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 June 30, 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 August 3, 2020, there were 32,854,914 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)

	June 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 96,709	$ 46,732
Marketable securities	130,005	227,311
Accounts receivable from collaboration	3,315	3,374
Prepaid expenses and other current assets	5,059	5,363
Total current assets	235,088	282,780
Property and equipment, net	2,063	1,830
Operating lease right-of-use (ROU) assets	10,780	11,975
Other assets	5,232	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 294,801**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,640	$ 1,731
Accrued clinical expenses	4,362	4,826
Other accrued expenses	6,019	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,250	3,186
Total current liabilities	17,271	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	—	30,637
Operating lease liabilities - long-term	7,884	9,082
Total liabilities	**27,686**	**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, $0.001 par value; 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 32,807,519 and 32,558,307 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	33	32
Additional paid-in capital	725,784	712,807
Accumulated other comprehensive income (loss)	104	(201)
Accumulated deficit	(458,806)	(439,421)
Total stockholders' equity	267,115	273,217
Total liabilities and stockholders' equity	**$ 294,801**	**$ 339,907**

See Accompanying Notes to Condensed Consolidated Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 39,376	$ 3,080	$ 43,457	$ 6,966
Operating expenses:				
Research and development	23,327	18,700	46,373	41,405
General and administrative	9,470	4,080	18,199	13,597
Total operating expenses	32,797	22,780	64,572	55,002
Income (loss) from operations	**6,579**	**(19,700)**	**(21,115)**	**(48,036)**
Other income				
Interest and other income, net	691	1,186	1,730	2,463
Total other income	691	1,186	1,730	2,463
Income (loss) before income taxes	**7,270**	**(18,514)**	**(19,385)**	**(45,573)**
Income tax benefit	—	11	—	18
Net income (loss)	**$ 7,270**	**$ (18,503)**	**$ (19,385)**	**$ (45,555)**
Other comprehensive income				
Unrealized gain on marketable securities, net of tax	190	52	305	160
Comprehensive income (loss)	**$ 7,460**	**$ (18,451)**	**$ (19,080)**	**$ (45,395)**
Net income (loss) per share, basic	$ 0.21	$ (0.72)	$ (0.55)	$ (1.77)
Weighted average common shares outstanding, basic	35,307,669	25,740,500	35,229,570	25,690,617
Net income (loss) per share, diluted	$ 0.19	$ (0.72)	$ (0.55)	$ (1.77)
Weighted average common shares outstanding, diluted	37,291,474	25,740,500	35,229,570	25,690,617

See Accompanying Notes to Condensed Consolidated Financial Statements

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (19,385)	$ (45,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	237	260
Stock-based compensation	12,058	8,645
Net accretion and amortization of investments in marketable debt securities	(101)	(1,141)
Non-cash rent expense	2,308	2,208
Deferred income tax benefit	—	(18)
Loss on disposal of fixed assets	—	102
Other	—	(5)
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	59	(473)
Prepaid expenses and other current assets	304	(5,068)
Other assets	(2,155)	1,655
Accounts payable	516	(279)
Accrued clinical expenses	(464)	248
Other accrued expenses	(2,416)	(2,428)
Deferred revenue	(37,048)	(996)
Operating lease liabilities	(2,247)	(2,099)
Net cash used in operating activities	(48,334)	(44,944)
Cash flows from investing activities		
Purchases of property and equipment	(470)	(1,539)
Purchases of marketable securities	(44,240)	(93,667)
Proceeds from maturities of marketable securities	119,252	131,591
Proceeds from sale of marketable securities	22,700	500
Net cash provided by investing activities	97,242	36,885
Cash flows from financing activities		
Proceeds from the exercise of stock options	602	331
Proceeds from the issuance of common stock under Employee Stock Purchase Plan (ESPP)	467	515
Net cash provided by financing activities	1,069	846
Net increase (decrease) in cash and cash equivalents	49,977	(7,213)
Cash and cash equivalents at the beginning of the period	46,732	41,471
Cash and cash equivalents at the end of the period	**$ 96,709**	**$ 34,258**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ 545	$ 14,225

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)

	For the Three Month Period					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2020	**32,624,725**	**$ 32**	**$ 717,898**	**$ (86)**	**$ (466,076)**	**$ 251,768**
Issuance of common stock upon exercise of stock options	74,879	1	482	—	—	483
Issuance of common stock under ESPP	42,266	—	467	—	—	467
Issuance of shares of common stock for settlement of restricted stock units (RSUs)	65,649	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	190	—	190
Stock-based compensation	—	—	6,937	—	—	6,937
Net income	—	—	—	—	7,270	7,270
Balance as of June 30, 2020	**32,807,519**	**$ 33**	**$ 725,784**	**$ 104**	**$ (458,806)**	**$ 267,115**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2019	**25,549,757**	**$ 26**	**$ 559,453**	**$ (239)**	**$ (368,839)**	**$ 190,401**
Issuance of common stock upon exercise of stock options	29,875	—	191	—	—	191
Issuance of common stock under ESPP	36,804	—	515	—	—	515
Issuance of shares of common stock for settlement of RSUs	30,347	—	—	—	—	—
Unrealized gain on marketable debt securities, net of tax	—	—	—	52	—	52
Stock-based compensation	—	—	2,051	—	—	2,051
Net loss	—	—	—	—	(18,503)	(18,503)
Balance as of June 30, 2019	**25,646,783**	**$ 26**	**$ 562,210**	**$ (187)**	**$ (387,342)**	**$ 174,707**

	For the Six Month Period					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (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	91,713	1	601	—	—	602
Issuance of common stock under ESPP	42,266	—	467	—	—	467
Issuance of shares of common stock for settlement of RSUs	115,233	—	—	—	—	—
Reclassification of stock-based awards from equity to accrued expenses	—	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	305	—	305
Stock-based compensation	—	—	11,909	—	—	11,909
Net loss	—	—	—	—	(19,385)	(19,385)
Balance as of June 30, 2020	**32,807,519**	**$ 33**	**$ 725,784**	**$ 104**	**$ (458,806)**	**$ 267,115**

	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	50,875	—	331	—	—	331
Issuance of common stock under ESPP	36,804	—	515	—	—	515
Issuance of shares of common stock for settlement of RSUs	63,679	1	(1)	—	—	—
Settlement of RSUs for cash	—	—	(4)	—	—	(4)
Unrealized gain on marketable debt securities, net of tax	—	—	—	160	—	160
Stock-based compensation	—	—	8,607	—	—	8,607
Net loss	—	—	—	—	(45,555)	(45,555)
Balance as of June 30, 2019	**25,646,783**	**$ 26**	**$ 562,210**	**$ (187)**	**$ (387,342)**	**$ 174,707**

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 California, Connecticut and China.

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) in connection with its Research, Development, Collaboration and License Agreement (the Allergan Collaboration Agreement) with Allergan Pharmaceuticals International Limited (Allergan), which was acquired by AbbVie Inc. (AbbVie) in May 2020. In June 2020, AbbVie made a strategic portfolio decision to terminate the Allergan Collaboration Agreement effective on October 10, 2020 (see Note 8). Assembly is also exploring the microbiome in connection with immune-mediated and metabolic disorders and oncology.

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 Allergan 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 global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact the Company's ability to access capital when and as needed.

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

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

Basis of Presentation

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

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the 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 and six months ended June 30, 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 Allergan 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 materially from those estimates and assumptions.

Other Risks and Uncertainties

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

Income Taxes

In March 2020, the Families First Coronavirus Response Act (FFCR Act) and 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.

In June 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

The FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company's condensed consolidated financial statements as of June 30, 2020; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, results of operations, financial condition and liquidity.

Net Income (Loss) per Share

Basic net income (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (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.

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, 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 income (loss) per common share computations is as follows (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net income (loss)	7,270	(18,503)	(19,385)	(45,555)
Denominator:				
Shares used in per share calculation - basic	35,307,669	25,740,500	35,229,570	25,690,617
Dilutive effect of securities	1,983,805	-	-	-
Shares used in per share calculation - diluted	37,291,474	25,740,500	35,229,570	25,690,617
Net income (loss) per share:				
Basic	0.21	(0.72)	(0.55)	(1.77)
Diluted	0.19	(0.72)	(0.55)	(1.77)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Warrants to purchase common stock	15,296	15,296	15,296	15,296
Options to purchase common stock	3,521,778	5,203,935	6,652,076	5,203,935
Common stock subject to purchase under our ESPP	8,991	5,976	8,991	5,976
Unvested RSUs	41,762	489,857	978,879	489,857
Total	3,587,827	5,715,064	7,655,242	5,715,064

As of June 30, 2020, 145,000 performance-based RSUs granted by the Company were excluded from the table above because they are subject to contingencies that were not achieved as of this date.

Adoption of Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board (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 material 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 material 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), which 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 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):

	June 30, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market funds	$ 94,524	$ —	$ —	$ 94,524
Total cash equivalents	94,524	—	—	94,524
Short-term investments				
U.S. and foreign corporate debt securities	32,958	161	—	33,119
Asset-backed securities	22,183	72	—	22,255
U.S. treasury securities	36,080	176	—	36,256
U.S. and foreign commercial paper	38,375	—	—	38,375
Total short-term investments	129,596	409	—	130,005
Total cash equivalents and investments	$ 224,120	$ 409	$ —	$ 224,529

	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 June 30, 2020 is less than one year. There were no long-term marketable securities held by the Company as of June 30, 2020.

Realized gains and losses for the three and six months ended June 30, 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 June 30, 2020.

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

	June 30, 2020			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 94,524	$ —	$ —	$ 94,524
Total cash equivalents	94,524	—	—	94,524
Short-term investments				
U.S. and foreign corporate debt securities	—	33,119	—	33,119
Asset-backed securities	—	22,255	—	22,255
U.S. treasury securities	—	36,256	—	36,256
U.S. and foreign commercial paper	—	38,375	—	38,375
Total short-term investments	—	130,005	—	130,005
Total assets measured at fair value	$ 94,524	$ 130,005	$ —	$ 224,529

	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)	June 30, 2020	December 31, 2019
Lab equipment	3 to 5	$ 290	$ 247
Office equipment	7	699	699
Leasehold improvement	1 to 5	2,084	2,084
Total property and equipment		3,073	3,030
Less: Accumulated depreciation and amortization		(1,437)	(1,200)
Construction in progress	N/A	427	—
Property and equipment, net		$ 2,063	$ 1,830

Depreciation expense was $0.1 million and $0.2 million for the three and six months ended June 30, 2020, respectively and $0.1 million and $0.3 million for the three and six months ended June 30, 2019, respectively 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):

	June 30, 2020	December 31, 2019
Accrued expenses:		
Accrued compensation	$ 4,186	$ 5,312
Accrued restructuring charges	1,019	2,094
Accrued professional fees and other	814	880
Total accrued expenses	$ 6,019	$ 8,286

Accrued restructuring charges relate to the Company's decision to relocate its headquarters 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 June 30, 2020 and December 31, 2019, respectively. As of June 30, 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 June 30, 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 June 30, 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 became immediately exercisable upon issuance at an exercise price of $0.001 per share, but under 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 June 30, 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 and six months ended June 30, 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 number of shares of common stock reserved under the 2018 Plan to 3,000,000.

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

As of June 30, 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 June 30, 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 six months ended June 30, 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	1,275,180	15.92		
Exercised	(91,713)	7.38		
Forfeited	(144,744)	25.57		
Outstanding as of June 30, 2020	6,652,076	$ 15.81	7.3	$ 63,186
Options vested and exercisable as of June 30, 2020	3,440,092	$ 14.22	5.6	$ 39,923

The weighted-average grant-date fair value of options granted was $10.52 and $12.68 during the six months ended June 30, 2020 and 2019, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2020 and 2019 was $1.0 million and $0.7 million, respectively.

RSUs

A summary of the Company's RSUs and related information for the six months ended June 30, 2020 is as follows:

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2019	758,718	$ 25.47
Granted	531,164	16.31
Vested	(99,224)	33.59
Forfeited	(54,279)	25.90
Nonvested as of June 30, 2020	1,136,379 [(1)]	$ 20.45

(1) Includes 157,500 RSUs that have vested but are subject to deferred settlement, which have a weighted average remaining contractual term of 1.7 years.

The total fair value of RSUs vested and settled during the six months ended June 30, 2020 and 2019 was $3.1 million and $2.9 million, respectively. The total intrinsic value of RSUs vested and settled during the six months ended June 30, 2020 and 2019 was $1.6 million and $1.3 million, respectively.

As of June 30, 2020, RSUs outstanding include 45,000 RSUs granted in December 2017 and 100,000 RSUs granted in September 2019 to executives of the Company with performance-based conditions vesting conditions. As of June 30, 2020, the performance condition for the 45,000 RSUs granted in December 2017 was deemed probable of being met and was subsequently achieved in July 2020. The Company recognized $0.7 million as a cumulative catch-up adjustment of stock-based compensation expense for this award for the three and six months ended June 30, 2020. The remaining 100,000 awards with an aggregate fair value of $1.2 million vest upon performance conditions not yet deemed probable and accordingly no stock-based compensation expense has been recognized as of June 30, 2020.

ESPP

Employees purchased 42,266 and 36,804 shares of common stock under the 2018 ESPP during the six months ended June 30, 2020 and 2019, respectively.

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Exercise price	$14.57 - $20.52	$15.22 - $57.33	$14.45 - $20.52	$15.22 - $57.33
Expected volatility	69.13% - 82.24%	66.2% - 83.0%	66.38% - 82.24%	66.2% - 83.2%
Risk-free rate	0.36% - 0.60%	2.17% - 2.47%	0.36% - 1.44%	2.17% - 2.65%
Expected term (years)	5.5 - 7.5	5.0 - 9.0	5.5 - 7.5	5.0 - 9.0
Expected dividend yield	0%	0%	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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 3,607	$ 3,116	$ 5,551	$ 5,845
General and administrative	3,527	(1,048) (1)	6,507	2,800
Total stock-based compensation expense	$ 7,134	$ 2,068	$ 12,058	$ 8,645

(1) Includes the reversal of previously recognized stock-based compensation expense of $3.6 million related to forfeited awards resulting from the departure of one of the Company's former officers during the period.

As of June 30, 2020, there was $32.2 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

Termination of Allergan Collaboration Agreement

In January 2017, the Company entered into the Allergan Collaboration Agreement with Allergan to develop and commercialize select microbiome gastrointestinal disease therapies. Pursuant to the Allergan Collaboration Agreement, the Company granted to Allergan an exclusive worldwide license to certain of its intellectual property, including its intellectual property arising under the Allergan 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 Allergan Collaboration Agreement, Allergan could select backups and additional target indications to add to the licenses granted for additional consideration and also had 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 participated in a Joint Development Committee (JDC) and Joint Patent Committee (JPC). Allergan had the right to terminate the Allergan Collaboration Agreement at any time upon advance written notice.

In June 2020, following its acquisition of Allergan, AbbVie, on behalf of Allergan, gave written notice of termination of the Allergan Collaboration Agreement, effective 120 days following the delivery of notice, on October 10, 2020. Upon termination, the licenses granted by the Company and its know-how will revert to the Company. Under the terms of the Allergan Collaboration Agreement, AbbVie is obligated to continue to reimburse the Company for certain research and development costs through October 10, 2020. Upon effectiveness of the termination, such reimbursements will cease. Due to the delivery of the termination notice, the Company determined that there were no further enforceable rights and obligations under the Allergan Collaboration Agreement beyond June 2020 and the remaining $36.0 million of deferred revenue was recognized in the period.

History of the Allergan Collaboration Agreement

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 was 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 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 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 could have elected 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 had an option to co-promote the licensed programs in the U.S. and China, subject to certain conditions set forth in the Allergan Collaboration Agreement.

The Company concluded that Allergan was a customer, and the contract was 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 Allergan 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 were to be accounted for as separate contracts when or if they occurred.

The Company concluded the Licenses each were considered to be functional as they had 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 was dependent on the Company to execute the Development Services, which it was uniquely able to perform, in order for Allergan to benefit from the Licenses. As such, the Company determined that it had four performance obligations under the Allergan 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 would have been performed over the duration of the contract, which began in February 2017 and ended upon receipt of the termination notice. The Company used a cost-based input method to measure proportional performance and to calculate the corresponding amount of revenue to recognize. The Company believed this was 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 measured costs incurred relative to budgeted costs to fulfill the four performance obligations. These costs consisted primarily of third-party contract costs and internal labor costs. Revenue was recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completed 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. A change in the assumptions used to determine its best estimate of selling price for the four performance obligations would not have had 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 the revenue from contracts with customers guidance 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 June 30, 2020. 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) would have been recognized when the related sales occur as they were determined to relate predominantly to the license granted to Allergan. The Company re-evaluated the transaction price in each reporting period and as uncertain events were resolved or other changes in circumstances occur.

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

For the six months ended June 30, 2020 and 2019, the Company recognized $43.5 million and $7.0 million, respectively, in revenue associated with the Allergan Collaboration Agreement. Short-term and long-term deferred revenue contract liabilities related to the Allergan Collaboration Agreement were $6.4 million and $30.6 million at December 31, 2019. There were no deferred revenue contract liabilities as of June 30, 2020 due to the Company recognizing a cumulative catch-up adjustment of the remaining deferred revenue balance during the three months ended June 30, 2020 for the determined completion of the Company's performance obligations under the Allergan Collaboration Agreement upon receipt of the notice of termination from AbbVie.

On the unaudited condensed consolidated balance sheets, contract asset balances of $3.3 million and $3.4 million were recorded as accounts receivable from collaboration as of June 30, 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
Six Months Ended June 30, 2020				
Contract liabilities:				
Deferred revenue	$ 37,048	$ —	$ (37,048)	$ —

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six Months Ended June 30, 2019				
Contract liabilities:				
Deferred revenue	$ 40,660	$ —	$ (996)	$ 39,664

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue recognized in the period from				
Amounts included in deferred revenue at the beginning of the period	$ 36,041	$ 137	$ 37,048	$ 996
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 six months ended June 30, 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 six months ended June 30, 2020. Two regulatory milestones were determined to have occurred under this agreement and $0.3 million was accrued and included in accrued expenses during the six months ended June 30, 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, which the Company has subleased. The Company also leases 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 2023.

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 June 30, 2020, the Company had operating lease liabilities of $11.1 million and ROU assets of $10.8 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Lease cost				
Operating lease cost	$ 1,158	$ 1,117	$ 2,308	$ 2,208
Short-term lease cost	100	112	200	433
Variable lease cost	408	300	692	599
Total lease cost	$ 1,666	$ 1,529	$ 3,200	$ 3,240

	Six Months Ended June 30,	
	2020	2019
Operating cash flows from operating leases	$ 2,247	$ 2,099
ROU assets exchanged for new operating lease liabilities	$ 545	$ 14,225

As of June 30, 2020 and December 31, 2019, the weighted-average remaining lease term for operating leases was 3.3 years and 2.7 years, respectively. As of June 30, 2020 and December 31, 2019, the weighted-average discount rate for operating leases was 9.5% and 9.4%, respectively.

As of June 30, 2020, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Six months ending December 31, 2020	$	2,356
Year Ending December 31, 2021		3,991
Year Ending December 31, 2022		3,627
Year Ending December 31, 2023		3,325
Total		13,299
Less: present value discount		(2,165)
Operating lease liabilities	$	11,134

Note 11 – Subsequent Events

On July 17, 2020, the Company entered into a Collaboration Agreement (China Collaboration Agreement) with BeiGene, Ltd. (BeiGene), granting BeiGene an exclusive, royalty-bearing license to develop and commercialize the Company's novel core inhibitor product candidates ABI-H0731, ABI-H2158 and ABI-H3733 for chronic HBV infection (the Licensed Product Candidates) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory).

Pursuant to the terms of the China Collaboration Agreement, the Company received an upfront cash payment of $40.0 million from BeiGene, and the Company is eligible to receive up to approximately $500.0 million in cash milestone payments, comprised of up to $113.8 million for development and regulatory milestones and up to $385.0 million in net sales milestones. In addition, the Company is eligible to receive tiered royalties at percentages ranging from the mid-teens to the low thirties of net sales. BeiGene also agreed to pay all development and regulatory costs for the Licensed Product Candidates in the Territory up to an aggregate of $45.0 million. Development and regulatory costs for the Licensed Product Candidates for the Territory in excess of $45.0 million will be shared equally by the Company and BeiGene.

The China Collaboration Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the China Collaboration Agreement, neither party will commercialize any competing products in the Territory.

If, after ABI-H2158 and ABI-H3733 reach the end of Phase 2 clinical trials, the Company and BeiGene are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the China Collaboration Agreement solely as it relates to that compound, as applicable. Such a termination would result in the Company regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the China Collaboration Agreement for convenience at any time upon 90 days' advance written notice to us. The China Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the China Collaboration Agreement, subject to cure.

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 clinical trials and pre-clinical studies have not been subject to significant impact.

Business Highlights

During the second 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, as well as upcoming milestones and subsequent events 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), and transition of patients who achieve agreed-upon stopping criteria off therapy. Study 211 is the first clinical trial with a core inhibitor to stop therapy and monitor for sustained virologic response in patients with chronic HBV infection.
    - Upcoming reporting of additional interim analyses from Study 211 at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress™ in an oral presentation (HBeAg negative patients) and late-breaker poster presentation (HBeAg positive patients). 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.
    - Initiation of a study evaluating treatment intensification with H0731 in patients with chronic HBV infection who are only partially virologically suppressed on nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy alone after at least a year of treatment.

- ABI-H2158 (H2158), our second-generation core inhibitor product candidate in the HBV Cure program:
  - Initiation of a Phase 2 clinical study using a 300 mg dose of H2158.
  - Upcoming reporting of detailed 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.
  - Receipt of Fast Track Designation from the U.S. Food and Drug Administration (FDA).
- 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 (PK) of H3733 in healthy subjects.
- China HBV Collaboration:
  - Subsequent to the period, on July 17, 2020, entry into a Collaboration Agreement (China Collaboration Agreement) with BeiGene, Ltd. (BeiGene) to develop, manufacture and commercialize H0731, H2158 and H3733.
  - Under the terms of the agreement, we granted BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing H0731, H2158 and H3733 in the People's Republic of China, Hong Kong, Taiwan and Macau.

Microbiome Program

- Presentation 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.
- Return of worldwide rights to all of our microbiome gastrointestinal programs previously licensed to Allergan Pharmaceuticals International Limited (Allergan) under the Research, Development, Collaboration and License Agreement (Allergan Collaboration Agreement) pending completion of transition in the fourth quarter of 2020 and exploration of strategic alternatives to continue development of the Microbiome programs following the return of rights.

Corporate Highlights

- Strengthening of our leadership team with the addition of William Delaney IV, Ph.D. as Chief Scientific Officer, Virology.

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 transition patients off therapy in Study 211. These criteria have been discussed with our lead investigators and reviewed and agreed upon by the FDA. In June 2020, we began transitioning patients who met the stopping criteria off treatment to observe for sustained virologic response. At this time, the ongoing COVID-19 pandemic has not impacted our timeline for 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 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 detailed data from these cohorts at EASL 2020.

Based on data from the Phase 1b dose-ranging study, we initiated a Phase 2 clinical study in June 2020 using a 300 mg 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. After a short delay in enrollment of the study due to the government-mandated shutdown of all clinical studies unrelated to COVID-19, we resumed enrollment during the second quarter of this year. This delay did not 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 developing additional product candidates for our HBV Cure program.

China HBV Collaboration Agreement

On July 17, 2020, we entered into the China Collaboration Agreement with BeiGene, granting BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing H0731, H2158 and H3733 in the People’s Republic of China, Hong Kong, Taiwan and Macau (the Territory).

Under the China Collaboration Agreement, we and BeiGene will collaborate on development activities with respect to the licensed products in accordance with a mutually agreed upon development plan.

Pursuant to the terms of the China Collaboration Agreement, BeiGene paid us an upfront amount of $40.0 million, and we are eligible to receive up to approximately $500.0 million in milestone payments, comprised of up to $113.8 million in development and regulatory and $385.0 million in net sales milestone payments. In addition, we are eligible to receive tiered royalties at percentages ranging from the mid-teens to the low 30s of net sales. BeiGene has also agreed to pay all development and regulatory costs up to an aggregate of $45.0 million in the territory for H0731, H2158 and H3733. Following this initial investment, we and BeiGene will share development costs for the Territory equally.

The China Collaboration Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the China Collaboration Agreement, neither party will commercialize any competing products in the Territory.

If, after ABI-H2158 and ABI-H3733 reach the end of Phase 2 clinical trials, we and BeiGene are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the China Collaboration Agreement solely as it relates to that compound, as applicable. Such a termination would result in us regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the China Collaboration Agreement for convenience at any time upon 90 days' advance written notice to us. The China Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the China Collaboration Agreement, subject to cure.

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 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 ulcerative colitis (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. Preclinical data from the M201 program was selected for presentation as a poster at Digestive Disease Week (DDW) in May 2020; however, DDW 2020 was cancelled due to the COVID-19 pandemic.

M201 is being developed as part of the Allergan Collaboration Agreement, which provides for the development and commercialization of microbiome gastrointestinal programs. We expect the Phase 1b study of M201 to continue despite the pending termination of the Allergan Collaboration Agreement. See "—Allergan Collaboration Agreement."

Additional Product Candidates

Using our microbiome platform capabilities, we are also exploring additional product candidates for other disease indications, including Crohn's disease and irritable bowel syndrome in connection with the Allergan 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 was presented as an e-poster at AACR in June 2020.

Allergan Collaboration Agreement

In May 2020, AbbVie Inc. (AbbVie) completed its acquisition of Allergan. In June 2020, AbbVie notified us that it decided to terminate the Allergan Collaboration Agreement. This decision was not based on any efficacy, safety or other data related to collaboration programs. The termination will be effective on October 10, 2020, until which time AbbVie is obligated to continue to reimburse us for certain research and development costs. After such time, we will regain worldwide rights to all microbiome candidates subject to the collaboration, including M201. We have begun exploring strategic alternatives to continue development of the Microbiome programs following the return of the related intellectual property rights.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California and research, development and small-scale manufacturing activities in Groton, Connecticut. 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 June 30, 2020, we had an accumulated deficit of $458.8 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop and seek regulatory approval for, and commercialize, our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In mid-March 2020, as a result of the COVID-19 pandemic, six San Francisco Bay Area counties announced a shelter-in-place order, restricting all residents to their homes, with few exceptions. Within a week, both California and Connecticut issued state-wide stay-at-home orders. As a biotechnology company, we were exempt from such orders. California’s state-wide and local orders remain in place. Connecticut’s order expired in May 2020.

Because of the exemptions described above, there has not been any significant interruption to date of essential activities at our offices, including work in our laboratories 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. Notwithstanding the expiration of Connecticut’s stay-at-home order, substantially all of our U.S.-based non-research employees at both our South San Francisco and Groton facilities have been working from their homes since mid-March 2020. Clinical study-related impacts of the COVID-19 pandemic to date have been limited to short enrollment delays for our Phase 1 study of H3733 and our Phase 1b study of M201. 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 June 30, 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 June 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
Collaboration revenue	$ 39,376	$ 3,080	$ 36,296	1178%

Collaboration revenue includes the recognition of deferred revenue and reimbursements incurred under the Allergan Collaboration Agreement, for which AbbVie (formerly Allergan pre-acquisition) gave written notice of termination in June 2020. As a result, we recognized in collaboration revenue the remaining deferred revenue balance of $36.0 million upon receipt of the termination notice.

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 June 30,		$ Change	% Change
Program/Description	2020	2019	2020 vs. 2019	2020 vs. 2019
HBV Cure program	$ 16,001	$ 12,141	$ 3,860	32%
Microbiome program (1)	7,326	6,559	767	12%
Total research and development expenses	$ 23,327	$ 18,700	$ 4,627	25%

(1) Expenses presented for the Microbiome program exclude collaboration revenue related to expense reimbursements under the Allergan Collaboration Agreement as discussed in Note 8 to the Condensed Consolidated Financial Statements.

Research and development expenses were $23.3 million for the three months ended June 30, 2020 compared to $18.7 million for the same period in 2019. The increase was primarily due to an increase of $3.9 million in research and development expenses related to the HBV Cure program and an increase of $0.8 million in research and development expenses related to the Microbiome program. Research and development expenses include non-cash stock-based compensation expenses of $3.6 million for the three months ended June 30, 2020 and $3.1 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 June 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
General and administrative expenses	$ 9,470	$ 4,080	$ 5,390	132%

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 $9.5 million for the three months ended June 30, 2020 compared to $4.1 million for the same period in 2019. The increase includes an increase of $0.7 million in salary and benefits and an increase of $0.2 million in recruitment expenses due to additional employees as well as an increase of $0.3 million in professional fees. These increases were partially offset by a decrease of $0.4 million in travel related expenses due to state and local laws restricting travel in response to the COVID-19 pandemic. General and administrative expenses include non-cash stock-based compensation expenses of $3.5 million for the three months ended June 30, 2020 and a $1.1 million reduction of expense for the same period in 2019. Stock-based compensation expense for the three months ended June 30, 2019 includes the reversal of previously recognized expense of $3.6 million related to forfeited awards resulting from the departure of one of the Company's former officers during the period.

Comparison of the Six Months Ended June 30, 2020 and 2019

Collaboration Revenue

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

	Six Months Ended June 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
Collaboration revenue	$ 43,457	$ 6,966	$ 36,491	524%

Collaboration revenue includes the recognition of deferred revenue and reimbursements incurred under the Allergan Collaboration Agreement, for which AbbVie (formerly Allergan pre-acquisition) gave written notice of termination in June 2020. As a result, we recognized in collaboration revenue the remaining deferred revenue balance of $36.0 million upon receipt of the termination notice.

Research and Development Expense

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

	Six Months Ended June 30,		$ Change	% Change
Program/Description	2020	2019	2020 vs. 2019	2020 vs. 2019
HBV Cure program	$ 31,637	$ 27,854	$ 3,783	14%
Microbiome program (1)	14,736	13,551	1,185	9%
Total research and development expenses	$ 46,373	$ 41,405	$ 4,968	12%

(1) Expenses presented for the Microbiome program exclude collaboration revenue related to expense reimbursements under the Allergan Collaboration Agreement as discussed in Note 8 to the Condensed Consolidated Financial Statements.

Research and development expenses were $46.4 million for the six months ended June 30, 2020 compared to $41.4 million for the same period in 2019. The increase was primarily due to an increase of $3.8 million in research and development expenses related to the HBV Cure program and an increase of $1.2 million in research and development expenses related to the Microbiome program. Research and development expenses include non-cash stock-based compensation expenses of $5.6 million for the six months ended June 30, 2020 and $5.8 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):

	Six Months Ended June 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
General and administrative expenses	$ 18,199	$ 13,597	$ 4,602	34%

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 $18.2 million for the six months ended June 30, 2020 compared to $13.6 million for the same period in 2019. The increase includes an increase of $1.2 million in salary and benefits and an increase of $0.2 million in recruitment expenses due to additional employees partially offset by a decrease of $0.6 million in travel related expenses due to state and local laws restricting travel in response to the COVID-19 pandemic. General and administrative expenses include non-cash stock-based compensation expenses of $6.5 million for the six months ended June 30, 2020 and $2.8 million for the same period in 2019. Stock-based compensation expense for the six months ended June 30, 2019 includes the reversal of previously recognized expense of $3.6 million related to forfeited awards resulting from the departure of one of the Company's former officers during the period.

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 June 30, 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 Six Months Ended June 30, 2020 and 2019

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

	Six Months Ended June 30,	
Cash provided by (used in):	2020	2019
Operating activities	$ (48,334)	$ (44,944)
Investing activities	97,242	36,885
Financing activities	$ 1,069	$ 846

Net Cash from Operating Activities

Net cash used in operating activities was $48.3 million for the six months ended June 30, 2020. This was primarily due to a $19.4 million net loss, $0.1 million of accretion of discount of marketable securities and a decrease of $43.5 million of operating assets and liabilities, which includes the recognition of the remaining deferred revenue balance of $36.0 million as revenue during the six months ended June 30, 2020 in connection with AbbVie's decision to terminate the Allergan Collaboration Agreement as discussed in Note 8. These decreases were partially offset by $12.1 million non-cash expense recorded for stock-based compensation, $2.3 million of amortization of operating lease right-of-use (ROU) assets and $0.2 million of depreciation and amortization expense.

Net cash used in operating activities was $44.9 million for the six months ended June 30, 2019. This was primarily due to a $45.6 million net loss, $1.1 million of accretion of discount of marketable securities and a decrease of $9.4 million of operating assets and liabilities, which were offset by $8.6 million non-cash expense recorded for stock-based compensation, $2.2 million of amortization of operating lease ROU assets and $0.3 million of depreciation and amortization expense.

Net Cash from Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2020 was $97.2 million due to $119.3 million of redemptions of marketable securities and $22.7 million of sale of marketable securities, which were partially offset by the purchase of $44.2 million of marketable securities and $0.5 million of property and equipment.

Net cash provided by investing activities for the six months ended June 30, 2019 was $36.9 million primarily due to $131.6 million of redemptions of marketable securities and $0.5 million of sale of marketable securities , which were partially offset by the purchase of $93.7 million of marketable securities and $1.5 million of property and equipment.

Net Cash from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2020 was $1.1 million resulting from the exercise of stock options to purchase 91,713 shares of common stock and the issuance of 42,266 shares of common stock under our ESPP.

Net cash provided by financing activities for the six months ended June 30, 2019 was $0.8 million resulting from the exercise of stock options to purchase 50,875 shares of common stock and the issuance of 36,804 shares of common stock under our ESPP.

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 therapeutics 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 June 30, 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 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 transition patients off of therapy in Study 211, 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 be unable to continue clinical development of our programs and may not generate product approvals or product revenue. If any of those occur, it will have a material adverse impact on our business, results of operations, financial condition and share price.

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

The COVID-19 outbreak began in December 2019 and has since spread globally, reaching pandemic status. The continued spread of COVID-19 could adversely impact our research and development through delay, modification or suspension of our clinical and/or nonclinical studies. Other clinical-stage biotechnology companies, like us, have already had their clinical and nonclinical studies affected by the COVID-19 pandemic.

The COVID-19 pandemic has and may continue to (1) impact patient enrollment, retention or compliance with clinical study protocols; (2) require modifications to or deviations from study protocols and procedures, such as the use of telehealth and home health visits instead of on-site monitoring and treatment, that could increase the cost of conducting clinical studies; (3) 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; (4) delay regulatory meetings and filings with regulatory agencies in the United States and other countries; and (5) disrupt supply chains and cause delays of shipments of critical reagents, personal protective equipment and disinfectants, each of which are necessary for our laboratories and the laboratories of our CROs to maintain normal workflows.

We cannot provide any assurances about when any of our clinical studies that have delayed or may in the future delay 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 obtaining 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 implemented significant measures to control the spread of the virus, including quarantines, travel restrictions, stay-at-home orders and business shutdowns. While governments are in various stages of relaxing these measures, we continue to take 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 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 completed, 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 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, delays or due to interruption in the supply chain due to shipment delays or custom holds;
- 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.

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.

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 FDA 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.

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.

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.

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

As of June 30, 2020, we had 139 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, distribution, 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 been 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 and July 2020, the FDA granted Fast Track designation to H0731 and H2158, respectively, 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 collaborations or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. For example, AbbVie recently provided notice of termination of the Allergan Collaboration Agreement, and we are currently exploring strategic alternatives to continue development of our Microbiome programs following the return of the rights licensed under the Allergan Collaboration Agreement. If other events such as this 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.

We are dependent on an in-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. For example, following its acquisition of Allergan, AbbVie made a strategic portfolio decision to terminate the Allergan Collaboration Agreement. The termination will be effective on October 10, 2020. We are currently exploring strategic alternatives to continue development of our Microbiome programs following the return of the rights licensed under the Allergan Collaboration Agreement.

If a collaboration, such as the one with AbbVie, is terminated, replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration is 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.

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, manufacturing 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 July 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of the U.S. Department of Health and Human Services (HHS) to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permitting the re-importation of insulin products and prioritizing finalization of FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center (FQHC) as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. It is unclear if, when, and to what extent the Executive Orders may be implemented. The regulatory and market implications of the Executive Orders are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for any products that we may develop and commercialize and could adversely affect our future revenues and prospects for profitability.

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 requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The California Attorney General has proposed final proposed regulations, which have not been approved 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. This system includes procedures for challenging issued patents and pending patent applications, which may create 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. In 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. 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: (1) reducing the liquidity and market price of our common stock; (2) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (3) 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 (4) 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 with $182.9 million of net operating losses that carry forward indefinitely and $114.7 million of net operating losses which begin to expire in 2027. There are State net operating loss carryforwards of $309.3 million with $1.0 million carrying forward indefinitely and $308.3 million beginning to expire in 2031. In addition, we have Federal research and development credit carryforwards of $9.0 million which begin to expire in 2028 if not utilized and California research and development credit carryforwards of $5.3 million, which will carryforward indefinitely. 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 $39.8 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
3.1	Fifth Amended and Restated Certificate of Incorporation, effective as of June 12, 2020.		8-K	06/16/2020	3.1
3.2	Amended and Restated Bylaws of Assembly Biosciences, Inc.		8-K	06/16/2020	3.2
10.1#	Amendment No. 3 to Assembly Biosciences, Inc. 2018 Stock Incentive Plan.		8-K	06/16/2020	10.1
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)	X			

Represents management contracts or compensatory plans or arrangements.

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

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

Assembly Biosciences, Inc.

Date: August 5, 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: August 5, 2020

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

EXHIBIT 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Date: August 5, 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: August 5, 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 June 30, 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: August 5, 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 June 30, 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: August 5, 2020