

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

**FORM 10-Q**

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

For the quarterly period ended **March 31, 2022**

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: **001-35005**

**ASSEMBLY BIOSCIENCES, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**20-8729264**

(I.R.S. Employer Identification No.)

**331 Oyster Point Blvd., Fourth Floor  
South San Francisco, California**

(Address of principal executive offices)

**94080**

(zip code)

**(833) 509-4583**

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	ASMB	The Nasdaq Global Select Market

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

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

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated Filer	<input checked="" type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of May 9, 2022, there were 48,216,473 shares of the registrant's common stock outstanding.

## Index

	<u>Page Number</u>
PART I: <a href="#">FINANCIAL INFORMATION</a>	2
Item 1. <a href="#">Financial Statements</a>	2
<a href="#">Condensed Consolidated Balance Sheets at March 31, 2022 (unaudited) and December 31, 2021</a>	2
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2022 and 2021 (unaudited)</a>	3
<a href="#">Condensed Consolidated Statements of Changes in Stockholders' Equity for the Three Months Ended March 31, 2022 and 2021 (unaudited)</a>	4
<a href="#">Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2022 and 2021 (unaudited)</a>	5
<a href="#">Notes to the Condensed Consolidated Financial Statements (unaudited)</a>	6
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	15
Item 3. <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>	22
Item 4. <a href="#">Controls and Procedures</a>	22
PART II: <a href="#">OTHER INFORMATION</a>	23
Item 1. <a href="#">Legal Proceedings</a>	23
Item 1A. <a href="#">Risk Factors</a>	23
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	36
Item 3. <a href="#">Defaults Upon Senior Securities</a>	36
Item 4. <a href="#">Mine Safety Disclosures</a>	36
Item 5. <a href="#">Other Information</a>	36
Item 6. <a href="#">Exhibits</a>	37
<a href="#">SIGNATURES</a>	38

---

## References to Assembly Biosciences, Inc.

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

## Forward-Looking Statements

This Quarterly Report on Form 10-Q contains “forward-looking statements” that are subject to certain risks and uncertainties, including, without limitation, those set forth in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchanges Commission (SEC) on March 11, 2022 (2021 Annual Report) and Part II, Item 1A of this Quarterly Report on Form 10-Q under the heading “Risk Factors,” that could cause actual results to materially differ. Such risks and uncertainties include, among other things:

- our ability to initiate and complete clinical trials involving our therapeutic product candidates, including studies contemplated by our clinical collaboration agreements, in the currently anticipated timeframes;
- safety and efficacy data from clinical studies may not warrant further development of our product candidates;
- clinical and nonclinical data presented at conferences may not differentiate our product candidates from other companies’ candidates;
- results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies;
- continued development and commercialization of our hepatitis B virus (HBV) product candidates, if successful, in the China territory will be dependent on, and subject to, our collaboration agreement governing our HBV-related activity in the China territory;
- our ability to maintain financial resources necessary to continue our clinical studies and fund business operations; and
- any impact that the COVID-19 pandemic may have on our business and operations, including initiation, enrollment and continuation of our clinical studies or timing of discussions with regulatory authorities.

You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. In particular, forward-looking statements include, but are not limited to, statements regarding the timing of commencement of future clinical studies involving our therapeutic product candidates; our ability to successfully complete, and receive favorable results in, clinical trials for our product candidates; and the expected impact of the COVID-19 pandemic on our business and operations. We intend such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

**PART I - FINANCIAL INFORMATION**  
**Item 1. Financial Statements**

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

	March 31, 2022 (Unaudited)	December 31, 2021
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 51,174	\$ 45,627
Marketable securities - short-term	71,826	101,000
Accounts receivable from collaborations	524	336
Prepaid expenses and other current assets	7,253	7,241
<b>Total current assets</b>	<b>130,777</b>	<b>154,204</b>
Marketable securities - long-term	23,459	27,972
Property and equipment, net	1,019	1,139
Operating lease right-of-use (ROU) assets	5,300	6,042
Other assets	2,175	1,703
<b>Total assets</b>	<b>\$ 162,730</b>	<b>\$ 191,060</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,407	\$ 2,659
Accrued research and development expenses	3,596	3,400
Other accrued expenses	2,499	6,863
Operating lease liabilities - short-term	3,207	3,151
<b>Total current liabilities</b>	<b>10,709</b>	<b>16,073</b>
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	2,497	3,325
<b>Total liabilities</b>	<b>15,939</b>	<b>22,131</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 48,132,937 and 48,120,437 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	48	48
Additional paid-in capital	802,170	800,728
Accumulated other comprehensive loss	(908)	(419)
Accumulated deficit	(654,519)	(631,428)
<b>Total stockholders' equity</b>	<b>146,791</b>	<b>168,929</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 162,730</b>	<b>\$ 191,060</b>

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

	Three Months Ended March 31,	
	2022	2021
<b>Operating expenses</b>		
Research and development	\$ 17,205	\$ 18,554
General and administrative	5,957	8,704
Total operating expenses	23,162	27,258
<b>Loss from operations</b>	<b>(23,162)</b>	<b>(27,258)</b>
<b>Other income</b>		
Interest and other income, net	71	58
Total other income	71	58
<b>Net loss</b>	<b>\$ (23,091)</b>	<b>\$ (27,200)</b>
<b>Other comprehensive loss</b>		
Unrealized loss on marketable securities	(489)	(1)
<b>Comprehensive loss</b>	<b>\$ (23,580)</b>	<b>\$ (27,201)</b>
Net loss per share, basic and diluted	\$ (0.48)	\$ (0.69)
Weighted average common shares outstanding, basic and diluted	48,123,930	39,679,734

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
<b>Balance as of December 31, 2021</b>	<b>48,120,437</b>	<b>\$ 48</b>	<b>\$ 800,728</b>	<b>\$ (419)</b>	<b>\$ (631,428)</b>	<b>\$ 168,929</b>
Issuance of common stock for settlement of restricted stock units (RSUs)	12,500	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(489)	—	(489)
Stock-based compensation	—	—	1,442	—	—	1,442
Net loss	—	—	—	—	(23,091)	(23,091)
<b>Balance as of March 31, 2022</b>	<b>48,132,937</b>	<b>\$ 48</b>	<b>\$ 802,170</b>	<b>\$ (908)</b>	<b>\$ (654,519)</b>	<b>\$ 146,791</b>

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

*See Accompanying Notes to Condensed Consolidated Financial Statements*

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (23,091)	\$ (27,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	120	107
Stock-based compensation	1,443	(286)
Net amortization of investments in marketable debt securities	149	92
Non-cash rent expense	893	1,135
Loss on disposal of property and equipment	—	1,611
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	(188)	1,027
Prepaid expenses and other current assets	(12)	303
Other assets	(472)	358
Accounts payable	(1,252)	(1,036)
Accrued research and development expenses	196	(102)
Other accrued expenses	(4,365)	(8,312)
Operating lease liabilities	(923)	(1,041)
Net cash used in operating activities	(27,502)	(33,344)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	—	(3,078)
Proceeds from sale of property and equipment	—	857
Purchases of marketable securities	(3,951)	(49,213)
Proceeds from maturities of marketable securities	30,000	66,450
Proceeds from sale of marketable securities	7,000	3,000
Net cash provided by investing activities	33,049	18,016
<b>Cash flows from financing activities</b>		
Proceeds from the issuance of common stock under ATM equity offering program, net of issuance costs	—	34,137
Net cash provided by financing activities	—	34,137
Net increase in cash and cash equivalents	5,547	18,809
Cash and cash equivalents at the beginning of the period	45,627	59,444
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 51,174</b>	<b>\$ 78,253</b>
<b>Supplemental non-cash investing and financing activities</b>		
Operating lease liabilities arising from obtaining ROU assets	\$ —	\$ 42
Remeasurement of lease liabilities arising from modification of ROU assets	\$ —	\$ (788)

*See Accompanying Notes to Condensed Consolidated Financial Statements*

**ASSEMBLY BIOSCIENCES, INC.**  
**NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
(Unaudited)

**Note 1 - Nature of Business**

**Overview**

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

The Company's research and development programs are pursuing multiple drug candidates that inhibit the HBV replication cycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of discovering and developing finite and curative therapies for patients with HBV. The Company has discovered several novel core inhibitors, which are small molecules that directly target and allosterically modify the HBV core (HBc) protein in a way that affects assembly and stability of HBV nucleocapsids and is currently advancing an early-stage program evaluating a novel small molecule approach to inhibit entry for both HBV and hepatitis delta viruses.

*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 or an applicable foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, proceeds from the exercise of warrants and stock options, issuance of debt, and upfront payments related to collaboration agreements. The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months following the date these unaudited condensed consolidated 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. The Company cannot assure such funding will be available on reasonable terms, if at all. Market volatility resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact the Company's ability to access capital when and as needed.

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

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

**Basis of Presentation**

The accompanying unaudited 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 condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the SEC. In management's opinion, the unaudited 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, 2021, which are contained in the 2021 Annual Report. The results for the three months ended March 31, 2022 are not necessarily indicative of results to be expected for the entire year ending December 31, 2022 or future operating periods.

### **Use of Estimates**

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

Estimates inherent in the preparation of the accompanying unaudited condensed consolidated financial statements include estimates of costs incurred but not yet invoiced for research and development accruals, recoverability and useful lives of our long-lived assets, amounts receivable under collaboration agreements, measurement of operating lease liabilities, and the fair value of stock options, stock appreciation rights, and RSUs granted to employees, directors, and consultants.

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

### **Other Risks and Uncertainties**

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The ongoing COVID-19 pandemic and its broad, global impacts, including supply chain disruptions, have impacted certain aspects of the Company's business, including where and how the Company's employees work in its labs and offices and how and when the Company's nonclinical and clinical studies are conducted. Early in the pandemic, the Company's clinical and preclinical studies were largely unaffected, but as the pandemic has continued, the Company has experienced enrollment delays for two of its multi-drug combination clinical studies, delayed animal studies and delayed shipping of compounds necessary for the Company's research programs. Although the clinical studies that experienced enrollment delays are now fully enrolled, the lockdowns resulting from China's strict "zero covid" policy are also impacting execution of one of these multi-drug clinical studies. The Company relies on contract research organizations (CROs), some of which are in China and India. While these CROs have experienced pandemic-related impacts from time to time, the latest shutdowns in China have impacted the Company more than earlier in the pandemic. The Company cannot at this time predict the specific extent, duration, or full impact the COVID-19 pandemic will have on its business, operations, strategy, prospects and financial condition and results. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

In addition, the study plan of the Company's triple combination study with Antios Therapeutics, Inc. (Antios) initially included a site in Ukraine, but the study will no longer be conducted there due to the instability resulting from Russia's invasion. These changes to the Company's study plan will result in a delayed data readout.

## Income Taxes

Effective January 1, 2022, a provision of the Tax Cuts and Jobs Act (TCJA) has taken effect creating a significant change to the treatment of research and experimental expenditures under Section 174 of the IRC (Sec. 174 expenses). Historically, businesses have had the option of deducting Sec. 174 expenses in the year incurred or capitalizing and amortizing the costs over five years. The new TCJA provision, however, eliminates this option and will require Sec. 174 expenses associated with research conducted in the U.S to be capitalized and amortized over a five-year period. For expenses associated with research outside of the United States, Sec. 174 expenses will be capitalized and amortized over a 15-year period. The Company prepared an analysis of the tax impact of capitalizing and amortizing these costs over the required periods and for calendar year 2022, it is expecting to be in a loss position after the estimated addback.

## Net Loss per Share

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

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

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net loss	\$ (23,091)	\$ (27,200)
Denominator:		
Weighted average common shares and pre-funded warrants outstanding - basic and diluted	48,123,930	39,679,734
Net loss per share - basic and diluted	\$ (0.48)	\$ (0.69)

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

	March 31,	
	2022	2021
Options to purchase common stock	7,475,876	7,382,515
Common stock subject to purchase under our Employee Stock Purchase Plan (ESPP)	129,107	44,870
Unvested RSUs	1,553,755	666,574
Total	9,158,738	8,093,959

## Note 3 – Fair Value Measurements and Investments in Marketable Securities

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

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

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

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

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

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

	March 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>Cash equivalents</b>				
Money market fund	\$ 48,361	\$ —	\$ —	\$ 48,361
<b>Total cash equivalents</b>	<b>48,361</b>	<b>—</b>	<b>—</b>	<b>48,361</b>
<b>Short-term marketable securities</b>				
U.S. and foreign corporate debt securities	4,097	—	(63)	4,034
Asset-backed securities	21,978	—	(97)	21,881
U.S. and foreign commercial paper	45,913	—	(2)	45,911
<b>Total short-term marketable securities</b>	<b>71,988</b>	<b>—</b>	<b>(162)</b>	<b>71,826</b>
<b>Long-term marketable securities</b>				
U.S. and foreign corporate debt securities	14,966	—	(280)	14,686
U.S. treasury securities	8,966	—	(193)	8,773
<b>Total long-term marketable securities</b>	<b>23,932</b>	<b>—</b>	<b>(473)</b>	<b>23,459</b>
<b>Total cash equivalents and marketable securities</b>	<b>\$ 144,281</b>	<b>\$ —</b>	<b>\$ (635)</b>	<b>\$ 143,646</b>

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>Cash equivalents</b>				
Money market fund	\$ 42,507	\$ —	\$ —	\$ 42,507
<b>Total cash equivalents</b>	<b>42,507</b>	<b>—</b>	<b>—</b>	<b>42,507</b>
<b>Short-term marketable securities</b>				
U.S. and foreign corporate debt securities	7,015	—	(2)	7,013
Asset-backed securities	29,097	—	(38)	29,059
U.S. and foreign commercial paper	64,929	—	(1)	64,928
<b>Total short-term marketable securities</b>	<b>101,041</b>	<b>—</b>	<b>(41)</b>	<b>101,000</b>
<b>Long-term marketable securities</b>				
U.S. and foreign corporate debt securities	19,117	—	(74)	19,043
U.S. treasury securities	8,960	—	(31)	8,929
<b>Total long-term marketable securities</b>	<b>28,077</b>	<b>—</b>	<b>(105)</b>	<b>27,972</b>
<b>Total cash equivalents and marketable securities</b>	<b>\$ 171,625</b>	<b>\$ —</b>	<b>\$ (146)</b>	<b>\$ 171,479</b>

Short-term marketable securities held as of March 31, 2022 had contractual maturities of less than one year. Long-term marketable securities held as of March 31, 2022 had contractual maturities of at least one year but less than two years.

Realized gains and losses for the three months ended March 31, 2022 and 2021 were not significant. None of the Company's investments have been in a continuous unrealized loss position for more than 12 months as of March 31, 2022.

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

	March 31, 2022			Fair Value
	Level 1	Level 2	Level 3	
<b>Cash equivalents</b>				
Money market fund	\$ 48,361	\$ —	\$ —	\$ 48,361
<b>Total cash equivalents</b>	<b>48,361</b>	<b>—</b>	<b>—</b>	<b>48,361</b>
<b>Short-term marketable securities</b>				
U.S. and foreign corporate debt securities	—	4,034	—	4,034
Asset-backed securities	—	21,881	—	21,881
U.S. and foreign commercial paper	—	45,911	—	45,911
<b>Total short-term marketable securities</b>	<b>—</b>	<b>71,826</b>	<b>—</b>	<b>71,826</b>
<b>Long-term marketable securities</b>				
U.S. and foreign corporate debt securities	—	14,686	—	14,686
U.S. treasury securities	—	8,773	—	8,773
<b>Total long-term marketable securities</b>	<b>—</b>	<b>23,459</b>	<b>—</b>	<b>23,459</b>
<b>Total assets measured at fair value</b>	<b>\$ 48,361</b>	<b>\$ 95,285</b>	<b>\$ —</b>	<b>\$ 143,646</b>

	December 31, 2021			Fair Value
	Level 1	Level 2	Level 3	
<b>Cash equivalents</b>				
Money market fund	\$ 42,507	\$ —	\$ —	\$ 42,507
<b>Total cash equivalents</b>	<b>42,507</b>	<b>—</b>	<b>—</b>	<b>42,507</b>
<b>Short-term marketable securities</b>				
U.S. and foreign corporate debt securities	—	7,013	—	7,013
Asset-backed securities	—	29,059	—	29,059
U.S. and foreign commercial paper	—	64,928	—	64,928
<b>Total short-term marketable securities</b>	<b>—</b>	<b>101,000</b>	<b>—</b>	<b>101,000</b>
<b>Long-term marketable securities</b>				
U.S. and foreign corporate debt securities	—	19,043	—	19,043
U.S. treasury securities	—	8,929	—	8,929
<b>Total long-term marketable securities</b>	<b>—</b>	<b>27,972</b>	<b>—</b>	<b>27,972</b>
<b>Total assets measured at fair value</b>	<b>\$ 42,507</b>	<b>\$ 128,972</b>	<b>\$ —</b>	<b>\$ 171,479</b>

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

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

#### Note 4 – Other Accrued Expenses

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

	March 31, 2022	December 31, 2021
<b>Accrued expenses:</b>		
Accrued compensation	\$ 2,161	\$ 6,426
Accrued professional fees and other	338	437
<b>Total accrued expenses</b>	<b>\$ 2,499</b>	<b>\$ 6,863</b>

## Note 5 – Sale of Common Stock

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC, File No. 333-248469, that became effective on September 4, 2020 (the 2020 Registration Statement). The Company may from time to time sell any combination of the securities described in the 2020 Registration Statement in one or more offerings up to an aggregate offering price of \$300.0 million. In connection with the filing of the 2020 Registration Statement, the Company entered into a sales agreement under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to \$100.0 million through “at-the-market” offerings (2020 ATM), which shares are included in the \$300.0 million of securities registered pursuant to the 2020 Registration Statement. During the three months ended March 31, 2021, the Company sold 5,991,858 shares of common stock under the 2020 ATM, for which the Company received net proceeds of \$34.1 million, after deducting commissions, fees and expenses. The Company did not sell any shares of common stock under the 2020 ATM during the three months ended March 31, 2022.

## Note 6 – Stock Plans and Stock-Based Compensation

### Equity Incentive Plans

In May 2021, the Company’s stockholders approved an amendment to the Assembly Biosciences, Inc. 2018 Stock Incentive Plan (2018 Plan) that increased the aggregate number of shares of common stock reserved under the 2018 Plan to 6,600,000 and an Amended and Restated Assembly Biosciences, Inc. 2018 Employee Stock Purchase Plan (the 2018 ESPP) that, among other things, increased the number of shares of common stock reserved to an aggregate of 1,300,000.

As of March 31, 2022, the Company had awards outstanding under the following shareholder-approved plans: the 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen; the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. As of March 31, 2022, the Company also had awards outstanding under the Assembly Biosciences, Inc. 2017 Inducement Award Plan, the Assembly Biosciences, Inc. 2019 Inducement Award Plan and the Assembly Biosciences, Inc. 2020 Inducement Award Plan.

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

### Stock Plan Activity

#### Stock Options

A summary of the Company’s option activity and related information for the three months ended March 31, 2022 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, 2021	6,161,901	\$ 11.77	6.4	\$ 53
Granted	1,479,550	2.29		
Forfeited	(141,264)	16.46		
Expired	(24,311)	26.86		
Outstanding as of March 31, 2022	7,475,876	\$ 9.76	6.9	\$ 6
Options vested and exercisable as of March 31, 2022	4,120,830	\$ 12.87	5.1	\$ —

The weighted-average grant-date fair value of options granted was \$1.63 and \$3.15 during the three months ended March 31, 2022 and 2021, respectively. There were no options exercised during the three months ended March 31, 2022 or 2021.

#### RSUs

A summary of the Company's RSUs and related information for the three months ended March 31, 2022 is as follows:

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2021	970,339	\$ 7.04
Granted	730,275	2.30
Vested	(92,286)	12.10
Forfeited	(54,573)	6.81
Nonvested as of March 31, 2022	1,553,755	\$ 4.96

The total fair value of RSUs vested and settled during the three months ended March 31, 2022 and 2021 was \$1.1 million and \$2.5 million, respectively. The total intrinsic value of RSUs vested and settled during the three months ended March 31, 2022 and 2021 was \$0.2 million and \$0.6 million, respectively.

In September 2019, the Company granted 100,000 RSUs with performance-based vesting conditions to its chief executive officer. On March 31, 2021, 25,000 of these awards were forfeited back to the Company due to the expiration of the time period to complete one of the performance conditions. On July 31, 2021, an additional 25,000 of these awards were forfeited back to the Company due to the expiration of the time period to complete one of the performance conditions. The outstanding 50,000 awards with an aggregate fair value of \$0.4 million vest upon performance conditions not yet deemed probable. Accordingly, no stock-based compensation expense has been recognized as of March 31, 2022.

In July 2021, the Company granted a total of 324,214 RSUs with performance-based vesting conditions upon the achievement of clinical milestones to the majority of employees, including its executive officers. The awards had a grant date fair value of \$1.2 million and vest upon performance conditions not yet deemed probable. Accordingly, no stock-based compensation expense has been recognized as of March 31, 2022.

In March 2022, the Company granted 255,000 RSUs with market-based vesting conditions to members of management, including its executive officers. The awards had a grant date fair value of \$0.4 million and are being recognized over the derived service period of 1.5 years and vest upon the achievement of certain market-based conditions which have not been achieved as of March 31, 2022. Stock-based compensation expense for the awards was nominal during the three months ended March 31, 2022.

#### ESPP

There were no shares purchased under the 2018 ESPP during the three months ended March 31, 2022 or 2021.

#### Valuation Assumptions

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

	Three Months Ended March 31,	
	2022	2021
Exercise price	\$1.53 - \$2.45	\$4.33 - \$5.79
Expected volatility	79.2% - 81.6%	81.4% - 91.2%
Risk-free rate	1.41% - 2.48%	0.50% - 1.37%
Expected term (years)	5.5 - 7.0	5.5 - 7.0
Expected dividend yield	0%	0%

The fair value of RSUs granted is determined based on the price of the Company's common stock on the date of grant. The fair value of market-based RSUs granted is determined using the Monte-Carlo simulation model.

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

### Stock-Based Compensation Expense

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

	Three Months Ended March 31,	
	2022	2021
Research and development	\$ 778	\$ (2,091) <sup>(1)</sup>
General and administrative	665	1,805
Total stock-based compensation expense	<u>\$ 1,443</u>	<u>\$ (286)</u>

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

As of March 31, 2022, there was \$10.9 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 7 - Collaboration Agreements

#### *BeiGene Agreement*

In July 2020, the Company and BeiGene, Ltd. (BeiGene) entered into a Collaboration Agreement (the BeiGene Agreement) to develop and commercialize the Company's novel core inhibitor product candidates VBR, ABI-H2158 and ABI-H3733 (the Licensed Product Candidates) for chronic HBV infection in the People's Republic of China, Hong Kong, Taiwan and Macau.

As of March 31, 2022 the only remaining performance obligation under the BeiGene Agreement not considered to be complete is the transfer of the ABI-H3733 License. The transaction price allocated to ABI-H3733 of \$2.7 million was recognized as a long-term deferred revenue contract liability as of both March 31, 2022 and December 31, 2021, and will be recognized as revenue when the Company provides pre-Phase 3 clinical study know-how and development results for ABI-H3733 to BeiGene or a termination of the BeiGene Agreement for ABI-H3733. During the three months ended March 31, 2022 and 2021, the Company did not recognize any revenue or increase or reduction of research and development expense under the BeiGene Agreement.

The Company incurred \$3.5 million in incremental costs of obtaining the BeiGene Agreement in 2020. These contract costs have been capitalized and are being recognized consistent with the pattern of recognition of revenue associated with the Licensed Product Candidates. As of March 31, 2022 and December 31, 2021, the remaining unamortized contract costs are \$0.2 million and are included in other assets on the condensed consolidated balance sheet.

#### *Arbutus Biopharma Agreement*

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

During the three months ended March 31, 2022 and 2021, the Company recognized a reduction of research and development expenses of \$0.6 million and \$0.5 million, respectively, under the Arbutus Biopharma Agreement.

#### *Antios Agreement*

In July 2021, the Company and Antios entered into a Clinical Trial Collaboration Agreement (the Antios Agreement) to collaborate on a triple combination therapy using VBR and Antios's active site polymerase inhibitor nucleotide ATI-2173 for the treatment of HBV. Assembly and Antios are individually responsible for the study's manufacturing costs but will equally share the remaining costs of the study.

During the three months ended March 31, 2022, the Company incurred \$0.1 million in research and development expenses under the Antios Agreement.

### **Note 8 - Milestones and Research Agreements**

#### *HBV Research Agreement with Indiana University*

Since September 2013, the Company has been party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it has licensed aspects of the Company's HBV program held by IURTC. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, should all milestones through development be met, is \$0.8 million, with a portion related to the first performance milestone having been paid. The Company is obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly receives. The Company is also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than such fees for that year. The Company paid IURTC \$0.1 million in diligence maintenance fees during the three months ended March 31, 2022. No amounts were paid during the three months ended March 31, 2021.

#### *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.

In connection with the wind-down of the Microbiome program, the License and Collaboration Agreement with Therabiome was terminated in January 2021, and the termination became effective in April 2021. No amounts were accrued for this agreement as of and for the three months ended March 31, 2022 or 2021.

#### *Door Pharma Agreement*

In November 2020, the Company and Door Pharmaceuticals, LLC (Door Pharma) entered into an exclusive, two-year Collaboration Agreement and Sublicense Agreement (collectively, the Door Pharma Agreement) focused on the development of a novel class of HBV inhibitors.

During the three months ended March 31, 2022 and 2021, the Company incurred research and development funding of \$0.7 million and \$0.4 million, respectively, under the Door Pharma Agreement. No success-based milestones were determined to have occurred under this agreement during the three months ended March 31, 2022 or 2021. The Company terminated the Door Pharma Agreement in May 2022, effective September 2022, to focus its resources on its other internal HBV programs and its programs targeting other viruses.

Under the consolidation accounting standard, the Company determined Door Pharma is a variable interest entity. The Company does not have the power to direct the activities which most significantly affect the economic performance of Door Pharma and as such the Company is not the primary beneficiary and consolidation is not required. As of March 31, 2022, the Company has not provided financial or other support to Door Pharma that was not contractually required.



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

*The 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, 2021 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, 2021 filed with the U.S. Securities and Exchange Commission on March 11, 2022 (2021 Annual Report). In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under “Part I. Item 1A. Risk Factors” in our 2021 Annual Report and “Part II. Item 1A. Risk Factors” in this report.*

### Overview

We are a clinical-stage biotechnology company focused on discovery and development of innovative therapeutics targeting hepatitis B virus (HBV) and other viral diseases.

The World Health Organization (WHO) estimates that 296 million people worldwide are chronically infected with HBV as of 2019. Our research and development organizations are pursuing multiple drug candidates designed to inhibit the HBV replication cycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of discovering and developing finite and curative therapies for patients with chronic HBV infection. We have discovered several novel core inhibitors, which are small molecules that directly target and allosterically modulate the HBV core protein in a way that affects assembly and stability of HBV nucleocapsids, and we are currently advancing an early-stage program evaluating a novel small molecule approach to inhibit entry for HBV and hepatitis delta virus (HDV). HDV is estimated to impact approximately 5% of those chronically infected with HBV, or approximately 12 million people. In addition, our research organization is working on discovering and developing small molecules targeting an additional novel, currently undisclosed HBV target.

While we continue our efforts to develop finite and curative therapies for patients with chronic HBV and HDV infection, our research organization recently launched an exploratory virology discovery program for compounds directed at a number of non-HBV viral targets. These targets, which we currently expect to disclose in mid-2022, were selected to leverage the deep antiviral expertise and experience of our research and development organizations against diseases with significant unmet medical need.

The ongoing COVID-19 pandemic and its broad, global impacts, including supply chain disruptions, have impacted certain aspects of our business, including where and how our employees work in our labs and offices and how and when our nonclinical and clinical studies are conducted. Early in the pandemic, our clinical and preclinical studies were largely unaffected, but as the pandemic has continued, we have experienced enrollment delays for two of our multi-drug combination clinical studies, delayed animal studies and delayed shipping of compounds necessary for our research programs. Although the clinical studies that experienced enrollment delays are now fully enrolled, the lockdowns resulting from China’s strict “zero covid” policy are also impacting execution of one of these multi-drug clinical studies. We rely on contract research organizations (CROs), some of which are in China and India. While these CROs have experienced pandemic-related impacts from time to time, the latest shutdowns in China have impacted us more than earlier in the pandemic.

As previously announced, in January 2021, we wound down our Microbiome program to prioritize and focus our resources on our virology programs. Our Microbiome program had been developing a novel class of oral live microbial biotherapeutics candidates designed to treat disorders associated with the microbiome.

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

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

Vebicorvir (VBR), our lead core inhibitor product candidate, is licensed from Indiana University. The conduct of our initial Phase 2 studies, Study 201 and 202, is complete. In these studies, VBR administered with NrtI therapy demonstrated a favorable safety profile and led to greater viral suppression of both HBV DNA and viral pgRNA than NrtI therapy alone.

Our most recently completed study for VBR, Study 211, involved transitioning patients who met the requisite stopping criteria, as determined in collaboration with our lead investigators and the U.S. Food and Drug Administration (FDA), off of therapy to test for sustained virologic response (SVR). SVR refers to sustained viral suppression (more than six months) of HBV DNA below LLOQ and would be consistent with a successful finite treatment for chronic HBV infection. During the trial, it became clear that patients who stopped therapy in Study 211 had not achieved SVR, as all patients relapsed, meaning they had detectable HBV and the dual combination therapy of VBR + NrtI was insufficient to cure chronic HBV infection in the studied population. Based on these results, we terminated Study 211 in the fourth quarter of 2020. We presented follow-up data from Study 211 related to virologic response, safety and resistance following treatment discontinuation, at the European Association for the Study of the Liver's (EASL) International Liver Congress™ in June 2021 (EASL 2021). At the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in November 2021 (AASLD 2021), we presented additional follow-up data from Study 211 demonstrating that patients had increases of HBV DNA and pgRNA after discontinuation of VBR despite continued NrtI treatment, further supporting that core inhibitors deepen viral suppression in combination with NrtIs. At the EASL International Liver Congress™ in June 2022 (EASL 2022), we plan to present additional VBR data related to the correlation between deeper virologic suppression and fibrosis-4 index in treatment naïve patients with HBeAg positive chronic HBV infection, an evaluation of the drug-drug interaction profile of VBR and an evaluation of the disposition and mass balance recovery of VBR in rats and humans.

Based on discussions with leading viral hepatitis experts, global regulatory discussions and feedback, and, with respect to the China territory, discussions and agreement with our collaboration partner, BeiGene, Ltd. (BeiGene), in early 2021, we decided to not move forward with the global registrational studies for VBR as a chronic suppressive treatment (CST) in combination with NrtI. The decision was made to focus on the greatest unmet medical need of patients, which lies predominantly in cure, rather than CST. As a result, we terminated Study 205 and began to focus our efforts with VBR in combination with NrtI and additional mechanisms targeting finite and curative combination therapy.

We currently have three Phase 2 triple combination studies involving VBR ongoing. These studies are detailed below. See “—Multi-Drug Combination Studies.”

#### *Next Generation Core Inhibitors*

##### ABI-H3733

Our first of two next-generation core inhibitor product candidates, ABI-H3733 (3733), was internally discovered and developed. The chemical scaffold of 3733 is novel and distinct from each of VBR, ABI-4334 (4334) and our discontinued core inhibitor product candidate, ABI-H2158 (2158).

In 2020, we initiated and completed a Phase 1a clinical study of 3733 to evaluate safety, tolerability and pharmacokinetics (PK) following single ascending dose and multiple ascending dose administration in healthy subjects in New Zealand. Preliminary data indicate that 3733 was generally well-tolerated and had favorable PK. Results detailing 3733's safety and PK from this study were presented in a poster presentation at AASLD 2021.

In addition, at EASL 2021, we presented observations on 3733's enhanced potency and target coverage for both antiviral activity and inhibition of cccDNA generation as compared to VBR and 2158. At EASL 2022, we plan to present 3733's improved PK profile resulting from new formulation activities.

We expect to initiate a Phase 1b study with the improved formulation of 3733 in patients with chronic HBV infection in the first half of 2022.

##### ABI-4334

In mid-2021, we announced the selection of 4334, our other next-generation core inhibitor product candidate. As with all of our core inhibitor product candidates nominated after VBR, 4334 was internally discovered and developed. In addition, the chemical scaffold of 4334 is also novel and distinct from each of VBR, 3733 and 2158.

We nominated 4334 based on a preclinical target drug profile that indicates enhanced target coverage and potency to prevent both formation of new virus and cccDNA, which is responsible for maintaining the HBV viral reservoir. We believe that 4334 has a best-in-class preclinical profile, with single-digit nanomolar potency against the production of new virus and the formation of cccDNA. Preclinically to date, 4334 has also demonstrated pan-genotypic activity, an improved resistance profile and a favorable safety profile. Preclinical characterization of 4334 was shared in a poster presentation at AASLD in November 2021. At EASL 2022, we plan to present preclinical data demonstrating that 4334 promotes formation of empty capsids and prevents cccDNA formation by disrupting incoming capsids.

Our preclinical work on 4334 is ongoing, with the aim of completing Investigational New Drug (IND) enabling studies and initiating a Phase 1a clinical study in the second half of 2022.

#### *ABI-H2158*

In September 2021, we discontinued development of 2158 following the observation of elevated alanine transaminase (ALT) levels in the Phase 2 clinical study consistent with drug-induced hepatotoxicity.

#### **Multi-Drug Combination Studies**

We believe that core inhibitors and NrtI will be central to finite and curative therapies for chronic HBV infection. Therefore, as we continue to develop and advance our current and future core inhibitors through clinical studies, we plan to conduct multi-drug combination studies in parallel that add additional drugs (or compounds) with nonoverlapping mechanisms of action to the core inhibitor + NrtI antiviral backbone. We currently have three ongoing triple combination studies.

Our first triple combination study is being conducted pursuant to a Clinical Trial Agreement with Arbutus Biopharma Corporation (Arbutus Biopharma) and consists of a randomized, multi-center, open-label Phase 2 clinical study to explore the safety, PK and antiviral activity of the triple combination of VBR, NrtI and AB-729 (Arbutus Biopharma's investigational RNAi candidate) compared to the double combinations of VBR + NrtI and AB-729 + NrtI in virologically suppressed patients. This clinical study initiated in the first quarter of 2021 and completed enrollment in February 2022. We expect to share interim on-treatment results from this study in the second half of 2022.

Our second triple combination study evaluates VBR and NrtI in combination with interferon in treatment-naïve HBeAg positive subjects. This study was also initiated in the first quarter of 2021 and completed enrollment in March 2022. We expect to share interim on-treatment results from this study in the second half of 2022.

Our third triple combination study is being conducted pursuant to a Clinical Trial Collaboration Agreement with Antios Therapeutics, Inc. (Antios) to evaluate ATI-2173, Antios's investigational proprietary active site polymerase inhibitor nucleotide (ASPIN), VBR and tenofovir disoproxil fumarate, an NrtI. This multi-center, double-blinded, placebo-controlled study to explore the safety, PK and antiviral activity of this all-oral triple combination. This study, which will enroll ten treatment-naïve or off-treatment HBeAg negative or positive patients in a 12-week treatment study, was initiated in April 2022. The study plan initially included a site in Ukraine, but the study will no longer be conducted there due to the instability resulting from Russia's invasion. We expect these changes to our study plan to result in a delayed data readout.

Both our first and second triple combination studies have experienced enrollment delays due to the ongoing COVID-19 pandemic. The pandemic has impacted patients and study sites through patient screening delays, travel restrictions and hesitancy to travel to study sites. The pandemic has also impacted our vendors, as our central laboratories have been unable to meet their contractual obligations, and our vendors have experienced staffing constraints and supply chain challenges as they seek to obtain lab kits, reagents and other items necessary to enroll patients in our studies. As a result, we were unable to fully enroll our first and second triple combination studies in 2021 as initially planned; however, enrollment for both of these studies was completed in the first quarter of 2022, and we do not believe these delays will impact interim data readouts for these studies, which remains on schedule in the second half of 2022.

#### **Beyond Core Inhibitors**

In addition to the development and advancement of our core inhibitor portfolio and our current and future multi-drug combination studies, our research and development team is working on discovering and developing small molecules to inhibit HBV and HDV viral entry and small molecules targeting an additional novel, currently undisclosed HBV target, which we expect to announce in the first half of 2022, to complement our HBV cure strategy.

### *HBV/HDV Inhibitor*

In March 2022, we announced our new research focused on a novel, orally bioavailable small molecule approach to inhibit entry of HBV and HDV. While HDV is less well known in the U.S., it is a significant and serious health problem with inadequate treatment in many parts of Europe, Africa, the Middle East, East Asia and parts of South America. HDV is a “satellite virus,” because it can only infect people (1) that are already infected with HBV or (2) at the same time as a person is infected with HBV. HDV is known to accelerate disease progression and increase the incidence of liver cirrhosis and liver cancer, which results in higher morbidity and mortality rates than HBV alone. The current standard of care treatment for HDV is a large, complex molecule that requires daily injections. Our research team has identified a potential opportunity to develop a safe and effective oral small molecule, which could significantly improve convenience and potentially enhance treatment uptake and diagnosis rates. Based on current progress, our research team’s aim is to nominate a product candidate for development in the first half of 2023.

### *cccDNA Disruptors*

In November 2020, we entered into an exclusive, two-year collaboration and option agreement with Door Pharmaceuticals, LLC (Door Pharma) focused on the development of a novel class of HBV inhibitors, which we terminated in May 2022. The termination will be effective September 2022. Prior to the termination of collaboration with Door Pharma, we worked with Door Pharma on identifying cccDNA disruptors aimed at inhibiting different intra-nuclear steps in the viral replication cycle that complement the activity of our core inhibitors.

We terminated this collaboration to focus our resources on our other internal HBV programs and our programs targeting other viruses.

### *Additional Antiviral Opportunities*

In addition to our work toward developing finite and curative therapies for patients with chronic HBV infection, we have expanded our research and development organizations’ reach by pursuing exploratory research on novel compounds targeting other viruses. Our expanded focus leverages the depth and breadth of virology expertise of our research and development organization to diversify our pipeline into areas of high unmet medical need.

We expect to disclose more information regarding these discovery programs on additional viral targets in mid-2022.

### **Operations**

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California as well as registrational offices in China.

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

We have generated significant losses to date, and we expect to continue to generate losses as we develop our product candidates. As of March 31, 2022, we had an accumulated deficit of \$654.5 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.

The COVID-19 pandemic resulted in substantially all of our U.S.-based non-research employees working from their homes beginning in mid-March 2020. In addition, we took the additional step of requiring all of our employees be fully vaccinated against COVID-19. As government restrictions have relaxed, our employees began returning to the office during the first quarter of 2022. We have adopted a hybrid working model, which allows our employees flexibility regarding when and how frequently to return to the office.

There has not been any significant interruption to date of essential activities at our offices, including work in our laboratories with proper protections and procedures in place. While we have experienced some shipping delays or shortages of personal protective equipment (PPE) that are important to maintaining normal workflows in our laboratories, we have been able to continue our critical research activities through schedule shifts, use of PPE on-

hand and reallocation of certain resources that allow our employees to practice “social distancing” and comply with applicable laws. Early in the pandemic, our clinical and preclinical studies were largely unaffected, but as the pandemic has continued, we have experienced enrollment delays for two of our multi-drug combination clinical studies, delayed animal studies and delayed shipping of compounds necessary for our research programs. Although the clinical studies that experienced enrollment delays are now fully enrolled, the lockdowns resulting from China’s strict “zero covid” policy are also impacting execution of one of these multi-drug clinical studies. We continually work with our CROs and other vendors to ensure, to the extent possible, that services are provided in a timely manner while also identifying alternative vendors and strategies to utilize in the event that COVID- or third party-related delays threaten our ability to meet our timelines. However, some of our CROs are in China and India, and while these CROs have experienced pandemic-related impacts from time to time, the latest shutdowns in China have impacted us more than earlier in the pandemic. We cannot currently predict the specific extent, duration or full impact the COVID-19 pandemic will have on our ongoing and planned research efforts, clinical studies and other business operations. We continue to monitor the situation regularly for additional potential delays, or modifications to our ongoing and planned studies and, if circumstances warrant, we may adjust our budget and operating plan.

### Critical Accounting 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 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 research and development expense and accruals 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 2021 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2021 Annual Report.

### Results of Operations

#### Comparison of the Three Months Ended March 31, 2022 and 2021

##### Research and Development Expense

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

	Three Months Ended March 31,		\$ Change 2022 vs. 2021	% Change 2022 vs. 2021
	2022	2021		
External expenses:				
VBR	\$ 1,921	\$ 5,568	\$ (3,647)	(65%)
2158	901	2,386	(1,485)	(62%)
3733	1,195	408	787	193%
4334	1,257	558	699	125%
Microbiome	—	488	(488)	(100%)
Research and discovery	2,087	1,148	939	82%
Total external expenses	7,361	10,556	(3,195)	(30%)
Employee and contractor-related expenses	8,185	4,896	3,289	67%
Facility and other expenses	1,659	3,102	(1,444)	(47%)
Total research and development expenses	\$ 17,205	\$ 18,554	\$ (1,350)	(7%)

Research and development expenses were \$17.2 million for the three months ended March 31, 2022 compared to \$18.6 million for the same period in 2021. VBR external expenses decreased due to the termination of Studies 211 and 205 and because costs under two of our currently ongoing Phase 2 triple combination studies are being shared with collaboration partners. Decreases in 2158 and Microbiome external expenses were due to the termination of both programs and were largely offset by increases in our external expenses for 3733, 4334 and our research

discovery program as we advance those programs. Employee and contractor-related expenses increased by \$3.3 million primarily due to the reversal of \$3.6 million of previously recognized stock-based compensation expense related to forfeited awards of terminated employees during the three months ended March 31, 2021, \$2.7 million of which resulted from the wind-down of our Microbiome program. Facility and other expenses consist primarily of rent and maintenance of our premises and other costs which are allocated based on headcount in each department. The decrease in facility and other expenses of \$1.4 million is primarily attributable to asset impairment and other charges incurred during the three months ended March 31, 2021 in connection with the wind-down of the Microbiome program.

#### *General and Administrative Expense*

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

	Three Months Ended March 31,		\$ Change 2022 vs. 2021	% Change 2022 vs. 2021
	2022	2021		
General and administrative expenses	\$ 5,957	\$ 8,704	\$ (2,747)	(32%)

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

General and administrative expenses were \$6.0 million for the three months ended March 31, 2022 compared to \$8.7 million for the same period in 2021. General and administrative expenses consist of stock-based compensation expense of \$0.7 million for the three months ended March 31, 2022 and \$1.8 million for the same period in 2021. The decrease in stock-based compensation expense of \$1.1 million was due to a decrease in the grant date fair value of recent option grants, a decrease in the number of employees and a reversal of \$0.4 million of previously recognized expense in the three months ended March 31, 2022 related to forfeited awards from terminated employees. We also experienced decreases of \$0.7 million in facility-related expenses due to termination of lease agreements related to the Microbiome program, \$0.3 million in recruitment expenses due to hiring of fewer employees during the three months ended March 31, 2022 compared to the same period in 2021, \$0.3 million in professional fees primarily due to decreases in legal expenses and \$0.2 million in salary and benefits primarily attributable to a decrease in headcount.

#### **Liquidity and Capital Resources**

##### *Sources of Liquidity*

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through March 31, 2022 principally through equity financings, raising an aggregate of \$604.6 million in net proceeds, and strategic collaborations, raising an aggregate of \$90.0 million through upfront payments.

##### **Cash Flows for the Three Months Ended March 31, 2022 and 2021**

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

	Three Months Ended March 31,	
	2022	2021
<b>Cash provided by (used in):</b>		
Operating activities	\$ (27,502)	\$ (33,344)
Investing activities	33,049	18,016
Financing activities	—	34,137

### *Net Cash from Operating Activities*

Net cash used in operating activities was \$27.5 million for the three months ended March 31, 2022. This was primarily due to our \$23.1 million net loss and a decrease of \$4.4 million in other accrued expenses due to payment of our 2021 annual bonuses during the three months ended March 31, 2022.

Net cash used in operating activities was \$33.3 million for the three months ended March 31, 2021. This was primarily due to our \$27.2 million net loss and a decrease of \$8.3 million in other accrued expenses due to payment of our 2020 annual bonuses and accrued severances associated with the wind-down of our Microbiome program, partially offset by a \$1.6 million loss on disposal of property and equipment associated with the wind-down of our Microbiome program during the three months ended March 31, 2021.

### *Net Cash from Investing Activities*

Net cash provided by investing activities for the three months ended March 31, 2022 was \$33.0 million, due to proceeds from sales and maturities of marketable securities, net of purchases.

Net cash provided by investing activities for the three months ended March 31, 2021 was \$18.0 million. This was due to proceeds of \$20.2 million from sales and maturities of marketable securities, net of purchases, offset by our purchase of leased equipment for \$3.1 million that we then sold for \$0.9 million in connection with the wind-down of the Microbiome program.

### *Net Cash from Financing Activities*

We did not have any cash flows from financing activities for the three months ended March 31, 2022.

Net cash provided by financing activities for the three months ended March 31, 2021 was \$34.1 million resulting from the sale of 5,991,858 shares of our common stock under the 2020 ATM.

### **Funding Requirements**

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

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

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. There were no material changes in our commitments under the contractual obligations disclosed in our 2021 Annual Report. Since our inception, we have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

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

- the scope, progress, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- the extent to which we further acquire or in-license other product candidates and technologies;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates;

- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting nonclinical testing and clinical studies is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will likely be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.

### **Item 4. Controls and Procedures**

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

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

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

There were no changes in our internal control over financial reporting in the quarter ended March 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

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

#### Risks Related to Our Business

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

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

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

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

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

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

The continued spread of COVID-19, including through infection by variants of the SARS-CoV-2 virus, could continue to adversely impact our research and development through delay, modification or suspension of our clinical and/or nonclinical studies. Other clinical-stage biotechnology companies, like us, have had their clinical and nonclinical studies affected by the COVID-19 pandemic.

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

data while the pandemic is ongoing, COVID-19 may negatively affect the quality, completeness, integrity, interpretability and cost of obtaining such clinical study data.

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

As a result of the COVID-19 pandemic, governments around the world implemented significant measures to control the spread of the virus, including quarantines, travel restrictions, stay-at-home orders and business shutdowns. While governments have relaxed these measures as case numbers decreased, periodic surges in COVID-19 cases have prompted, and may in the future prompt, many governments to reimplement these restrictions, including in the United States, Europe, India and China, which is currently experiencing severe lockdowns in connection with its zero covid policy. We continue to take precautionary measures intended to minimize our employees' potential exposure to the virus, including temporarily requiring all employees who can do so to work remotely and suspending all non-essential business travel worldwide for our employees and requiring employees to be fully vaccinated against COVID-19. The majority of our employees continuing to work remotely may disrupt our operations, increase the risk of a cybersecurity incident or otherwise negatively affect our business.

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

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

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

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

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

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

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

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

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

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

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

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

Furthermore, these CROs may also have relationships with other entities, some of which may be our competitors. CRO personnel are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our clinical and nonclinical studies. If these CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our research, nonclinical or clinical studies may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, any of which could materially harm our business, prospects, financial condition and results of operations.

***We have international operations, including in China, and conduct clinical studies and discovery research activities outside of the United States, including in Eastern Europe. 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:

- business interruptions resulting from geopolitical actions such as Russia's invasion of Ukraine and the resulting war, as well as tariffs, other wars, acts of terrorism, natural disasters or outbreaks of disease;
- 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; and
- 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.

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

We may publicly disclose top-line or preliminary data based on analysis of then-available efficacy, tolerability, 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. We also make assumptions, estimates, calculations and conclusions as part of our data analyses, and we may not have received or had the opportunity to fully and carefully evaluate all data prior to release. As a result, the top-line or preliminary results that we report may differ from final results of the same studies or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remains subject to audit and verification procedures that may result in the final data differing materially from previously published preliminary data. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

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

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

We rely on third-party manufacturers to supply the quantities of VBR, 3733 and 4334 used in our clinical and nonclinical studies. If any product candidate we develop or acquire in the future receives FDA or other regulatory approval, we expect to continue our reliance on one or more third-party contractors to manufacture our products. If, for any reason, we are unable to rely on any third-party sources we have identified to manufacture our product candidates, we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substances and drug products for nonclinical, clinical and commercial purposes. We may be unsuccessful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity, the development and sales of our products and our financial performance may be materially and adversely affected.

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

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

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

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

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

***The Fast Track Designation for VBR may not result in faster development, regulatory review or approval.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

### **Risks Related to Our Regulatory and Legal Environment**

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

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

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

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

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

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

The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might: delay commercialization of, and our ability to derive product revenues from,



our product candidates; impose costly procedures on us; and diminish any competitive advantages that we might otherwise enjoy.

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

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

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

Regulators globally are imposing greater monetary fines for privacy violations. The GDPR applies to any company established in the EU as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products or even prevent us from offering certain products in jurisdictions that we may operate in.

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

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

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

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

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

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

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

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

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

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

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

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

It is not always possible to identify and deter misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations.

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

## **Risks Related to Our Intellectual Property**

### ***Our business depends on protecting our intellectual property.***

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

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

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

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

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

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

Beyond the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our

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

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

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

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

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

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

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

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

We have made, and will continue to make, certain strategic decisions in balancing the costs and the potential protections afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and may infringe our patents in territories which

provide inadequate enforcement mechanisms. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Such competition could materially and adversely affect our business and financial condition.

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

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

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

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

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

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

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

#### **Risks Related to Our Common Stock**

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

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

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

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

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

None.

#### **Item 3. Defaults upon Senior Securities**

None.

#### **Item 4. Mine Safety Disclosures**

Not applicable.

#### **Item 5. Other Information**

None.

**Item 6. Exhibits**

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

<u>Exhibit Number</u>	<u>Description of Document</u>	<u>Filed Herewith</u>	<u>Incorporated by Reference from</u>	<u>Date</u>	<u>Number</u>
10.1#	<a href="#">Assembly Biosciences, Inc. 2022 Corporate Bonus Plan.</a>		Form 8-K	02/04/2022	10.1
31.1	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X			
31.2	<a href="#">Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X			
32.1*	<a href="#">Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X			
32.2*	<a href="#">Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	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 or the Exchange Act, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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

**Assembly Biosciences, Inc.**

Date: May 12, 2022

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

Date: May 12, 2022

By: /s/ Michael P. Samar  
Michael P. Samar  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)



## CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2022

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

## CERTIFICATION

I, Michael P. Samar, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2022

By: /s/ Michael P. Samar  
Michael P. Samar  
Chief Financial Officer  
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2022 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 and President, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

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

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

Date: May 12, 2022

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Michael P. Samar, 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/ Michael P. Samar

---

Michael P. Samar  
Chief Financial Officer  
(Principal Financial Officer)

Date: May 12, 2022