addition, this year, the stock market has experienced significant price and volume fluctuations related to the COVID-19 pandemic. This volatility has had a significant impact on the market price of our common stock and securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors unrelated to our business and operations, and these fluctuations could materially reduce our share price.

We might not be able to maintain the listing of our common stock on the Nasdaq Global Select Market.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ASMB." We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the "pink sheets" maintained by OTC Markets Group Inc. These alternative markets are generally considered to be markets that are less efficient and less broad than the Nasdaq Global Select Market. A delisting of our common stock from the Nasdaq Global Select Market and our inability to list the stock on another national securities exchange could negatively impact us by: (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets and (iv) impairing our ability to provide equity incentives to our employees.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our ability to use our net operating loss and credit carryforwards to offset future taxable income may be subject to certain limitations.

At December 31, 2019, we had potentially utilizable gross Federal net operating loss carryforwards of $297.6 million, State net operating loss carry-forwards of $309.3 million, Federal and California research and development credit carry forwards of $9.0 million and $5.3 million, respectively, which will begin to expire in 2027. Our ability to utilize our net operating loss and credit carryforwards is dependent upon our ability to generate taxable income in future periods and may be limited due to restrictions imposed on utilization of net operating loss and credit carryforwards under federal and state laws upon a change in ownership.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change," is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period (calculated on a rolling basis). We have determined that an ownership change occurred in each of December 2010, January 2013 and October 2014. The result of these ownership changes is that $40.0 million of our $337.4 million of Federal net operating losses will not be available to us to offset future taxable income leaving potentially utilizable gross Federal net operating loss carryforwards of $297.6 million. In addition, we may experience ownership changes in the future, some of which are outside our control. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. Limitations on our ability to utilize our net operating losses to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Because U.S. federal net operating losses incurred in taxable periods beginning before January 1, 2018 generally may be carried forward for up to 20 years, the annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses, including certain recognized built-in losses that may be utilized. Such pre-ownership change losses in excess of the cap may be lost. In addition, if an ownership change were to occur, it is possible that the limitations imposed on our ability to use pre-ownership change losses and certain recognized built-in losses could cause a net increase in our U.S. federal income tax liability and require U.S. federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. Further, if for financial reporting purposes the amount or value of these deferred tax assets is reduced, such reduction would have a negative impact on the book value of our common stock.

In addition, under the Tax Cust and Jobs Act (the Tax Act), the amount of U.S. federal net operating losses generated in taxable periods beginning after December 31, 2017 that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any post-2017 NOL to prior taxable years, while allowing unused post-2017 NOLs to be carried forward indefinitely. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law by President Trump in March 2020. The CARES Act allows NOLs in tax periods beginning after December 31, 2017 and beginning before January 1, 2021 to be carried back five years, carried forward indefinitely, and permitted to deduct 100% of our taxable income for tax periods beginning before January 1, 2021. In tax periods beginning after December 31, 2020, the 80% taxable income limit discussed above will apply to all U.S. NOLs generated in taxable periods beginning after December 31, 2017.

There is a risk that due to ownership changes, changes in law or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

We do not intend to pay dividends for the foreseeable future and our stock may not appreciate in value.

We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in shares of our common stock will depend upon any future appreciation in its value. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

The requirements of being a public company add to our operating costs and might strain our resources and distract our management.

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We have incurred and will continue to incur significant additional legal, accounting and other expenses to which we were not subject to as a private company, including expenses related to our efforts in complying with the requirements of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and other public company disclosure and corporate governance requirements and responding to requests of government regulators. We are subject to the reporting requirements of the Exchange Act, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act, and the listing standards of the Nasdaq Global Select Market, each of which imposes additional reporting and other obligations on public companies. Although we are currently unable to estimate these costs with any degree of certainty, we expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly and place significant strain on our personnel, systems and resources. These increased costs will require us to divert a significant amount of money that we could otherwise use to develop our product candidates or otherwise expand our business. Complying with these requirements might divert management's attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our securities.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our securities could be reduced as a result. These provisions may include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholders' approval;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;

- prohibiting cumulative voting in the election of directors;
- prohibiting shareholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, a limited number of financial analysts publish reports about us and our business. We do not control these analysts or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any analyst who covers us downgrades our stock, our stock price could decline rapidly. If one or more analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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
10.1#	Assembly Biosciences, Inc. 2020 Corporate Bonus Plan.		8-K	02/11/2020	10.1
10.2#	Omnibus Amendment to Assembly Biosciences, Inc. Stock Incentive Plans.	X			
10.3#	Assembly Biosciences, Inc. 2020 Inducement Award Plan (the 2020 Inducement Award Plan).	X			
10.4#	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2020 Inducement Award Plan.	X			
10.5#	Form of Restricted Stock Unit Award Notice and Restricted Stock Unit Award Agreement under the 2020 Inducement Award Plan.	X			
10.6#	Amendment No. 1 to Employment Agreement, dated February 26, 2020, between Assembly Biosciences, Inc. and Thomas J. Russo, CFA.	X			
10.7#	Amendment No. 1 to Employment Agreement, dated February 26, 2020, between Assembly Biosciences, Inc. and Luisa M. Stamm, M.D., Ph.D.	X			
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 certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is 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 8, 2020

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 8, 2020

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

Exhibit 10.2

OMNIBUS AMENDMENT

TO

ASSEMBLY BIOSCIENCES, INC.

STOCK INCENTIVE PLANS

Assembly Biosciences, Inc., a Delaware corporation (the "Company") adopted the Amended and Restated 2014 Stock Incentive Plan on June 2, 2016 (as amended from time to time, the "2014 Plan").

The Company adopted the 2017 Inducement Award Plan on April 3, 2017 (as amended from time to time, the "2017 Plan").

The "Company adopted the 2018 Stock Incentive Plan on May 30, 2018, as amended by Amendment No.1 to the Plan effective as of May 17, 2019 (as amended from time to time, the "2018 Plan").

The Company adopted the 2019 Inducement Award Plan on August 6, 2019 (as amended from time to time, the "2019 Plan" and together with the 2014 Plan, the 2017 Plan and the 2018 Plan, collectively the "Stock Plans" and individually, a "Stock Plan").

The Company desires to amend each of the Stock Plans to provide for acceleration of certain unvested Awards if such Awards are not Assumed or Replaced in connection with a Corporate Transaction.

Pursuant to Section 15(a) of each of the Company's Stock Plans, the Board of Directors of the Company (the "Board") may, amend each of the Stock Plans.

Pursuant to Section 13(b) of each of the Stock Plans, the Administrator may, in advance of or in anticipation of a Corporate Transaction, provide for acceleration of unvested Awards in connection with a Corporate Transaction.

The Board has determined that it is advantageous to the Company and necessary to attract and retain the best available personnel to amend Section 13(a) of each of the Stock Plans to provide for acceleration in connection with a Corporate Transaction if the Awards are not Assumed or Replaced in the Corporate Transaction.

Now, therefore,

Section 13(a) of each of the Stock Plans is hereby amended as follows:

"(a) Treatment of Awards in Corporate Transaction. Except as the Administrator may otherwise specify with respect to particular Awards in the relevant Award Agreement, in the case of and subject to the consummation of a Corporate Transaction, the parties to the Corporate Transaction may cause the Awards to be Assumed or Replaced by the successor entity as such parties shall agree. To the extent the parties to such Corporate Transaction do not provide for the Awards to be Assumed or Replaced upon the effective time of the Corporate Transaction, the Plan and all outstanding Awards granted under the Plan shall terminate. In such case, except as may be otherwise expressly provided in the relevant Award Agreement, all Awards with solely time-based vesting that are not vested and/or exercisable immediately prior to the effective time of the Corporate Transaction shall become fully vested and exercisable as of immediately prior to the effective time of the Corporate Transaction and all Awards with conditions and restrictions relating to the attainment of performance goals shall be deemed to vest and become nonforfeitable as of the Corporate Transaction as provided in the relevant Award Agreement or if not provided for in the relevant Award Agreement shall be deemed to vest and become nonforfeitable as of the Corporate Transaction assuming the higher of (i) achievement of all relevant performance goals at the "target" level (prorated based upon the length of time within the performance period that has elapsed prior the Corporate Transaction or partial achievement of the performance goals), or (ii) actual achievement of all relevant performance goals as of the date of such Corporate Transaction. In the event of such termination of the Awards, the Company shall have the option (in its sole discretion) to (1) make or provide for a payment, in cash or in kind, to the Grantees holding Options and SARs, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of Shares subject to outstanding Options and SARs and (B) the aggregate exercise price of all such outstanding Options and SARs (provided that, in the case of an Option or SAR with an exercise price equal to or more than the Sale Price, such Option or SAR shall be cancelled for no consideration); or (2) permit each Grantee, within a specified period of time prior to the consummation of the Corporate Transaction as determined by the Administrator, to exercise all outstanding Options and SARs (to the extent then exercisable including due to acceleration as contemplated by this Section 13(a) if the Awards are not Assumed or Replaced) held by such Grantee as of immediately prior to the effective time of the Corporate Transaction. In the event of a termination of Awards pursuant to this Section 13(a), the Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the Grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested Shares under such Awards. For purposes of this Section 13(a), "***Sale Price***" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per Share pursuant to a Corporate Transaction."

Except as expressly set forth in this Omnibus Amendment to Stock Plans, all other terms and conditions set forth in each of the Stock Plans shall remain in full force and effect. Each capitalized term used and not defined herein shall have the meaning set forth in the applicable Stock Plan.

This Amendment has been adopted by the Board of Directors of the Company as of March 11, 2020.

March 11, 2020: Adopted by Board of Directors

EXHIBIT 10.3

ASSEMBLY BIOSCIENCES, INC.

2020 INDUCEMENT AWARD PLAN

1. Purposes of the Plan. The purposes of this Plan are to attract and retain the best available personnel, to provide an inducement material for such persons to enter into employment with the Company or a Related Entity within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules and to promote the success of the Company's business.

2. Definitions. The following definitions shall apply as used herein and in the individual Award Agreements except as defined otherwise in an individual Award Agreement. In the event a term is separately defined in an individual Award Agreement, such definition shall supersede the definition contained in this Section 2.

(a) "***Administrator***" means the Board or any of the Committees appointed to administer the Plan.

(b) "***Affiliate***" and "***Associate***" shall have the respective meanings ascribed to such terms in Rule 12b-2 promulgated under the Exchange Act.

(c) "***Applicable Laws***" means the legal requirements relating to the Plan and the Awards under applicable provisions of federal and state securities laws, the corporate laws of the state of Delaware, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein.

(d) "***Assumed***" means that pursuant to a Corporate Transaction either (i) the Award is expressly affirmed by the Company or (ii) the contractual obligations represented by the Award are expressly assumed (and not simply by operation of law) by the successor entity or its Parent in connection with the Corporate Transaction with appropriate adjustments to the number and type of securities of the successor entity or its Parent subject to the Award and the exercise or purchase price thereof which at least preserves the compensation element of the Award existing at the time of the Corporate Transaction as determined in accordance with the instruments evidencing the agreement to assume the Award.

(e) "***Award***" means the grant of an Option, SAR, Dividend Equivalent Right, Restricted Stock, Restricted Stock Unit or other right or benefit under the Plan.

(f) "***Award Agreement***" means the written agreement evidencing the grant of an Award executed by the Company and the Grantee, including any amendments thereto.

(g) "***Board***" means the Board of Directors of the Company.

(h) "***Cause***" means, with respect to the termination by the Company or a Related Entity of the Grantee's Continuous Service, that such termination is for "Cause" as such term (or word of like import) is expressly defined in a then-effective written agreement between the Grantee and the Company or such Related Entity, or in the absence of such then-effective written agreement and definition, is based on, in the determination of the Administrator, the Grantee's: (i) performance of any act or failure to perform any act in bad faith and to the detriment of the Company or a Related Entity; (ii) dishonesty, intentional misconduct or material breach of any agreement with the Company or a Related Entity; or (iii) commission of a crime involving dishonesty, breach of trust, or physical or emotional harm to any person; provided, however, that with regard to any agreement that defines "Cause" on the occurrence of or in connection with a Corporate Transaction, such definition of "Cause" shall not apply until a Corporate Transaction actually occurs.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended, or any successor statute.

(j) "***Committee***" means any committee composed of members of the Board appointed by the Board to administer the Plan.

(k) "***Common Stock***" means the Company's Common Stock, par value $0.001 per share.

(l) "***Company***" means Assembly Biosciences, Inc., a Delaware corporation, or any successor entity that adopts the Plan in connection with a Corporate Transaction.

(m) "***Consultant***" means any natural person (other than an Employee or a Director, solely with respect to rendering services in such person's capacity as a Director) who provides bona fide services to the Company or any Related Entity, within the meaning of Form S-8 promulgated under the Securities Act of 1933, as amended.

(n) "***Continuous Service***" means that the provision of services to the Company or a Related Entity in any capacity of Employee, Director or Consultant is not interrupted or terminated. In jurisdictions requiring notice in advance of an effective termination as an Employee, Director or Consultant, Continuous Service shall be deemed terminated upon the actual cessation of providing services to the Company or a Related Entity notwithstanding any required notice period that must be fulfilled before a termination as an Employee, Director or Consultant can be effective under Applicable Laws. A Grantee's Continuous Service shall be deemed to have terminated either upon an actual termination of Continuous Service or upon the entity for which the Grantee provides services ceasing to be a Related Entity. Continuous Service shall not be considered interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entity, or any successor in any capacity of Employee, Director or Consultant, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director or Consultant (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave.

(o) "***Corporate Transaction***" means any of the following transactions, provided, however, that the Administrator shall determine under parts (iv) and (v) whether multiple transactions are related, and its determination shall be final, binding and conclusive:

(i) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company;

(iii) the complete liquidation or dissolution of the Company;

(iv) any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the shares of Common Stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger; or

(v) acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities.

(p) "***Director***" means a member of the Board or the board of directors of any Related Entity.

(q) "***Disability***" means "disability" as defined in the long-term disability policy of the Company or the Related Entity to which the Grantee provides services regardless of whether the Grantee is covered by such policy. If the Company or the Related Entity to which the Grantee provides service does not have a long-term disability plan in place, "Disability" means that a Grantee is unable to carry out the responsibilities and functions of the position held by the Grantee by reason of any medically determinable physical or mental impairment for a period of not less than ninety (90) consecutive days. A Grantee will not be considered to have incurred a Disability unless he or she furnishes proof of such impairment sufficient to satisfy the Administrator in its discretion.

(r) "***Dividend Equivalent Right***" means a right entitling the Grantee to compensation measured by dividends paid with respect to Common Stock.

(s) "***Employee***" means any person, including an Officer or Director, who is in the employ of the Company or any Related Entity, subject to the control and direction of the Company or any Related Entity as to both the work to be performed and the manner and method of performance. The payment of a director's fee by the Company or a Related Entity shall not be sufficient to constitute "employment" by the Company.

(t) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(u) "***Fair Market Value***" means, as of any date, the value of Common Stock determined as follows.

(i) If the Common Stock is listed on one or more established stock exchanges or national market systems, including without limitation The NASDAQ Global Select Market, The NASDAQ Global Market or The NASDAQ Capital Market of The NASDAQ Stock Market LLC, its Fair Market Value shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on the principal exchange or system on which the Common Stock is listed (as determined by the Administrator) on the date of determination (or, if no closing sales price or closing bid was reported on that date, as applicable, on the last trading date such closing sales price or closing bid was reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted on an automated quotation system (including the OTC Bulletin Board) or by a recognized securities dealer, its Fair Market Value shall be the closing sales price for such stock as quoted on such system or by such securities dealer on the date of determination, but if selling prices are not reported, the Fair Market Value of a share of Common Stock shall be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or, if no such prices were reported on that date, on the last date such prices were reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

(iii) In the absence of an established market for the Common Stock of the type described in (i) and (ii), above, the Fair Market Value thereof shall be determined by the Administrator in a manner in compliance with Section 409A of the Code.

(v) "***Grantee***" means an individual who receives an Award under the Plan.

(w) "***Non-Qualified Stock Option***" means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.

(x) "***Officer***" means a person who is an officer of the Company or a Related Entity within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(y) "***Option***" means a Non-Qualified Stock Option to purchase Shares pursuant to an Award Agreement granted under the Plan.

(z) "***Parent***" means a "parent corporation," whether now or hereafter existing, as defined in Section 424(e) of the Code.

(aa) "***Plan***" means this Assembly Biosciences, Inc. 2020 Inducement Award Plan.

(bb) "***Post-Termination Exercise Period***" means the period specified in the Award Agreement of not less than thirty (30) days commencing on the date of termination (other than termination by the Company or any Related Entity for Cause) of the Grantee's Continuous Service, or such longer period as may be applicable upon death or Disability.

(cc) "***Related Entity***" means any Parent or Subsidiary of the Company**.**

(dd) "***Replaced***" means that pursuant to a Corporate Transaction the Award is replaced with a comparable stock award or a cash incentive program of the Company, the successor entity (if applicable) or Parent of either of them which preserves the compensation element of such Award existing at the time of the Corporate Transaction and provides for subsequent payout in accordance with the same (or a more favorable) vesting schedule applicable to such Award. The determination of Award comparability shall be made by the Administrator and its determination shall be final, binding and conclusive.

(ee) "***Restricted Stock***" means Shares issued under the Plan to the Grantee for such consideration, and subject to such restrictions on transfer, rights of first refusal, repurchase provisions, forfeiture provisions, and other terms and conditions as established by the Administrator.

(ff) "***Restricted Stock Units***" means an Award which may be earned in whole or in part upon the passage of time or the attainment of performance criteria established by the Administrator and which may be settled for cash, Shares or other securities or a combination of cash, Shares or other securities as established by the Administrator.

(gg) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor thereto.

(hh) "***SAR***" means a stock appreciation right entitling the Grantee to Shares or cash compensation, as established by the Administrator, measured by appreciation in the value of Common Stock.

(ii) "***Share***" means a share of the Common Stock.

(jj) "***Subsidiary***" means a "subsidiary corporation," whether now or hereafter existing, as defined in Section 424(f) of the Code.

3. Stock Subject to the Plan.

(a) Subject to the provisions of Sections 3(b) and 12 below, the maximum aggregate number of Shares which may be issued pursuant to all Awards is Eight Hundred Thousand (800,000) Shares. The Shares granted under the Plan may be authorized, but unissued, or reacquired Common Stock.

(b) Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the Plan. Shares that actually have been issued under the Plan pursuant to an Award shall not be returned to the Plan and shall not become available for future issuance under the Plan, except that if Options or other Awards granted under this Plan are forfeited, canceled, expired or repurchased by the Company, such Shares shall become available for future grant under the Plan. In the event any Option or other Award granted under the Plan is exercised through the tendering of shares of Common Stock (either actually or through attestation) or withholding shares of Common Stock, or in the event tax withholding obligations are satisfied by tendering or withholding shares of Common Stock, any shares of Common Stock so tendered or withheld shall not again be available for awards under the Plan. Shares of Common Stock subject to an SAR granted pursuant to Section 6(k) of this Plan that are not issued in connection with cash or stock settlement of the exercise of the SAR shall not again be available for award under the Plan. Shares of Common Stock reacquired by the Company on the open market or otherwise using cash proceeds from the exercise of Options shall not be available for awards under the Plan.

4. Administration of the Plan.

(a) Plan Administrator.

(i) Administration – General. The Plan shall be administered by (A) the Board or (B) a Committee designated by the Board, which Committee shall be constituted in such a manner as to satisfy the Applicable Laws and to permit such grants and related transactions under the Plan to be exempt from Section 16(b) of the Exchange Act in accordance with Rule 16b-3. Once appointed, such Committee shall continue to serve in its designated capacity until otherwise directed by the Board.

(ii) Administration in Compliance with Rule 5605(a)(2) of the NASDAQ Listing Rules. Notwithstanding the foregoing or anything in the Plan to the contrary, the grant of Awards will be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the NASDAQ Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the NASDAQ Listing Rules.

(b) Powers of the Administrator. Subject to Applicable Laws and the provisions of the Plan (including any other powers given to the Administrator hereunder), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

(i) to select the individuals to whom Awards may be granted from time to time hereunder; provided that Awards may only be granted to individuals who satisfy the standards for inducement grants under Rule 5635(c)(4) of the NASDAQ Listing Rules;

(ii) to determine whether and to what extent Awards are granted hereunder;

(iii) to determine the number of Shares or the amount of other consideration to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the type, terms and conditions of any Award granted hereunder;

(vi) to establish additional terms, conditions, rules or procedures to accommodate the rules or laws of applicable non-U.S. jurisdictions and to afford Grantees favorable treatment under such rules or laws; provided, however, that no Award shall be granted under any such additional terms, conditions, rules or procedures with terms or conditions which are inconsistent with the provisions of the Plan;

(vii) to amend the terms of any outstanding Award granted under the Plan, provided that any amendment that would adversely affect the Grantee's rights under an outstanding Award shall not be made without the Grantee's written consent;

(viii) to construe and interpret the terms of the Plan and Awards, including without limitation, any notice of award or Award Agreement, granted pursuant to the Plan;

(ix) to institute an option exchange program; and

(x) to take such other action, not inconsistent with the terms of the Plan, as the Administrator deems appropriate.

The express grant in the Plan of any specific power to the Administrator shall not be construed as limiting any power or authority of the Administrator; provided that the Administrator may not exercise any right or power reserved to the Board. Any decision made, or action taken, by the Administrator or in connection with the administration of this Plan shall be final, conclusive and binding on all persons having an interest in the Plan.

(c) Indemnification. In addition to such other rights of indemnification as they may have as members of the Board or as Officers or Employees of the Company or a Related Entity, members of the Board and any Officers or Employees of the Company or a Related Entity to whom authority to act for the Board, the Administrator or the Company is delegated shall be defended and indemnified by the Company to the extent permitted by law on an after-tax basis against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any claim, investigation, action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any Award granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by the Company) or paid by them in satisfaction of a judgment in any such claim, investigation, action, suit or proceeding, except in relation to matters as to which it shall be

adjudged in such claim, investigation, action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct; provided, however, that within thirty (30) days after the institution of such claim, investigation, action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at the Company's expense to defend the same.

5. Eligibility. Awards may be granted to individuals who become employees of the Company and any Related Entity who satisfy the standards for inducement grants under Rule 5635(c)(4) of the NASDAQ Listing Rules and where the Award is an inducement material to the individual's entering into employment with the Company or a Related Entity. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a bona fide period of non-employment. Subject to the foregoing, Awards may be granted to such individuals who are residing in non-U.S. jurisdictions as the Administrator may determine from time to time. For clarity, Awards may not be granted to (1) Consultants or Directors for service in such capacity, or (2) any individual who was previously an Employee or Director, other than following a bona fide period of non-employment. All Awards must be granted either by a majority of the Company's independent directors or by the Company's compensation committee comprised of independent directors within the meaning of Rule 5605(a)(2) of the NASDAQ Listing Rules.

6. Terms and Conditions of Awards.

(a) Types of Awards. The Administrator is authorized under the Plan to award any type of arrangement to an individual who becomes an employee that is not inconsistent with the provisions of the Plan and that by its terms involves or might involve the issuance of (i) Shares, (ii) cash or (iii) an Option, an SAR, or similar right with a fixed or variable price related to the Fair Market Value of the Shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. Such awards include, without limitation, Options, SARs, Restricted Stock, Restricted Stock Units or Dividend Equivalent Rights, and an Award may consist of one such security or benefit, or two (2) or more of them in any combination or alternative.

(b) Designation of Award. Each Award shall be designated in the Award Agreement. In the case of an Option, the Option shall be designated as a Non-Qualified Stock Option.

(c) Conditions of Award. Subject to the terms of the Plan, the Administrator shall determine the provisions, terms, and conditions of each Award including, but not limited to, the Award vesting schedule, repurchase provisions, rights of first refusal, forfeiture provisions, form of payment (cash, Shares, or other consideration) upon settlement of the Award, payment contingencies, and satisfaction of any performance criteria. The performance criteria established by the Administrator may be based on any one of, or combination of, increase in share price, earnings per share, total stockholder return, return on equity, return on assets, return on investment, net operating income, cash flow, revenue, economic value added, initiation or completion of clinical trials, results of clinical trials, regulatory approval, regulatory submissions, drug development or commercialization milestones, collaboration milestones or strategic partnerships. Partial achievement of the specified criteria may result in a payment or vesting corresponding to the degree of achievement as specified in the Award Agreement.

(d) Acquisitions and Other Transactions. The Administrator may issue Awards under the Plan in settlement, assumption or substitution for, outstanding awards or obligations to grant future awards in connection with the Company or a Related Entity acquiring another entity, an interest in another entity or an additional interest in a Related Entity whether by merger, stock purchase, asset purchase or other form of transaction.

(e) Deferral of Award Payment. The Administrator may establish one or more programs under the Plan to permit selected Grantees the opportunity to elect to defer receipt of consideration upon exercise of an Award, satisfaction of performance criteria, or other event that absent the election would entitle the Grantee to payment or receipt of Shares or other consideration under an Award. The Administrator may establish the election procedures, the timing of such elections, the mechanisms for payments of, and accrual of interest or other earnings, if any, on amounts, Shares or other consideration so deferred, and such other terms, conditions, rules and procedures that the Administrator deems advisable for the administration of any such deferral program.

(f) Separate Programs. The Administrator may establish one or more separate programs under the Plan for the purpose of issuing particular forms of Awards to one or more classes of Grantees on such terms and conditions as determined by the Administrator from time to time.

(g) Early Exercise. The Award Agreement may, but need not, include a provision whereby the Grantee may elect at any time while an Employee, Director or Consultant to exercise any part or all of the Award prior to full vesting of the Award. Any unvested Shares received pursuant to such exercise may be subject to a repurchase right in favor of the Company or a Related Entity or to any other restriction the Administrator determines to be appropriate.

(h) Term of Option or SAR. The term of each Option or SAR shall be the term stated in the Award Agreement, provided, however, that the term shall be no more than ten (10) years from the date of grant thereof.

(i) Transferability of Awards. Unless the Administrator provides otherwise, in its sole discretion, no Award may be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Grantee, only by the Grantee. Notwithstanding the foregoing, the Grantee may designate one or more beneficiaries of the Grantee's Award in the event of the Grantee's death on a beneficiary designation form provided by the Administrator.

(j) Time of Granting Awards. The date of grant of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award, or such other later date as is determined by the Administrator.

(k) Stock Appreciation Rights. An SAR may be granted (i) with respect to any Option granted under this Plan, either concurrently with the grant of such Option or at such later time as determined by the Administrator (as to all or any portion of the shares of Common Stock subject to the Option), or (ii) alone, without reference to any related Option. Each SAR granted by the Administrator under this Plan shall be subject to the following terms and

conditions. Each SAR granted to any participant shall relate to such number of shares of Common Stock as shall be determined by the Administrator, subject to adjustment as provided in Section 12. In the case of an SAR granted with respect to an Option, the number of shares of Common Stock to which the SAR pertains shall be reduced in the same proportion that the holder of the Option exercises the related Option. The exercise price of an SAR will be determined by the Administrator, in its discretion, at the date of grant but may not be less than one-hundred percent (100%) of the Fair Market Value of the shares of Common Stock subject thereto on the date of grant. Subject to the right of the Administrator to deliver cash in lieu of shares of Common Stock (which, as it pertains to Officers and Directors of the Company, shall comply with all requirements of the Exchange Act), the number of shares of Common Stock which shall be issuable upon the exercise of an SAR shall be determined by dividing:

(i) the number of shares of Common Stock as to which the SAR is exercised multiplied by the amount of the appreciation in such shares (for this purpose, the "appreciation" shall be the amount by which the Fair Market Value of the shares of Common Stock subject to the SAR on the exercise date exceeds (1) in the case of an SAR related to an Option, the exercise price of the shares of Common Stock under the Option or (2) in the case of an SAR granted alone, without reference to a related Option, an amount which shall be determined by the Administrator at the time of grant, subject to adjustment under Section 12); by

(ii) the Fair Market Value of a share of Common Stock on the exercise date.

In lieu of issuing shares of Common Stock upon the exercise of an SAR, the Administrator may elect to pay the holder of the SAR cash equal to the Fair Market Value on the exercise date of any or all of the shares which would otherwise be issuable. No fractional shares of Common Stock shall be issued upon the exercise of an SAR; instead, the holder of the SAR shall be entitled to receive a cash adjustment equal to the same fraction of the Fair Market Value of a share of Common Stock on the exercise date or to purchase the portion necessary to make a whole share at its Fair Market Value on the date of exercise. The exercise of an SAR related to an Option shall be permitted only to the extent that the Option is exercisable under Section 10 on the date of surrender.

(l) Compliance with Section 409A of the Code. Notwithstanding anything to the contrary set forth herein, any Award that is not exempt from the requirements of Section 409A of the Code shall contain such provisions so that such Award will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Administrator and contained in the Award Agreement evidencing such Award. To the extent that the Administrator determines that any Award granted hereunder is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the effective date of the Plan. Notwithstanding any provision of the Plan to the contrary, in the event that following the effective date of the Plan, the Administrator determines that any Award may be subject to Section 409A of the Code and related Department

of Treasury guidance (including such Department of Treasury guidance as may be issued after the effective date of the Plan), the Administrator may adopt such amendments to the Plan and the applicable Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Administrator determines are necessary or appropriate to (1) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (2) comply with the requirements of Section 409A of the Code and related Department of Treasury guidance.

(m) Minimum Vesting. Awards granted to Employees under the Plan that are subject to time vesting shall not vest or become exercisable until at least one year after the date of grant, except in the case of death, Disability, retirement, separation of service or a Corporate Transaction.

7. Award Exercise or Purchase Price, Consideration and Taxes.

(a) Exercise or Purchase Price. The exercise or purchase price, if any, for an Award shall be as follows.

(i) In the case of an Option, the per Share exercise price shall be not less than one-hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(ii) In the case of other Awards, such price as is determined by the Administrator.

(iii) Notwithstanding the foregoing provisions of this Section 7(a), in the case of an Award issued pursuant to Section 6(d), above, the exercise or purchase price for the Award shall be determined in accordance with the provisions of the relevant instrument evidencing the agreement to issue such Award.

(b) Consideration. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Option or upon the issuance of another Award, including the method of payment, shall be determined by the Administrator. In addition to any other types of consideration the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the Plan the following:

(i) cash;

(ii) check;

(iii) surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require which have a Fair Market Value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;

(iv) payment through a broker-dealer sale and remittance procedure pursuant to which the Grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to

the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates (or other evidence satisfactory to the Company to the extent that the Shares are uncertificated) for the purchased Shares directly to such brokerage firm in order to complete the sale transaction;

(v) with respect to Options, payment through a "net exercise" such that, without the payment of any funds, the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Administrator) less the Exercise Price per Share, and the denominator of which is such Fair Market Value per Share; or

(vi) future services to be rendered to the Company or a Related Entity; or

(vii) any combination of the foregoing methods of payment.

The Administrator may at any time or from time to time, by adoption of or by amendment to the standard forms of Award Agreement described in Section 4(c)(iv), or by other means, grant Awards which do not permit all of the foregoing forms of consideration to be used in payment for the Shares or which otherwise restrict one or more forms of consideration.

8. [Intentionally Omitted].

9. Withholding of Additional Income Taxes.

(a) Upon the exercise of an Option or SAR, the grant of any other Award for less than the Fair Market Value of the Common Stock or the vesting of restricted Common Stock acquired on the exercise of an Award hereunder, the Company, in accordance with Section 3402(a) of the Code and any applicable state statute or regulation, may require the Grantee to pay to the Company additional withholding taxes in respect of the amount that is considered compensation includable in such person's gross income. With respect to (i) the exercise of an Option, (ii) the grant of any other Award for less than its Fair Market Value, (iv) the vesting of restricted Common Stock acquired by exercising an Award, or (v) the exercise of an SAR, the Committee in its discretion may condition such event on the payment by the Grantee of any such additional withholding taxes.

(b) At the sole and absolute discretion of the Administrator, the holder of Awards may pay all or any part of the total estimated federal and state income tax liability arising out of the exercise or receipt of such Awards or the vesting of restricted Common Stock acquired on the exercise of an Award hereunder (each of the foregoing, a "***Tax Event***") by tendering already-owned shares of Common Stock or by directing the Company to withhold shares of Common Stock otherwise to be transferred to the Grantee as a result of the exercise or receipt thereof in an amount equal to the estimated federal and state income tax liability arising out of such event, provided that no more Shares may be withheld than are necessary to satisfy the Grantee's withholding obligation with respect to the exercise of Awards; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid liability accounting treatment for Awards granted under the Plan. In such

event, the Grantee must, however, notify the Administrator of his or her desire to pay all or any part of the total estimated federal and state income tax liability arising out of a Tax Event by tendering already-owned shares of Common Stock or having shares of Common Stock withheld prior to the date that the amount of federal or state income tax to be withheld is to be determined. For purposes of this Section 9, shares of Common Stock shall be valued at their Fair Market Value on the date that the amount of the tax withholdings is to be determined.

10. Exercise of Award.

(a) Procedure for Exercise; Rights as a Stockholder.

(i) Any Award granted hereunder shall be exercisable at such times and under such conditions as determined by the Administrator under the terms of the Plan and specified in the Award Agreement.

(ii) An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised has been made, including, to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in Section 7(b)(v).

(b) Exercise of Award Following Termination of Continuous Service. In the event of termination of a Grantee's Continuous Service for any reason other than Disability or death (but not in the event of a Grantee's change of status from Employee to Consultant), such Grantee may, but only during the Post-Termination Exercise Period (but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Administrator. The Grantee's Award Agreement may provide that upon the termination of the Grantee's Continuous Service for Cause, the Grantee's right to exercise the Award shall terminate concurrently with the termination of Grantee's Continuous Service. To the extent that the Grantee's Award was unvested at the date of termination, or if the Grantee does not exercise the vested portion of the Grantee's Award within the Post-Termination Exercise Period, the Award shall terminate.

(c) Disability of Grantee. In the event of termination of a Grantee's Continuous Service as a result of his or her Disability, such Grantee may, but only within twelve (12) months from the date of such termination (or such longer period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(d) Death of Grantee. In the event of a termination of the Grantee's Continuous Service as a result of his or her death, or in the event of the death of the Grantee during the Post-Termination Exercise Period or during the twelve (12) month period following the Grantee's termination of Continuous Service as a result of his or her Disability, the Grantee's

estate or a person who acquired the right to exercise the Award by bequest or inheritance may exercise the portion of the Grantee's Award that was vested as of the date of termination, within twelve (12) months from the date of death (or such longer period as specified in the Award Agreement but in no event later than the expiration of the term of such Award as set forth in the Award Agreement). To the extent that, at the time of death, the Grantee's Award was unvested, or if the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(e) Extension if Exercise Prevented by Law. Notwithstanding the foregoing, if the exercise of an Award within the applicable time periods set forth in this Section 10 is prevented by the provisions of Section 11 below, the Award shall remain exercisable until one (1) month after the date the Grantee is notified by the Company that the Award is exercisable, but in any event no later than the expiration of the term of such Award as set forth in the Award Agreement.

11. Conditions Upon Issuance of Shares.

(a) If at any time the Administrator determines that the delivery of Shares pursuant to the exercise, vesting or any other provision of an Award is or may be unlawful under Applicable Laws, the vesting or right to exercise an Award or to otherwise receive Shares pursuant to the terms of an Award shall be suspended until the Administrator determines that such delivery is lawful and shall be further subject to the approval of counsel for the Company with respect to such compliance. The Company shall have no obligation to effect any registration or qualification of the Shares under foreign, federal or state laws.

(b) As a condition to the exercise of an Award, the Company may require the person exercising such Award to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any Applicable Laws.

12. Adjustments. Subject to any required action by the stockholders of the Company, the number of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under the Plan but as to which no Awards have yet been granted or which have been returned to the Plan, the exercise or purchase price of each such outstanding Award, as well as any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) any other transaction with respect to the Company's Common Stock including a corporate merger, consolidation, acquisition of property or stock, separation (including a spin-off or other distribution of stock or property), reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." Such adjustment shall be made by the Administrator and its determination shall be final, binding and

conclusive. Except as the Administrator determines, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award. No adjustments shall be made for dividends paid in cash or in property other than Common Stock of the Company, nor shall cash dividends or dividend equivalents accrue or be paid in respect of unexercised Options or unvested Awards hereunder.

13. Corporate Transactions.

(a) Treatment of Awards in Corporate Transaction. Except as the Administrator may otherwise specify with respect to particular Awards in the relevant Award Agreement, in the case of and subject to the consummation of a Corporate Transaction, the parties to the Corporate Transaction may cause the Awards to be Assumed or Replaced by the successor entity as such parties shall agree. To the extent the parties to such Corporate Transaction do not provide for the Awards to be Assumed or Replaced upon the effective time of the Corporate Transaction, the Plan and all outstanding Awards granted under the Plan shall terminate. In such case, except as may be otherwise expressly provided in the relevant Award Agreement, all Awards with solely time-based vesting that are not vested and/or exercisable immediately prior to the effective time of the Corporate Transaction shall become fully vested and exercisable as of immediately prior to the effective time of the Corporate Transaction and all Awards with conditions and restrictions relating to the attainment of performance goals shall be deemed to vest and become nonforfeitable as of the Corporate Transaction as provided in the relevant Award Agreement or if not provided for in the relevant Award Agreement shall be deemed to vest and become nonforfeitable as of the Corporate Transaction assuming the higher of (i) achievement of all relevant performance goals at the "target" level (prorated based upon the length of time within the performance period that has elapsed prior the Corporate Transaction or partial achievement of the performance goals), or (ii) actual achievement of all relevant performance goals as of the date of such Corporate Transaction. In the event of such termination of the Awards, the Company shall have the option (in its sole discretion) to (1) make or provide for a payment, in cash or in kind, to the Grantees holding Options and SARs, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the Sale Price multiplied by the number of Shares subject to outstanding Options and SARs and (B) the aggregate exercise price of all such outstanding Options and SARs (provided that, in the case of an Option or SAR with an exercise price equal to or more than the Sale Price, such Option or SAR shall be cancelled for no consideration); or (2) permit each Grantee, within a specified period of time prior to the consummation of the Corporate Transaction as determined by the Administrator, to exercise all outstanding Options and SARs (to the extent then exercisable including due to acceleration as contemplated by this Section 13(a) if the Awards are not Assumed or Replaced) held by such Grantee as of immediately prior to the effective time of the Corporate Transaction. In the event of a termination of Awards pursuant to this Section 13(a), the Company shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the Grantees holding other Awards in an amount equal to the Sale Price multiplied by the number of vested Shares under such Awards. For purposes of this Section 13(a), "**Sale Price**" means the value as determined by the Administrator of the consideration payable, or otherwise to be received by stockholders, per Share pursuant to a Corporate Transaction."

(b) Acceleration of Award Upon Corporate Transaction. The Administrator shall have the authority, exercisable either in advance of any actual or anticipated Corporate Transaction or at the time of an actual Corporate Transaction and exercisable at the time of the grant of an Award under the Plan or any time while an Award remains outstanding, to provide for the full or partial automatic vesting and exercisability of one or more outstanding unvested Awards under the Plan and the release from restrictions on transfer and repurchase or forfeiture rights of such Awards in connection with a Corporate Transaction on such terms and conditions as the Administrator may specify. The Administrator also shall have the authority to condition any such Award vesting and exercisability or release from such limitations upon the subsequent termination of the Continuous Service of the Grantee within a specified period following the effective date of the Corporate Transaction. The Administrator may provide that any Awards so vested or released from such limitations in connection with a Corporate Transaction shall remain fully exercisable until the expiration or sooner termination of the Award.

14. Effective Date and Term of Plan. The Plan shall become effective upon the its adoption by the Board. It shall continue in effect for a term of ten (10) years from the date of its adoption.

15. Amendment, Suspension or Termination of the Plan.

(a) The Board may at any time amend, suspend or terminate the Plan in any respect, except that it may not, without the approval of the stockholders obtained within twelve (12) months before or after the Board adopts a resolution authorizing any of the following actions, do any of the following:

(i) increase the total number of shares that may be issued under the Plan (except by adjustment pursuant to Section 12);

(ii) modify the provisions of Section 7(a) regarding the exercise price at which shares may be offered pursuant to Options (except by adjustment pursuant to Section 12);

(iii) extend the expiration date of the Plan; and

(iv) except as provided in Section 12 (including, without limitation, due to any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares), amend an Award granted under the Plan to reduce its exercise price per share, cancel and regrant new Awards with lower prices per share than the original prices per share of the cancelled Awards, or cancel any Awards in exchange for cash or the grant of replacement Awards with an exercise price that is less than the exercise price of the original Awards, essentially having the effect of a repricing.

(b) No Award may be granted during any suspension of the Plan or after termination of the Plan.

(c) No suspension or termination of the Plan (including termination of the Plan under Section 15, above) shall adversely affect any rights under Awards already granted to a Grantee without his or her consent.

16. Reservation of Shares.

(a) The Company, during the term of the Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.

(b) The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

17. No Effect on Terms of Employment/Consulting Relationship. The Plan shall not confer upon any Grantee any right with respect to the Grantee's Continuous Service, nor shall it interfere in any way with his or her right or the right of the Company or a Related Entity to terminate the Grantee's Continuous Service at any time, with or without Cause, and with or without notice. The ability of the Company or any Related Entity to terminate the employment of a Grantee who is employed at will is in no way affected by its determination that the Grantee's Continuous Service has been terminated for Cause for the purposes of this Plan.

18. No Effect on Retirement and Other Benefit Plans. Except as specifically provided in a retirement or other benefit plan of the Company or a Related Entity, Awards shall not be deemed compensation for purposes of computing benefits or contributions under any retirement plan of the Company or a Related Entity, and shall not affect any benefits under any other benefit plan of any kind or any benefit plan subsequently instituted under which the availability or amount of benefits is related to level of compensation. The Plan is not a "Retirement Plan" or "Welfare Plan" under the Employee Retirement Income Security Act of 1974, as amended.

19. Electronic Delivery. The Administrator may, in its sole discretion, decide to deliver any documents related to any Award granted under the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company or to request a Grantee's consent to participate in the Plan by electronic means. Each Grantee hereunder consents to receive such documents by electronic delivery and agrees to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company, and such consent shall remain in effect throughout Grantee's term of employment or service with the Company and any Related Entity and thereafter until withdrawn in writing by Grantee.

20. Data Privacy. The Administrator may, in its sole discretion, decide to collect, use and transfer, in electronic or other form, personal data as described in this Plan or any Award for the exclusive purpose of implementing, administering and managing participation in the Plan. Each Grantee hereunder acknowledges that the Company holds certain personal information about Grantee, including, but not limited to, name, home address and telephone number, date of

birth, social security number or other identification number, salary, nationality, job title, details of all Awards awarded, cancelled, exercised, vested or unvested, for the purpose of implementing, administering and managing the Plan (the "***Data***"). Each Grantee hereunder further acknowledges that Data may be transferred to any third parties assisting in the implementation, administration and management of the Plan and sale and issuance of shares issued pursuant to Awards and that these third parties may be located in jurisdictions that may have different data privacy laws and protections, and Grantee authorizes such third parties to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Plan, including any requisite transfer of such Data as may be required to a broker or other third party with whom the recipient or the Company may elect to deposit any shares of Common Stock acquired upon any Award.

21. Unfunded Obligation. Grantees shall have the status of general unsecured creditors of the Company. Any amounts payable to Grantees pursuant to the Plan shall be unfunded and unsecured obligations for all purposes, including, without limitation, Title I of the Employee Retirement Income Security Act of 1974, as amended. Neither the Company nor any Related Entity shall be required to segregate any monies from its general funds, or to create any trusts, or establish any special accounts with respect to such obligations. The Company shall retain at all times beneficial ownership of any investments, including trust investments, which the Company may make to fulfill its payment obligations hereunder. Any investments or the creation or maintenance of any trust or any Grantee account shall not create or constitute a trust or fiduciary relationship between the Administrator, the Company or any Related Entity and a Grantee, or otherwise create any vested or beneficial interest in any Grantee or the Grantee's creditors in any assets of the Company or a Related Entity. The Grantees shall have no claim against the Company or any Related Entity for any changes in the value of any assets that may be invested or reinvested by the Company with respect to the Plan.

22. Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

As approved by the Board of Directors on _____, 2020

EXHIBIT 10.4

ASSEMBLY BIOSCIENCES, INC.
2020 Inducement Award Plan
NOTICE OF STOCK OPTION GRANT

Grant Number 2020-IAP-###

_____

_____

You have been granted an option to purchase Common Stock of Assembly Biosciences, Inc. (the "Company"), as follows:

Date of Grant	[_____]
Vesting Commencement Date	[_____]
Exercise Price per Share	$_____
Total Number of Shares Granted	_____
Total Exercise Price	$_____
Type of Option:	Nonstatutory Stock Option
Term/Expiration Date:	10 years
Vesting Schedule:	[___] to vest on the first anniversary of the vesting commencement date; and thereafter [__] of remaining option shares to vest each month thereafter for [___] months; in each case subject to your Continuous Services through such vesting date and otherwise in accordance with the terms and conditions of the Plan (as defined below) and the Stock Option Agreement attached hereto. Shares to vest on any vesting date shall be rounded down to nearest whole number. Monthly installments shall take into effect prior rounding so that each monthly installment including the last installment is approximately the same. On the [____] anniversary of the vesting commencement date, assuming Continuous Service through each vesting date, the option shall be fully vested. Upon the termination of your employment by the Company for any reason other than for Cause within 6 months following the occurrence of a Corporate Transaction, all unvested options shall immediately vest. [Notwithstanding the foregoing, this option shall be subject to additional provisions relating to the acceleration of vesting of time-based vesting equity awards as set forth in Section [XX] of your Employment Agreement executed on [DATE] and effective [DATE] (your "Employment Agreement"), including the condition that you execute a release in form and substance reasonably satisfactory to the Company in connection with your termination of employment.][1]

[1] Add if Participant is an Executive officer.

[Notwithstanding the foregoing, this option shall be subject to additional provisions relating to acceleration of vesting of time-based vesting equity awards as set forth in the Non-Executive Officers Severance Benefit Plan ("Severance Plan"), if you incur a "Change in Control Termination" (as defined in the Severance Plan) and satisfy the requirements of the Severance Plan. For avoidance of doubt and notwithstanding anything in an employment offer letter to the contrary, this award
and the Severance Plan reflect the sole agreement governing acceleration of vesting under this award upon a termination of continuous service.][2]

Termination Period: Vested option may be exercised for up to 90 days after termination of Continuous Service.

By your signature or your electronic acceptance of this option and the signature of the Company's representative below, you and the Company agree that this option is granted under and governed by the terms and conditions of the Assembly Biosciences, Inc. 2020 Inducement Award Plan (the "Plan") and the Stock Option Agreement, both of which are attached and made a part of this document. Capitalized terms used in this Notice of Stock Option Grant and not otherwise defined herein shall have the meaning assigned to such term in the Plan.

Dated: _____

OPTIONEE:

_____
[Name]

ASSEMBLY BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

[2] Add if Participant is a Non-executive officer (VP,SVP)

ASSEMBLY BIOSCIENCES, INC.

STOCK OPTION AGREEMENT

1. Grant of Option. Assembly Biosciences, Inc. (the "Company"), hereby grants to the Optionee named in the Notice of Stock Option Grant (the "Optionee") an option (the "Option") to purchase a total number of shares of Common Stock (the "Shares") set forth in the Notice of Stock Option Grant, at the exercise price per share set forth in the Notice of Stock Option Grant (the "Exercise Price") subject to the terms, definitions and provisions of the Assembly Biosciences, Inc. 2020 Inducement Award Plan (the "Plan") adopted by the Company, which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Option.

2. Exercise of Option. This Option shall be exercisable during its term in accordance with the Vesting Schedule set out in the Notice of Stock Option Grant and with the provisions of Sections 10 and 11 of the Plan as follows:

(a) Right to Exercise.

(i) This Option may not be exercised for a fraction of a share.

(ii) In no event may this Option be exercised after the date of expiration of the term of this Option as set forth in the Notice of Stock Option Grant.

(b) Method of Exercise. This Option shall be exercisable by written notice (in the form attached hereto as ***Exhibit A***) which shall state the election to exercise this Option, the number of Shares in respect of which this Option is being exercised, and such other representations and agreements as to the holder's investment intent with respect to such shares of Common Stock as may be required by the Company pursuant to the provisions of the Plan. Such written notice shall be signed by the Optionee and shall be delivered in person, by certified mail or electronic transmission (with confirmation of receipt) to the Secretary of the Company. The written notice shall be accompanied by payment of the Exercise Price. This Option shall be deemed to be exercised upon receipt by the Company of such written notice accompanied by the Exercise Price. Alternatively, this Option may be exercised through the Company's online equity platform and in compliance with the procedures set forth therein.

Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act of 1933, as amended (the "Securities Act"), or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations. No Shares will be issued pursuant to the exercise of this Option unless such issuance and such exercise shall comply with all relevant provisions of law and the requirements of any stock exchange upon which the Shares may then be listed. Assuming such compliance, for income tax purposes the Shares shall be considered transferred to the Optionee on the date on which the Option is exercised with respect to such Shares.

3. Method of Payment. Payment of the Exercise Price shall be by any of the following, or a combination thereof, at the election of the Optionee:

(i) cash; or

(ii) check; or

(iii) surrender of other shares of Common Stock of the Company, or attestation of ownership of such shares, as described in Section 7(b)(iv) of the Plan; or

(iv) "net exercise" as described in Section 7(b)(vi) of the Plan; or

(v) a broker-assisted exercise as described in Section 7(b)(v) of the Plan; or

(vi) any combination of the foregoing methods of payment.

4. Nontransferability of Option. This Option may not be transferred in any manner other than as set forth in the Plan. The terms of this Option shall be binding upon the executors, administrators, heirs, successors transferees and assigns of the Optionee as if such persons were the Optionee.

5. Termination of Relationship. In the event of termination of Optionee's Continuous Service with the Company, Optionee may, to the extent otherwise so entitled at the date of such termination (the "Termination Date"), exercise this Option during the Termination Period set out in the Notice of Stock Option Grant. To the extent that the Optionee was not entitled to exercise this Option at the date of such termination, or if Optionee does not exercise this Option within the time specified herein, this Option shall terminate.

6. Term of Option. This Option may be exercised only within the term set out in the Notice of Stock Option Grant and the Plan, and may be exercised during such term only in accordance with the Plan and the terms of this Option.

7. Disability of Optionee. Notwithstanding the provisions of Section 5 above, in the event of termination of Optionee's Continuous Service as a result of Optionee's Disability, Optionee may, but only within twelve (12) months from the date of termination of Continuous Service (but in no event later than the date of expiration of the term of this Option as set forth in the Notice of Stock Option Grant), exercise this Option to the extent Optionee was entitled to exercise it at the Termination Date. To the extent that Optionee was not entitled to exercise this Option at the Termination Date, or if Optionee does not exercise such Option (which Optionee was entitled to exercise) within the time specified herein, this Option shall terminate.

8. Death of Optionee. In the event of the death of the Optionee during the Optionee's Continuous Service or within ninety (90) days of termination of such Continuous Service, this Option may be exercised at any time within twelve (12) months following the Termination Date (but in no event later than the date of expiration of the term of this Option as set forth in the Notice of Stock Option Grant), by Optionee's estate or by a person who acquired the right to exercise this Option by bequest or inheritance, but only to the extent of the right to exercise that Optionee was entitled to at the date of death.

9. Taxation Upon Exercise of Option. Pursuant to Section 9 of the Plan, the Company may require the Optionee to pay to the Company amounts necessary to satisfy any applicable Company withholding obligations. The Optionee shall satisfy Optionee's tax withholding obligation arising upon the exercise of this Option by one or some combination of the following methods: (i) by cash payment, or (ii) out of Optionee's current compensation, or (iii) if permitted by the Board or Committee, in its discretion, by surrendering to the Company already-owned Shares or by directing the Company to withhold shares otherwise to be transferred to the Optionee, in each case in accordance with Section 9(b) of the Plan. For this purpose, the fair market value of the Shares to be withheld shall be determined on the date that the amount of tax to be withheld is to be determined (the "Tax Date").

If the Optionee is subject to Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (an "Insider"), any surrender of previously owned Shares to satisfy tax withholding obligations arising upon exercise of this Option must comply with the applicable provisions of Rule 16b-3 promulgated under the Exchange Act ("Rule 16b-3") and shall be subject to such additional conditions or restrictions as may be required thereunder to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

All elections by an Optionee to have Shares withheld to satisfy tax-withholding obligations shall be made in writing in a form acceptable to the Committee and shall be subject to the following restrictions:

(1) the election must be made on or prior to the applicable Tax Date;

(2) once made, the election shall be irrevocable as to the particular Shares of this Option as to which the election is made;

(3) all elections shall be subject to the consent or disapproval of the Board or Committee;

(4) if the Optionee is an Insider, the election must comply with the applicable provisions of Rule 16b-3 and shall be subject to such additional conditions or restrictions as may be required thereunder to qualify for the maximum exemption from Section 16 of the Exchange Act with respect to Plan transactions.

10. Tax Consequences. Set forth below is a brief summary as of the date of this Option of some of the federal tax consequences of exercise of this Option and disposition of the Shares. THIS SUMMARY IS NECESSARILY INCOMPLETE, AND THE TAX LAWS AND REGULATIONS ARE SUBJECT TO CHANGE. OPTIONEE SHOULD CONSULT A TAX ADVISER BEFORE EXERCISING THIS OPTION OR DISPOSING OF THE SHARES.

(a) Exercise of Nonstatutory Stock Option. There may be a regular federal income tax liability and a state income tax liability upon the exercise of this Option. The Optionee will be treated as having received compensation income (taxable at ordinary income tax rates) equal to the excess, if any, of the fair market value of the Shares on the date of exercise over the Exercise Price and the Company will qualify for a deduction in the same amount, subject to the requirement that the compensation be reasonable. If Optionee is an employee, the Company will be required to withhold from Optionee's compensation or collect from Optionee and pay to the applicable taxing authorities an amount equal to a percentage of this compensation income at the time of exercise.

(b) Disposition of Shares. If Shares are held for at least one year, any gain realized on disposition of the Shares will be treated as long-term capital gain for federal income tax purposes.

11. Successors and Assigns. The Company may assign any of its rights under this Stock Option Agreement (this "Agreement") to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth, this Agreement shall be binding upon Optionee and his or her heirs, executors, administrators, successors, transferees and assigns.

12. Interpretation. Any dispute regarding the interpretation of this Agreement shall be submitted by Optionee or by the Company forthwith to the Company's Board of Directors or the Committee that administers the Plan, which shall review such dispute at its next regular meeting. The resolution of such a dispute by the Board or committee shall be final and binding on the Company and on Optionee.

13. Governing Law; Severability. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware excluding that body of law pertaining to conflicts of law. Should any provision of this Agreement be determined by a court of law to be illegal or unenforceable, the other provisions shall nevertheless remain effective and shall remain enforceable.

14. Notices. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon receipt or three (3) days after deposit in the United States mail by certified mail, with postage and fees prepaid, addressed to in the case of the Company at its corporate headquarters and in the case of Optionee at the last address Optionee provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. You hereby consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. Option Not a Service Contract.

(a) Your Continuous Service with the Company or a Related Entity is not for any specified term and may be terminated by you or by the Company or a Related Entity at any time, for any reason, with or without cause and with or without notice. Nothing in this Agreement (including, but not limited to, the vesting of your Option pursuant to the schedule set forth in the Notice of Stock Option Grant or the issuance of the shares upon exercise of your option), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or a Related Entity; (ii) constitute any promise or commitment by the Company or a Related Entity regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Option, you acknowledge and agree that, subject to Section 8(b) of your Employment Agreement (as defined in the Notice of Stock Option Grant), the right to continue vesting in this Option pursuant to the schedule set forth in Notice of Stock Option Grant is earned only by Continuous Service (not through the act of being hired, being granted this option or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Related Entity at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Related Entity status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the option (subject to Section 8(b) of your Employment Agreement). You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the Company's right to terminate your Continuous Service at any time, with or without Cause and with or without notice.

16. Further Instruments. The parties agree to execute such further instruments and to take such further action as may be reasonably necessary to carry out the purposes and intent of this Agreement.

17. 2020 Inducement Award Plan. This Option shall be subject to and governed by the terms and conditions of the Plan in all respects, and to the extent of any inconsistency between this Option and the terms of the Plan, the terms of the Plan will control. Optionee acknowledges receipt of a copy of the Plan and represents that Optionee is familiar with the terms and provisions thereof, and hereby accepts this Option subject to all of the terms and provisions thereof. Optionee has reviewed the Plan and this Option in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option and fully understands all provisions of this Option. Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or Committee upon any questions arising under the Plan or this Option.

18. Other Documents. You acknowledge receipt of the Company's insider trading policy and agree to comply with its terms.

EXHIBIT A

ASSEMBLY BIOSCIENCES, INC.

EXERCISE NOTICE[3]

Assembly Biosciences, Inc.
_____
_____
Attention: Secretary

1. Exercise of Option. Effective as of today, the undersigned ("Optionee") hereby elects to exercise Optionee's option to purchase _____ shares of the Common Stock (the "Shares") of Assembly Biosciences, Inc. (the "Company") under and pursuant to the Company's 2020 Inducement Award Plan (as amended from time to time, the "Plan") and the Notice of Stock Option Grant dated _____, 20___ with its attached Stock Option Agreement (the "Option Agreement"). The purchase price for the Shares shall be $_____ as required by this Option Agreement. Optionee herewith delivers to the Company the full Exercise Price for the Shares.

2. Representations of Optionee. Optionee acknowledges that Optionee has received, read and understood the Plan and this Option Agreement and agrees to abide by and be bound by their terms and conditions. Optionee represents that Optionee is purchasing the Shares for Optionee's own account for investment and not with a view to, or for sale in connection with, a distribution of any of such Shares.

3. Rights as Stockholder. Until the stock certificate evidencing such Shares is issued (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company), no right to vote or receive dividends or any other rights as a stockholder shall exist with respect to the optioned Shares, notwithstanding the exercise of the Option. The Company shall issue (or cause to be issued) such stock certificate promptly after the Option is exercised.

4. Tax Consultation. Optionee understands that Optionee may suffer adverse tax consequences as a result of Optionee's purchase or disposition of the Shares. Optionee represents that Optionee has consulted with any tax consultants Optionee deems advisable in connection with the purchase or disposition of the Shares and that Optionee is not relying on the Company for any tax advice.

5. Entire Agreement. The Plan and the Option Agreement are incorporated herein by reference. This Exercise Notice, the Plan and the Option Agreement shall constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Optionee with respect to the subject matter hereof, and is governed by Delaware law except for that body of law pertaining to conflict of laws.

[3] Exercises may be effected through the Company's online equity award platform in lieu of this Exercise Notice.

Submitted by:

OPTIONEE:

_____

Address: _____

_____

_____

Accepted by:

Assembly Biosciences, Inc.

By: _____

Name: _____

Title: _____

Address: _____

_____

_____

Exhibit 10.5

ASSEMBLY BIOSCIENCES, INC.
2020 INDUCEMENT AWARD PLAN
RESTRICTED STOCK UNIT AWARD NOTICE

_____ _____
Grant Number

_____

_____

You have been granted Restricted Stock Units ("RSUs") of Assembly Biosciences, Inc. (the "Company"), as follows:

Effective Date:	[ ]
Vesting Commencement Date:	[ ]
Total Number of RSUs Granted:	[ ]
Term/Expiration Date:	The RSUs shall terminate immediately following the settlement date of all vested RSUs in connection with the Payment Date (as defined below). All unvested RSUs shall terminate immediately following the cessation of Continuous Service.

Vesting Schedule:	[One-fourth of the granted RSUs to vest on the first anniversary of the Vesting Commencement Date; One-fourth of the granted RSUs to vest on the second anniversary of the Vesting Commencement Date; One-fourth of the granted RSUs to vest on the third anniversary of the Vesting Commencement Date; One-fourth of the granted RSU to vest on the fourth anniversary of the Vesting Commencement Date , in each case subject to your Continuous Service through such vesting date and otherwise in accordance with the terms and conditions of the Plan (as defined below) and the Restricted Stock Unit Award Agreement attached hereto (each such date, a "Vesting Date")] [Alt: [performance milestones] [time-vesting] [combination]]. RSUs to vest on any vesting date shall be rounded down to nearest whole number. Each installment shall take into effect prior rounding so that each annual installment including the last installment is approximately the same. On the [fourth] anniversary of the Vesting Commencement Date, assuming Continuous Service through each Vesting Date, the RSUs shall be fully vested. Upon the termination of your employment by the Company for any reason other than for Cause within 6 months following the occurrence of a Corporate Transaction, all unvested RSUs shall immediately vest. [Notwithstanding the foregoing, the RSUs shall be subject to additional provisions relating to the acceleration of vesting of time-based vesting equity awards as set forth in Section [__] of your Employment Agreement executed on [__date__] and effective [__date__] (your "Employment Agreement"), including the condition that you execute a release in form and substance reasonably satisfactory to the Company in connection with your termination of employment.][1] [Notwithstanding the foregoing, the RSUs shall be subject to additional provisions relating to the acceleration of vesting of time-based vesting equity awards as set forth in the Non-Executive Officers Severance Benefit Plan ("Severance Plan"), if you incur a "Change in Control Termination" (as defined in the Severance Plan) and satisfy the requirements of the Severance Plan. For avoidance of doubt and notwithstanding anything in an employment offer letter to the contrary, this award and the Severance Plan reflect the sole agreement governing acceleration of vesting under this award upon a termination of Continuous Service.][2]
Payment Date:	The Company shall deliver, to you one Share (as defined in the Plan) in respect of each vested RSU. Delivery shall be made as soon as practicable following each vesting date and in no event later than 30 days following the applicable vesting date (the date of delivery, the "Payment Date").

[1] Add if Participant is an Executive officer.
[2] Add if Participant is a Non-executive officer

By your signature or your electronic acceptance of the RSUs and the signature of the Company's representative below, you and the Company agree that the RSUs are granted under and governed by the terms and conditions of the Assembly Biosciences, Inc. 2020 Inducement Award Plan (the "Plan") and the Restricted Stock Unit Award Agreement, both of which are attached and made a part of this document.

Dated: _____

GRANTEE:

_____
[ ]

ASSEMBLY BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

ASSEMBLY BIOSCIENCES, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT
UNDER THE 2020 INDUCEMENT AWARD PLAN

THIS RESTRICTED STOCK UNIT AWARD AGREEMENT (this "Award Agreement") is made and entered into by and between Assembly Biosciences, Inc. (the "Company") and the individual (the "Grantee") named in the Restricted Stock Unit Award Notice (the "Award Notice") under the Company's 2020 Inducement Award Plan (the "Plan"). The Award Notice also establishes the Effective Date of the Award, the number of Restricted Stock Units awarded, vesting conditions, and the Payment Date of the Award.

WHEREAS, the Grantee is expected to provide valuable services to the Company;

WHEREAS, the Company considers it desirable and in the best interests of the Company that the Grantee be given an opportunity to acquire a proprietary interest in the Company as an incentive to advance the interests of the Company and to perform future services that will contribute materially to the successful operation of the Company

WHEREAS, the Award granted hereby is a material inducement for the Grantee to enter into employment with the Company and to promote the success of the Company's business; and

WHEREAS, the Company, acting through the Board of Directors of the Company (the "Board") or (ii) the Committee appointed by the Board under the Plan (the "Committee"), desires to grant the Grantee a Restricted Stock Unit Award measured in shares of common stock of the Company (the "Common Stock"), in accordance with the Plan. Capitalized terms used herein which are not otherwise defined herein shall have the meanings ascribed to them under the Plan.

NOW, THEREFORE, in consideration of the premises, it is agreed by and between the parties as follows:

1. Grant of Restricted Stock Unit Award. The Company awards the Grantee Restricted Stock Units in a number that is specified in the Award Notice provided to the Grantee. The Award is subject to the vesting, payment and other provisions of this Award Agreement, the Award Notice and the Plan. Each Restricted Stock Unit represents one (1) Share of Common Stock of the Company. The Company will account for the Restricted Stock Units in a bookkeeping account on the Grantee's behalf until they become payable or are forfeited. The number of Restricted Stock Units shall be adjusted if the Common Stock is split, combined, if stock dividends are paid on Common Stock, or upon a similar event in the same manner that the Common Stock is adjusted.

2. Dividend Equivalents. For each Restricted Stock Unit that is granted and credited to the Grantee's account, the Grantee's account will also be credited with a Dividend Equivalent Rights in an amount equal to any cash dividends paid by the Company upon one Share of Common Stock after the Effective Date and before the Payment Date (as provided in the Award Notice) for the Restricted Stock Unit, subject to the vesting and other provisions of this Award Agreement and the Award Notice.

3. Vesting. The Restricted Stock Units (and Dividend Equivalent Rights associated with the Restricted Stock Units) shall be unvested and shall be subject to the restrictions set forth in this Award Agreement and the Award Notice. Unless sooner forfeited in accordance with Section 5, the Restricted Stock Units and Dividend Equivalent Rights associated with the Restricted Stock Unit shall vest as set forth in the Grantee's Award Notice.

4. Settlement of Vested Restricted Stock Units and Restricted Dividend Equivalents. If any of the Restricted Stock Units vest on a vesting date, the Company shall settle such Restricted Stock Units (the "Vested Restricted Stock Units") and Dividend Equivalent Rights attributable to such Vested Restricted Stock Units ("Vested Dividend Equivalents") on the Payment Date established in the Award Notice (the "Payment Date") by delivering to the Grantee (a) shares of Common Stock of the Company and (b) cash, determined as follows:

(a) *Number of Shares of Common Stock*. The Company will determine the value as of the Payment Date of the Vested Restricted Stock Units and the Vested Dividend Equivalent Rights (together, the "Total Amount"). For this purpose, the Vested Dividend Equivalents shall be valued at their original value and shall not be increased or decreased by an interest or earnings factor. The Total Amount will be reduced by any tax withholding that is not paid by the Grantee under the procedure in Section 6 below (the amount after the reduction is the "Net Amount"). The Net Amount will be divided by the value of one (1) Common Share of the Company as of the Vesting Date, and the resulting whole number (without remainder) shall be the number of shares of Common Stock that will be delivered to the Grantee, and

(b) *Cash*. The remainder resulting from the division in (a) above to determine the number of shares of Common Stock will be the dollar amount of the cash payable to the Grantee, and such amount shall be paid to the Grantee by check.

The Vested Restricted Stock Units and Vested Dividend Equivalents will be settled by the Company within thirty (30) days of the applicable vesting date.

5. Forfeiture of Restricted Stock Units (and Dividend Equivalent Rights Attributable to Restricted Stock Units). Except as set forth in Section 8(b) of your Employment Agreement (as defined in the Award Notice) or in the Award Notice, in the event of a termination of the Grantee's Continuous Service for any reason (including Disability), any Restricted Stock Units and Dividend Equivalent Rights attributable to such Restricted Stock Units that were not already vested on the date of termination shall be forfeited on that date.

6. Certain Tax Matters. The Grantee acknowledges that the Grantee understands the federal, state and local income, employment and foreign (if applicable) tax consequences of the Restricted Stock Unit Award, and the issuance, vesting and forfeiture provisions relating to the Restricted Stock Unit Award.

The Grantee understands that, at the time that the Grantee realizes any compensation income in respect of the Restricted Stock Unit Award, the Company will be required to withhold federal, state and local income and employment taxes on the full amount of the compensation income realized by the Grantee, and if the Grantee is located outside of the United States, the

Company may be required to withhold to meet tax, employment, or other obligations imposed by the tax jurisdiction that may be applicable to the Grantee. It is understood that all matters with respect to the total amount of taxes to be withheld in respect of such compensation income shall be determined by the Board (or the Committee) in its reasonable discretion. It is understood that although the Company may pay withheld amounts for the taxing jurisdiction that may be credited to the Grantee against taxes due by the Grantee, the Grantee is responsible for payment of all taxes due as a result of compensation arising under this Award Agreement.

The Board (or the Committee) may make such provisions and take such steps as it may deem necessary or appropriate for the withholding of taxes by the Company on compensation income the Grantee realizes. The Company shall accept payment by the Grantee of an amount in cash for all or part of the withholding obligation of the Company on the compensation income, so that the payment(s) to the Grantee under this Award Agreement are not reduced for tax withholding to the extent of the payment. Such payment by the Grantee must be made to the Company by the time that the Company is required to pay the withholding to the taxing authority, but in any event not later than thirty (30) days from the Payment Date. If the Grantee does not make a payment for the full withholding obligation, the Company shall withhold part of the payment due for redemption of the Vested Restricted Stock Units and Vested Dividend Equivalent Rights in the amount needed by the Company to meet its withholding obligations, with the result that the payment amount for the Vested Restricted Stock Units and Vested Dividend Equivalent Rights will be reduced as provided in Section 4(a) above by the amount needed to meet the Company's withholding obligations.

7. Rights Prior to Vesting. The Restricted Stock Units and Dividend Equivalent Rights represent a right to payment from the Company if the conditions of this Award Agreement are met and do not give the Grantee ownership of any Common Stock prior to delivery as provided in Section 4. No assets have been set aside by the Company or otherwise to pay the amounts promised by this Award Agreement, the right to payment is unsecured, and the Grantee is a general creditor of the Company for payment under this Award Agreement.

8. Investment Representation. The Grantee represents and warrants to the Company that the Grantee has read this Award Agreement carefully, and to the extent believed necessary, has discussed this Award Agreement and its impact and limitations upon the Grantee with counsel.

9. Transferability. The right to payment under this Award Agreement may not be sold, exchanged, transferred, pledged, hypothecated, encumbered or otherwise disposed of except as provided in the Plan. The Company shall have the right to assign to any of its affiliates any of its rights, or to delegate to any of its affiliates any of its obligations under this Award Agreement.

10. Binding Effect. This Award Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, successors and assigns.

11. Gender and Number. All terms used in this Award Agreement shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the context may require.

12. Terms and Conditions of Plan. The terms and conditions included in the Plan and the Award Notice are incorporated by reference herein, and to the extent that any conflict may exist between any term or provision of this Award Agreement and any term or provision of the Plan as in effect from time to time, such term or provision of the Plan shall control.

13. Certain Remedies. Without intending to limit the remedies available to the Company, the Grantee agrees that damages at law will be an insufficient remedy in the event the Grantee violates the terms of this Award Agreement. The Grantee agrees that the Company may apply for and have injunctive or other equitable relief in any court of competent jurisdiction to restrain the breach or threatened breach of, or otherwise specifically to enforce, any of the provisions hereof.

14. Waiver. The waiver by either party of compliance with any provision of this Award Agreement by the other party shall not operate or be construed as a waiver of any other provision of this Award Agreement, or of any subsequent breach by such party of a provision of this Award Agreement.

15. No Restriction on Right of Company to Effect Corporate Changes. Neither the Plan nor this Award Agreement shall affect in any way the right or power of the Company or its stockholders to make or authorize any or all adjustments, recapitalizations, reorganizations or other changes in the capital structure or business of the Company, or any merger or consolidation of the Company, or any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of the assets or business of the Company, or any other corporate act or proceeding, whether of a similar character or otherwise.

16. Entire Agreement. This Award Agreement (including, for all purposes of this Section 16, the Award Notice, and the Plan which are incorporated herein by reference and all additional riders incorporated herein) sets forth all of the promises, agreements, conditions and understandings between the parties hereto with respect to the Award, and there are no promises, agreements, conditions, understandings, warranties or representations, oral or written, express or implied, between them with respect to the Restricted Stock Unit Award other than as set forth therein or herein. This Award Agreement supersedes and replaces any and all prior agreements between the parties hereto with respect to Restricted Stock Units and Dividend Equivalent Rights. This Award Agreement is, and is intended by the parties to be, an integration of any and all prior agreements or understandings, oral or written, with respect to the Restricted Stock Units and Dividend Equivalent Rights subject to this Award Agreement. No modification, amendment or waiver of any of the provisions of this Award Agreement shall be effective unless approved in writing by both parties.

17. Invalid or Unenforceable Provision. The invalidity or unenforceability of any particular provision of this Award Agreement shall not affect the other provisions hereof, and this Award Agreement shall be construed in all respects as if such invalid or unenforceable provision was omitted.

18. Governing Law. This Award Agreement shall be construed and enforced in accordance with the laws of Delaware, without giving effect to principles of conflicts of laws.

19. Miscellaneous.

(a) Neither the granting or vesting of the Restricted Stock Units and Dividend Equivalent Rights nor any other provision of this Award Agreement shall be construed as conferring upon the Grantee any right to continue in the service of the Company, or as interfering with or restricting in any way the right of the Company to terminate such service at any time.

(b) The Company, the Board (or the Committee) and any employees or agents thereof are relieved from any liability for the non-issuance or non-transfer, or any delay in the issuance or transfer, of any Common Stock which results from the inability of the Company to obtain, or in any delay in obtaining, from each regulatory body having jurisdiction all requisite authority to issue or transfer the Common Stock in satisfaction of this Award Agreement if counsel for the Company deems such authorization necessary for the lawful issuance or transfer of any of the Common Stock.

(c) No Common Stock shall be sold or otherwise disposed of in violation of any federal or state securities law or regulations.

(d) All decisions of the Board (or the Committee) with respect to the interpretation, construction and application of the Plan and/or this Award Agreement shall be conclusive and binding upon the Grantee and all other persons.

(e) This Award Agreement has been drafted with the intent that payments (and the right to payments) under it are exempt from or comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations thereunder applicable to nonqualified deferred compensation. This Award Agreement shall be interpreted in a manner consistent with such intent. The parties agree that this Award Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party. The Company makes no representation or warranty and shall have no liability to the Grantee or any other person if any provisions of this Award Agreement or the Award Notice are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

Exhibit 10.6

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

Amendment No. 1 to Employment Agreement (this "**Amendment No. 1**"), is entered into on February 26, 2020 (the "**Amendment No. 1 Effective Date**"), by and between Assembly Biosciences, Inc., a Delaware corporation with principal executive offices at 331 Oyster Pt. Blvd, Fourth Floor, South San Francisco, CA 94080 (the "**Company**"), and Thomas J. Russo, CFA (the "**Executive**").

W I T N E S S E T H:

WHEREAS, the Company and Executive have entered into the Employment Agreement dated as of September 30, 2019 and effective as of October 28, 2019 (the "**Existing Agreement**").

WHEREAS, the Company and the Executive desire to amend the Existing Agreement as provided in this Amendment No. 1 to, among other things, modify the definition of "Good Reason" following a Change of Control (as defined in the Existing Agreement) to include certain adverse modifications to the Executive's reporting lines.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto hereby agree to amend the Existing Agreement as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment No.1, including the recitals, have the respective meanings assigned to them in the Existing Agreement.

2. Amendments to the Existing Agreement. As of the Amendment No. 1 Effective Date, Section 7(d) of the Existing Agreement is hereby amended and restated as follows:

> "(d) The Executive's employment hereunder may be voluntarily terminated by the Executive for Good Reason. For purposes of this Agreement, "Good Reason" shall mean any of the following: (i) any material reduction by the Company of the Executive's duties, or responsibilities or authority that, taken as a whole, results in a material diminution of position; provided, however, that a change in the Executive's title or reporting relationship shall not by itself constitute a termination by the Executive for Good Reason under this clause (i); (ii) any material (meaning 10% or more) reduction by the Company of the Executive's Base Salary and/or target Annual Performance Bonus payable hereunder (it being understood that an across-the-board reduction applicable to all similarly situated employees of the Company, including the Executive, shall not be deemed a reduction for purposes of this definition); (iii) in connection with a Change of Control or within the COC Period following a Change of Control, a material adverse change in the reporting structure or title applicable to the Executive, including an adverse change arising from a material diminution in the authority, duties or responsibilities of the supervisor to whom the Executive is required to report (e.g., the Executive no longer reports to the Chief Executive Officer of the Company or its successor); (iv) any requirement by the Company, without the Executive's prior written consent, that the Executive locate the Executive's residence or primary place of employment

to a location outside a 50-mile radius of such location mutually agreed upon between the Company and the Executive as of the Effective Date, or such other location that the Company and the Executive may mutually agree upon and designate from time to time during the Term; or (v) a material breach by the Company of Section 6(b) of this Agreement which is not cured by the Company within thirty (30) days after written notice thereof is given to the Company by the Executive. However, notwithstanding the above, Good Reason shall not exist unless: (x) the Executive notifies in writing the Chief Executive Officer within thirty (30) days of the initial existence of one of the adverse events described above, and (y) the Company fails to correct the adverse event within thirty (30) days of such written notice, and (z) the Executive's voluntary termination because of the existence of one or more of the adverse events described above occurs within ninety (90) days of the initial existence of the event."

3. Date of Effectiveness; Limited Effect. This Amendment No.1 will become effective as of the Amendment No.1 Effective Date. Except as expressly provided in this Amendment No.1, all of the terms and provisions of the Existing Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties. Without limiting the generality of the foregoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Existing Agreement or as a waiver of or consent to any further or future action on the part of either Party that would require the waiver or consent of the other Party. On and after the Amendment No.1 Effective Date, each reference in the Existing Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or words of like import shall mean the Existing Agreement as amended by this Amendment No.1.

4. Miscellaneous.

(a) This Amendment No.1 is governed by and construed in accordance with, the laws of the State of California, without regard to the conflict of laws provisions of such State.

(b) This Amendment No.1 shall inure to the benefit of and be binding upon each of the Parties and each of their respective permitted successors and permitted assigns.

(c) The headings in this Amendment No.1 are for reference only and do not affect the interpretation of this Amendment No.1.

(d) This Amendment No.1 may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment No.1 electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Amendment No.1.

(e) The Existing Agreement, as amended by this Amendment No.1, constitutes the sole and entire agreement between the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter.

IN WITNESS WHEREOF, the Parties have executed this Amendment No.1 as of the date first written above.

ASSEMBLY BIOSCIENCES, INC.

By /s/ John G. McHutchison, A.O., M.D.

Name: John G. McHutchison, A.O., M.D.

Title: Chief Executive Officer and President

/s/ Thomas J. Russo, CFA

Thomas J. Russo, CFA

EXHIBIT 10.7

AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT

Amendment No. 1 to Employment Agreement (this "**Amendment No. 1**"), is entered into on February ___, 2020 (the "**Amendment No. 1 Effective Date**"), by and between Assembly Biosciences, Inc., a Delaware corporation with principal executive offices at 331 Oyster Pt. Blvd, Fourth Floor, South San Francisco, CA 94080 (the "**Company**"), and Luisa M. Stamm, M.D., Ph.D. (the "**Executive**").

W I T N E S S E T H:

WHEREAS, the Company and Executive have entered into the Employment Agreement dated as of October 22, 2019 and effective as of November 6, 2019 (the "**Existing Agreement**").

WHEREAS, the Company and the Executive desire to amend the Existing Agreement as provided in this Amendment No. 1 to, among other things, modify the definition of "Good Reason" following a Change of Control (as defined in the Existing Agreement) to include certain adverse modifications to the Executive's reporting lines.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the parties hereto hereby agree to amend the Existing Agreement as follows:

1. Definitions. Capitalized terms used and not defined in this Amendment No.1, including the recitals, have the respective meanings assigned to them in the Existing Agreement.

2. Amendments to the Existing Agreement. As of the Amendment No. 1 Effective Date, Section 7(d) of the Existing Agreement is hereby amended and restated as follows:

> "(d) The Executive's employment hereunder may be voluntarily terminated by the Executive for Good Reason. For purposes of this Agreement, "**Good Reason**" shall mean any of the following: (i) any material reduction by the Company of the Executive's duties, or responsibilities or authority that, taken as a whole, results in a material diminution of position; provided, however, that a change in the Executive's title or reporting relationship shall not by itself constitute a termination by the Executive for Good Reason under this clause (i); (ii) any material (meaning 10% or more) reduction by the Company of the Executive's Base Salary and/or target Annual Performance Bonus payable hereunder (it being understood that an across-the-board reduction applicable to all similarly situated employees of the Company, including the Executive, shall not be deemed a reduction for purposes of this definition); (iii) in connection with a Change of Control or within the COC Period following a Change of Control, a material adverse change in the reporting structure or title applicable to the Executive, including an adverse change arising from a material diminution in the authority, duties or responsibilities of the supervisor to whom the Executive is required to report (e.g., the Executive no longer reports to the Chief Executive Officer of the Company or its successor); (iv) any requirement by the Company, without the Executive's prior written consent, that the Executive locate the Executive's residence or primary place of employment

to a location outside a 50-mile radius of such location mutually agreed upon between the Company and the Executive as of the Effective Date, or such other location that the Company and the Executive may mutually agree upon and designate from time to time during the Term; or (v) a material breach by the Company of Section 6(b) of this Agreement which is not cured by the Company within thirty (30) days after written notice thereof is given to the Company by the Executive. However, notwithstanding the above, Good Reason shall not exist unless: (x) the Executive notifies in writing the Chief Executive Officer within thirty (30) days of the initial existence of one of the adverse events described above, and (y) the Company fails to correct the adverse event within thirty (30) days of such written notice, and (z) the Executive's voluntary termination because of the existence of one or more of the adverse events described above occurs within ninety (90) days of the initial existence of the event."

3. Date of Effectiveness; Limited Effect. This Amendment No.1 will become effective as of the Amendment No.1 Effective Date. Except as expressly provided in this Amendment No.1, all of the terms and provisions of the Existing Agreement are and will remain in full force and effect and are hereby ratified and confirmed by the Parties. Without limiting the generality of the foregoing, the amendments contained herein will not be construed as an amendment to or waiver of any other provision of the Existing Agreement or as a waiver of or consent to any further or future action on the part of either Party that would require the waiver or consent of the other Party. On and after the Amendment No.1 Effective Date, each reference in the Existing Agreement to "this Agreement," "the Agreement," "hereunder," "hereof," "herein," or words of like import shall mean the Existing Agreement as amended by this Amendment No.1.

4. Miscellaneous.

(a) This Amendment No.1 is governed by and construed in accordance with, the laws of the State of California, without regard to the conflict of laws provisions of such State.

(b) This Amendment No.1 shall inure to the benefit of and be binding upon each of the Parties and each of their respective permitted successors and permitted assigns.

(c) The headings in this Amendment No.1 are for reference only and do not affect the interpretation of this Amendment No.1.

(d) This Amendment No.1 may be executed in counterparts, each of which is deemed an original, but all of which constitute one and the same agreement. Delivery of an executed counterpart of this Amendment No.1 electronically or by facsimile shall be effective as delivery of an original executed counterpart of this Amendment No.1.

(e) This Amendment No.1 constitutes the sole and entire agreement between the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter.

IN WITNESS WHEREOF, the Parties have executed this Amendment No.1 as of the date first written above.

ASSEMBLY BIOSCIENCES, INC.

By /s/ John G. McHutchison, A.O., M.D.
Name: John G. McHutchison, A.O., M.D.
Title: Chief Executive Officer and President

/s/ Luisa M. Stamm, M.D., Ph.D.
Luisa M. Stamm, M.D., Ph.D.

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 8, 2020

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 8, 2020

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, 2020 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 8, 2020

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, 2020 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 8, 2020