

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2020

**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 001-37566

**SYNLOGIC, INC.**

(Exact name of Registrant as specified in its Charter)

**Delaware**  
State or other jurisdiction of  
incorporation or organization)

**301 Binney St., Suite 402**  
**Cambridge, MA**  
(Address of principal executive offices)

**(617) 401-9975**

(Registrant's telephone number, including area code)

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

**26-1824804**  
(I.R.S. Employer  
Identification No.)

**02142**  
(Zip Code)

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, par value \$0.001 per share	SYBX	The Nasdaq Capital 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 checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of May 1, 2020, there were 32,838,515 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained herein are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the success of our research and development efforts;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the time and costs involved in obtaining regulatory approvals for our product candidates;
- the success of our collaborations with third parties;
- the progress, timing and costs involved in developing manufacturing processes and in manufacturing products, as well as agreements with third-party manufacturers;
- the rate of progress and cost of our commercialization activities;
- the expenses we incur in marketing and selling our product candidates;
- the revenue generated by sales of our product candidates;
- the emergence of competing or complementary technological developments;
- the terms and timing of any additional collaborative, licensing or other arrangements that we may establish;
- the acquisition of businesses, products and technologies;
- our need to implement additional infrastructure and internal systems;
- our need to add personnel and financial and management information systems to support our product development and potential future commercialization efforts, and to enable us to operate as a public company;
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 on our clinical trials, business operations and funding requirements; and
- other risks and uncertainties, including those listed under Part II, Item 1A. “Risk Factors”.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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**SYNOLOGIC, INC. AND SUBSIDIARIES**

Unaudited Consolidated Balance Sheets

(In thousands, except share amounts)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 19,453	\$ 26,184
Short-term marketable securities	94,796	93,387
Prepaid expenses and other current assets	<u>13,166</u>	<u>13,675</u>
Total current assets	127,415	133,246
Long-term marketable securities	—	7,502
Property and equipment, net	12,661	13,021
Right of use asset - operating lease	16,843	17,263
Restricted cash	1,097	1,097
Prepaid research and development, net of current portion	13,055	16,381
Other assets	64	64
Total assets	<u>\$ 171,135</u>	<u>\$ 188,574</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,696	\$ 2,165
Accrued expenses	2,327	3,946
Deferred revenue	445	544
Lease liability - operating lease	2,210	2,000
Finance lease obligations	141	208
Total current liabilities	<u>6,819</u>	<u>8,863</u>
Long-term liabilities:		
Lease liability - operating lease, net of current portion	22,198	22,804
Finance lease obligations, net of current portion	1	2
Total long-term liabilities	<u>22,199</u>	<u>22,806</u>
Commitments and contingencies (Note 11)		
Stockholders' Equity		
Common stock, \$0.001 par value		
250,000,000 shares authorized as of March 31, 2020 and December 31, 2019.		
32,459,394 and 32,266,814 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively.	33	33
Additional paid-in capital	328,995	327,900
Accumulated other comprehensive loss	55	110
Accumulated deficit	<u>(186,966)</u>	<u>(171,138)</u>
Total stockholders' equity	142,117	156,905
Total liabilities and stockholders' equity	<u>\$ 171,135</u>	<u>\$ 188,574</u>

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**SYNOLOGIC, INC. AND SUBSIDIARIES**

Unaudited Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	<b>For the Three Months Ended</b>	
	<b>March 31, 2020</b>	<b>March 31, 2019</b>
Revenue	\$ 100	\$ 338
Operating expenses:		
Research and development	12,677	10,384
General and administrative	3,821	3,651
Total operating expenses	<u>16,498</u>	<u>14,035</u>
Loss from operations	(16,398)	(13,697)
Other income (expense):		
Interest and investment income	574	757
Interest expense	(3)	(7)
Other income (expense)	(1)	1
Other income (expense), net	<u>570</u>	<u>751</u>
Net loss	<u>\$ (15,828)</u>	<u>\$ (12,946)</u>
Net loss per share - basic and diluted	\$ (0.46)	\$ (0.51)
Weighted-average common stock outstanding - basic and diluted	34,233,688	25,293,791
Comprehensive loss:		
Net loss	\$ (15,828)	\$ (12,946)
Net unrealized gain (loss) on marketable securities	(55)	104
Comprehensive loss	<u>\$ (15,883)</u>	<u>\$ (12,842)</u>

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**SYNOLOGIC, INC. AND SUBSIDIARIES**

Unaudited Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)

	Common stock \$0.001 par value		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total equity
	Shares	Amount				
	<b>For the Three Months Ended March 31, 2020</b>					
Balance at December 31, 2019	32,266,814	\$ 33	\$ 327,900	\$ 110	\$ (171,138)	\$ 156,905
Issuance of restricted stock	226,335	—	—	—	—	—
Cancellation of restricted stock	(33,755)	—	—	—	—	—
Equity-based compensation expense	—	—	1,095	—	—	1,095
Unrealized gain (loss) on securities	—	—	—	(55)	—	(55)
Net loss	—	—	—	—	(15,828)	(15,828)
Balance at March 31, 2020	<u>32,459,394</u>	<u>\$ 33</u>	<u>\$ 328,995</u>	<u>\$ 55</u>	<u>\$ (186,966)</u>	<u>\$ 142,117</u>
	<b>For the Three Months Ended March 31, 2019</b>					
Balance at December 31, 2018	25,401,479	\$ 25	\$ 243,903	\$ (65)	\$ (119,765)	\$ 124,098
Cancellation of restricted stock	(12,836)	—	—	—	—	—
Equity-based compensation expense	—	—	954	—	—	954
Unrealized gain (loss) on securities	—	—	—	104	—	104
Net loss	—	—	—	—	(12,946)	(12,946)
Balance at March 31, 2019	<u>25,388,643</u>	<u>\$ 25</u>	<u>\$ 244,857</u>	<u>\$ 39</u>	<u>\$ (132,711)</u>	<u>\$ 112,210</u>

The accompanying notes are an integral part of the unaudited consolidated financial statements.

**SYNOLOGIC, INC. AND SUBSIDIARIES**

Unaudited Consolidated Statements of Cash Flows

(In thousands)

	<u>Three Months Ended</u> <u>March 31, 2020</u>	<u>Three Months Ended</u> <u>March 31, 2019</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (15,828)	\$ (12,946)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	667	683
Equity-based compensation expense	1,095	954
Accretion/amortization of investment securities	(45)	(446)
Reduction in carrying amount of operating lease right-of-use asset	420	221
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	—	(2,500)
Prepaid expenses and other current assets	509	152
Prepaid research and development, net of current portion	3,327	—
Accounts payable and accrued expenses	(2,129)	(1,084)
Deferred revenue	(100)	2,161
Operating lease liabilities	(395)	(313)
<b>Net cash used in operating activities</b>	<u>(12,479)</u>	<u>(13,118)</u>
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(14,269)	(39,346)
Proceeds from maturity of marketable securities	18,852	57,282
Proceeds from redemption of marketable securities	1,500	—
Purchases of property and equipment	(266)	(261)
<b>Net cash provided by investing activities</b>	<u>5,817</u>	<u>17,675</u>
<b>Cash flows from financing activities:</b>		
Payments on finance lease obligations	(69)	(65)
<b>Net cash used in financing activities</b>	<u>(69)</u>	<u>(65)</u>
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<u>(6,731)</u>	<u>4,492</u>
Cash, cash equivalents and restricted cash at beginning of period	27,281	12,349
<b>Cash, cash equivalents and restricted cash at end of period</b>	<u>\$ 20,550</u>	<u>\$ 16,841</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Property and equipment purchases included in accounts payable and accrued expenses	\$ 41	\$ (71)
Cash paid for interest	\$ 3	\$ 7

The accompanying notes are an integral part of the unaudited consolidated financial statements.

## Notes to Unaudited Consolidated Financial Statements

**(1) Nature of Business****Organization**

Synlogic, Inc., together with its wholly owned and consolidated subsidiaries (“Synlogic” or the “Company”), is a clinical-stage biopharmaceutical company focused on advancing its drug discovery and development platform for Synthetic Biotic™ medicines. Synthetic Biotic medicines are generated from Synlogic’s proprietary drug discovery and development platform applying the principles and tools of synthetic biology to engineer beneficial microbes to perform or deliver critical therapeutic functions to treat metabolic and inflammatory diseases and cancer. As living medicines, Synthetic Biotic medicines can be designed to sense a local disease context within a patient’s body and to respond by metabolizing a toxic substance, compensating for missing or damaged metabolic pathways in patients, or by delivering combinations of therapeutic factors. Synlogic’s goal is to lead in the discovery and development of Synthetic Biotic therapies as living medicines capable of robust and precise pathway complementation and delivery of therapeutic benefit. Since incorporation, the Company has devoted substantially all of its efforts to the research and development of its product candidates.

Synlogic, Inc. (“Private Synlogic” when referred to prior to the Merger (as defined below)) was founded and began operations on March 14, 2014, as TMC Therapeutics, Inc., located in Cambridge, Massachusetts. On July 15, 2014, TMC Therapeutics, Inc. changed its name to Synlogic, Inc. On July 2, 2015, the common and preferred stockholders of Private Synlogic executed the Synlogic, LLC Contribution Agreement (the “Contribution Agreement”), pursuant to which such common and preferred stockholders contributed such stockholders’ equity interests in Private Synlogic in exchange for common and preferred units in a newly formed parent company named Synlogic, LLC. In addition, Synlogic IBDCo, Inc. (“IBDCo”) was formed as a subsidiary of Synlogic, LLC (the “2015 Reorganization”). In conjunction with the 2015 Reorganization, Private Synlogic entered into a license, option and merger agreement with AbbVie S.à.r.l. (“AbbVie”), for the development of treatments for inflammatory bowel disease (“IBD”).

In May 2017, Private Synlogic completed a reorganization (“2017 Reorganization”) pursuant to which Synlogic, LLC merged with and into Private Synlogic, with Private Synlogic continuing as the surviving corporation. Pursuant to the 2017 Reorganization, the common units and preferred units of Synlogic, LLC, together consisting of Class A preferred units, contingently redeemable Class A preferred units and Class B preferred units, were exchanged for common stock and preferred stock of Private Synlogic, respectively. Additionally, Private Synlogic issued equity awards under the Synlogic 2017 Stock Incentive Plan (“2017 Plan”) to replace the canceled incentive units pursuant to the termination of the Synlogic, LLC 2015 Equity Incentive Plan (“2015 LLC Plan”).

On August 28, 2017, Synlogic, Inc., formerly known as Mirna Therapeutics, Inc. (NASDAQ: MIRM) (“Mirna”), completed its business combination with Private Synlogic pursuant to the Agreement and Plan of Merger and Reorganization, dated as of May 15, 2017, by and among Mirna, Meerkat Merger Sub, Inc. (“Merger Sub”), and Private Synlogic (the “Merger Agreement”), pursuant to which Merger Sub merged with and into Private Synlogic, with Private Synlogic surviving as a wholly owned subsidiary of Mirna (the “Merger”). Immediately after completion of the Merger, Mirna changed its name to “Synlogic, Inc.” (NASDAQ: SYBX).

**Risks and Uncertainties**

At March 31, 2020, the Company had approximately \$114.2 million in cash, cash equivalents, and short-term marketable securities, \$1.1 million of restricted cash and an accumulated deficit of approximately \$187.0 million. Since its inception through March 31, 2020, the Company has primarily financed its operations through the issuance of preferred stock, units and warrants, the sale of its common stock, the AbbVie collaboration, and cash received in the Merger. In the absence of positive cash flows from operations, the Company is highly dependent on its ability to find additional sources of funding in the form of debt or equity financing. Management believes that the Company has sufficient cash to fund its operations through at least twelve months from the issuance of these financial statements.



**Notes to Unaudited Consolidated Financial Statements (continued)**

As an early-stage company, the Company is subject to a number of risks common to other life science companies, including, but not limited to, raising additional capital, development by its competitors of new technological innovations, risk of failure in preclinical and clinical studies, safety and efficacy of its product candidates in clinical trials, the risk of relying on external parties such as contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”), the regulatory approval process, market acceptance of the Company’s products once approved, lack of marketing and sales history, dependence on key personnel and protection of proprietary technology. The Company’s therapeutic programs are currently pre-commercial, spanning discovery through early development and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization of any product candidates. These efforts require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance-reporting capabilities. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company may never achieve profitability, and unless and until it does, it will continue to need to raise additional capital or obtain financing from other sources, such as strategic collaborations or partnerships.

**(2) Summary of Significant Accounting Policies**

The significant accounting policies described in the Company’s audited financial statements as of and for the year ended December 31, 2019, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the Securities and Exchange Commission (“SEC”) on March 12, 2020 (the “2019 Annual Report”), have had no material changes during the three months ended March 31, 2020. The updated accounting policy and the impact of adoption are discussed in the “Recently Adopted Accounting Pronouncements” section in this note.

***Basis of Presentation***

The accompanying consolidated financial statements and the related disclosures as of March 31, 2020 and for the three months ended March 31, 2020 and 2019 are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and the rules and regulations of the SEC for interim financial statements. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These interim consolidated financial statements should be read in conjunction with the Company’s 2019 and 2018 audited consolidated financial statements and notes included in the Company’s 2019 Annual Report. The December 31, 2019 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by GAAP for complete financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair presentation of the Company’s financial position and results of operations for the three months ended March 31, 2020 and 2019. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or any other interim period or future year or period.

***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of Synlogic and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

***Recently Issued Accounting Pronouncements***

In June 2016, the FASB issued ASU 2016-13 - *Measurement of Credit Losses on Financial Statements*. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. In November 2019, the FASB issued ASU 2019-10 – *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which amended the effective date for certain companies. The standard is effective for public companies eligible to be smaller reporting companies for annual and interim periods beginning after December 15, 2022. Early adoption is available. The Company is currently evaluating the potential impact ASU 2016-13, and related updates, will have on its consolidated financial statements and disclosures.

## Notes to Unaudited Consolidated Financial Statements (continued)

**(3) Fair Value of Financial Instruments**

The tables below present information about the Company's assets that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, as described under Note 2, *Summary of Significant Accounting Policies*, in the audited financial statements included in the Company's 2019 Annual Report.

The Company's investment portfolio includes many fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company applied other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare evaluations. In addition, model processes were used to assess interest rate impact and develop prepayment scenarios. These models take into consideration relevant credit information, perceived market movements, sector news and economic events. The inputs into these models may include benchmark yields, reported trades, broker-dealer quotes, issuer spreads and other relevant data.

At March 31, 2020 and December 31, 2019, the Company has classified assets measured at fair value on a recurring basis as follows (in thousands):

Description	Fair Value Measurements at Reporting Date Using			
	March 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 8,177	\$ 8,177	\$ —	\$ —
Commercial paper (included in marketable securities)	16,404	—	16,404	—
Corporate debt securities (included in marketable securities)	70,878	—	70,878	—
U.S. government agency securities and treasuries	7,514	—	7,514	—
<b>Total</b>	<b>\$ 102,973</b>	<b>\$ 8,177</b>	<b>\$ 94,796</b>	<b>\$ —</b>

Description	Fair Value Measurements at Reporting Date Using			
	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 3,240	\$ 3,240	\$ —	\$ —
Commercial paper (included in cash and cash equivalents)	4,249	—	4,249	—
Commercial paper (included in marketable securities)	20,501	—	20,501	—
Corporate debt securities (included in cash and cash equivalents)	6,005	—	6,005	—
Corporate debt securities (included in marketable securities)	71,383	—	71,383	—
U.S. government agency securities and treasuries	9,005	—	9,005	—
<b>Total</b>	<b>\$ 114,383</b>	<b>\$ 3,240</b>	<b>\$ 111,143</b>	<b>\$ —</b>

Cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses at March 31, 2020 and December 31, 2019 are carried at amounts that approximate fair value due to their short-term maturities. Finance lease obligations at March 31, 2020 and December 31, 2019 approximate fair value as they bear interest at a rate approximating a market interest rate.

## Notes to Unaudited Consolidated Financial Statements (continued)

## (4) Available-for-Sale Investments

The following tables summarize the available-for-sale securities held at March 31, 2020 and December 31, 2019 (in thousands):

<u>March 31, 2020</u>	<u>Amortized cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair Value</u>
Commercial paper	\$ 16,356	\$ 48	\$ —	\$ 16,404
Corporate debt securities	70,882	45	(49)	70,878
U.S. government agency securities	7,503	11	—	7,514
Total	<u>\$ 94,741</u>	<u>\$ 104</u>	<u>\$ (49)</u>	<u>\$ 94,796</u>

  

<u>December 31, 2019</u>	<u>Amortized cost</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair Value</u>
Commercial paper	\$ 20,484	\$ 18	\$ (1)	\$ 20,501
Corporate debt securities	71,288	96	(1)	71,383
U.S. government agency securities	9,005	2	(2)	9,005
Total	<u>\$ 100,777</u>	<u>\$ 116</u>	<u>\$ (4)</u>	<u>\$ 100,889</u>

The contractual maturity of all securities held at March 31, 2020 was eleven months or less. There were nine investments in an unrealized loss position at March 31, 2020 and December 31, 2019, none of which had been in an unrealized loss position for more than twelve months. The aggregate fair value of the securities in an unrealized loss position at March 31, 2020 and December 31, 2019 was \$25.7 million and \$24.8 million, respectively. The Company reviews its investments for other-than-temporary impairment whenever the fair value of an investment is less than amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and considers whether evidence indicating the cost of the investment is recoverable outweighs evidence to the contrary. The Company did not hold any securities with an other-than-temporary impairment at March 31, 2020.

Gross realized gains and losses on the sales of investments have not been material to the Company's consolidated statement of operations.

## (5) Property and Equipment, net

Property and equipment, net consists of the following (in thousands):

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
Laboratory equipment	\$ 7,772	\$ 7,523
Computer and office equipment	782	782
Furniture and fixtures	421	421
Leasehold improvements	9,514	9,514
Construction in progress	470	412
	<u>18,959</u>	<u>18,652</u>
Less accumulated depreciation	<u>(6,298)</u>	<u>(5,631)</u>
	<u>\$ 12,661</u>	<u>\$ 13,021</u>

## Notes to Unaudited Consolidated Financial Statements (continued)

**(6) Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	March 31, 2020	December 31, 2019
Payroll related	\$ 1,034	\$ 2,372
Professional fees	489	444
Research and development	649	1,005
Other	155	125
	<u>\$ 2,327</u>	<u>\$ 3,946</u>

**(7) Stockholders' Equity**

In June 2019, the Company issued to Ginkgo Bioworks, Inc. an aggregate of 6,340,771 shares of common stock at a purchase price per share of \$9.00, and pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 2,548,117 shares of common stock at an exercise price of \$9.00 per share, with \$8.99 of such exercise price paid at the closing of the offering. The net proceeds to the Company were approximately \$79.9 million.

The Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full to the extent that, after giving effect to such issuance after exercise, Ginkgo would not beneficially own in excess of 19.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance.

The Pre-Funded Warrants were classified as a component of permanent equity and were recorded at the issuance date using a relative fair value allocation method. The Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of common shares upon exercise. In addition, such warrants do not provide any guarantee of value or return. None of the Pre-Funded Warrants have been exercised as of March 31, 2020.

**(8) Equity-based Compensation and Equity Incentive Plans**

The Company is displaying all equity in its post-Merger amounts.

**Equity Plans**

The Company currently has three active equity plans.

The 2015 Equity Incentive Award Plan (the "2015 Plan") was adopted by Mirna in 2015 and remains active after the Merger, now functioning as the primary equity plan for the Company. The 2015 Plan provides for the granting of a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, deferred stock awards, dividend equivalent awards, stock payment awards, performance awards and other stock-based awards. Pursuant to the evergreen provision of the 2015 Plan, which allows for an annual increase in the number of shares of common stock available for issuance, the Company added 1,613,340 shares to the 2015 Plan on January 1, 2020.

The 2017 Stock Incentive Plan (the "2017 Plan") was adopted by Private Synlogic in 2017 at the time of the 2017 Reorganization and assumed by the Company during the Merger. The 2017 Plan provides for the grant of incentive stock options, non-qualified stock options, restricted and unrestricted stock awards and other stock-based awards.

## Notes to Unaudited Consolidated Financial Statements (continued)

The 2015 Employee Stock Purchase Plan (“ESPP”) was adopted by Mirna in 2015 and allows eligible employees to purchase shares of the Company’s common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP generally provides for set offering periods, and at the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of the Company’s common stock on the first trading day of the offering period or on the last trading day of the offering period. The Company suspended the ESPP in 2017. In December 2019, the Board reactivated the ESPP and approved an amendment to the ESPP to (i) reduce the permitted aggregate yearly payroll deduction and maximum number of shares of the Company’s common stock that a participant may purchase per offering period under the ESPP and (ii) establish a period for enrollment for eligible participants. The reactivation of the ESPP was effective immediately. The Company’s executive officers are eligible to participate in the ESPP. There were no options to purchase shares of common stock under the ESPP exercised as of March 31, 2020.

As of March 31, 2020, there were 1,131,108 shares available for future grant under the 2017 Plan and the 2015 Plan, and 375,519 shares available for future grant under the ESPP.

For a full description of the Company’s equity plans, refer to Note 9, *Equity-based Compensation and Equity Incentive Plans* in the Company’s 2019 Annual Report.

**Stock Options**

The following table summarizes stock option activity during the three months ended March 31, 2020 under the 2015 Plan and the 2017 Plan.

	Stock options outstanding			
	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate Intrinsic value (a) (in thousands)
Outstanding at December 31, 2019	2,286,419	\$ 9.24	8.7	\$ 43
Granted	1,052,113	1.77		—
Forfeited	(86,073)	9.30		1
Outstanding at March 31, 2020	<u>3,252,459</u>	6.82	8.9	<u>\$ 18</u>
Vested or expected to vest at March 31, 2020	<u>3,252,459</u>	6.82	8.9	<u>18</u>
Exercisable at March 31, 2020	<u>919,285</u>	11.26	8.0	<u>\$ —</u>

(a) The aggregate intrinsic value is calculated as the difference between the exercise price of the options and the fair market value of the underlying common stock for the options that were in the money at March 31, 2020 and December 31, 2019.

As of March 31, 2020, there was \$6.9 million of unrecognized share-based compensation related to unvested stock option grants which is expected to be recognized over a weighted average period of 2.4 years. The total unrecognized share-based compensation cost will be adjusted for actual forfeitures as they occur.

## Notes to Unaudited Consolidated Financial Statements (continued)

**Restricted Common Stock**

The following table shows restricted stock activity during the three months ended March 31, 2020:

	Restricted stock awards	
	Number of shares	Grant date fair value (per share)
Unvested at December 31, 2019	586,929	\$ 2.97
Granted	226,335	1.70
Vested	(9,318)	13.53
Forfeited	(33,755)	2.45
Unvested at March 31, 2020	770,191	\$ 2.49

As of March 31, 2020, there was approximately \$1.3 million of unrecognized share-based compensation related to restricted stock awards granted, which is expected to be recognized over a weighted average period of 1.9 years. The total unrecognized share-based compensation cost will be adjusted for actual forfeitures as they occur.

**Equity Compensation**

The Company has recorded total equity-based compensation expense of approximately \$1.1 million during the three months ended March 31, 2020 and \$1.0 million and during the three months ended March 31, 2019.

The following table summarizes equity-based compensation expense within the Company's consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	\$ 441	\$ 284
General and administrative	654	670
	\$ 1,095	\$ 954

The following table summarizes equity-based compensation expense by type of award for the three months ended March 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31,	
	2020	2019
Stock options	\$ 875	\$ 926
Restricted stock awards	220	28
	\$ 1,095	\$ 954

**(9) Collaboration Agreements****Ginkgo Collaboration**

In 2017, the Company established a technology collaboration with Ginkgo Bioworks, Inc. (Ginkgo). In June 2019, in connection with the issuance to Ginkgo of an aggregate of 6,340,771 shares of common stock and Pre-Funded warrants to purchase an aggregate of 2,548,117 common stock (See Note 7), the Company expanded its collaboration and entered into an agreement with Ginkgo for the research and development of engineered microbial therapeutic products. Under the 2019 expanded agreement, the Company made a prepayment to Ginkgo of \$30.0 million for its foundry services that will be provided to the Company over an initial term of five years. The prepayment of foundry services is recorded in Prepaid expenses and other current assets and Prepaid research and development, net of current portion on the March 31, 2020 consolidated balance sheet. At March 31, 2020, the Company had remaining balances of \$11.3 million and \$12.4 million of current and non-current pre-paid research and development costs related to this transaction, respectively. Upon the expiration of such initial term and, if applicable, an additional period, any portion of the prepayment that has not been used to purchase services from Ginkgo will be retained by Ginkgo.

## Notes to Unaudited Consolidated Financial Statements (continued)

**AbbVie Collaboration Agreement**

In July 2015, the Company entered into the AbbVie Agreement under which the Company granted AbbVie an exclusive option to purchase IBDCo and, in exchange, agreed to collaborate in researching and developing an Investigational New Drug (“IND”) candidate for the treatment of IBD. The AbbVie Agreement sets forth the Company’s and AbbVie’s respective obligations for development and delivery of an IND candidate package using reasonable commercial efforts.

In exchange for the exclusive option to acquire IBDCo, initial research and development services for drug discovery and pre-clinical development, and participation on the joint research committee (“JRC”), AbbVie agreed to pay IBDCo an upfront, non-refundable cash payment of \$2.0 million, which IBDCo received in December 2015. AbbVie also agreed to pay IBDCo up to \$16.5 million in milestone payments associated with specified research and pre-clinical events, which were determined to represent customer options for accounting purposes, as well as an option exercise fee upon the execution of their option to buy IBDCo and other royalty and milestone payments. The upfront cash payment and any payments for option fees and royalties are non-refundable, non-creditable and not subject to set-off.

The research and development is performed by the Company over four phases of research defined in the research plan. The Company is eligible to receive payments from AbbVie upon the election to continue the research and development at the achievement of certain milestone events. The JRC will make a determination as to the continuation of the collaboration at the achievement of research and pre-clinical milestones, except for the final milestone, which AbbVie has the discretion to determine achievement without the approval of the JRC. If the parties make the determination to continue on with the AbbVie Agreement upon achievement of each milestone event, then AbbVie will pay the consideration associated with that milestone and the collaboration will continue through the remaining term of the option to purchase IBDCo, which was initially considered to be approximately 54 months. However, AbbVie has the right to terminate the contract at any time with 90 days’ notice.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, AbbVie, is a customer. The Company identified the following material promises at the outset of the arrangement: (1) a non-exclusive royalty-free research and development license; (2) research and development services for pre-clinical activities under the research plan through to the first research and development phase (or an estimated 17 months); (3) three option rights for AbbVie to continue the collaboration as related to three phases of research and development; (4) participation on the JRC; and (5) the transfer of ownership of IBDCo upon exercise of the option to buy IBDCo. The Company determined that the license and research and development activities were not distinct from one another. Participation on the JRC to oversee the research and development activities was determined to be quantitatively and qualitatively immaterial and therefore is excluded from performance obligations. As such, the Company determined that the license and research and development services should be combined into a single performance obligation.

The Company evaluated the milestone payments, which represent customer options as described above, and the option to purchase IBDCo, to determine whether they provide AbbVie with any material rights. The Company concluded that the options were not issued at a significant and incremental discount, and therefore do not provide material rights. As such, they were excluded as performance obligations at the outset of the arrangement. If AbbVie elects to exercise the options, the additional consideration will be added to the transaction price and allocated to the resulting performance obligations.

Based on these assessments, the Company identified one performance obligation at the outset of the AbbVie Agreement, which consists of: (1) the non-exclusive license and (2) the research and development activities through the first research and development phase.

At the outset of the arrangement, the transaction price included only the \$2.0 million up-front consideration received which was allocated to the single performance obligation. The option exercise fees (\$16.5 million for the milestones and the IBDCo purchase option exercise fee) that may be received are excluded from the transaction price until each customer option is exercised. The Company reevaluates the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

In May 2017, the Company completed the research and development services for the first phase of the research plan and was paid \$2.0 million to commence the second phase of the research plan. At this time, the \$2.0 million was added to the transaction price and allocated to a new performance obligation consisting of the underlying license and research and development services to be performed over the second phase of the research plan.

## Notes to Unaudited Consolidated Financial Statements (continued)

On September 27, 2018, AbbVie and the Company signed an amendment (the “Second Amendment”) to the AbbVie Agreement. The Second Amendment clarified the requirements necessary to complete the second phase which resulted in additional time and effort in the second phase of the research plan. Additionally, the Second Amendment split the next milestone payment under the AbbVie Agreement into two payments: a milestone payment of \$2.0 million earned by the Company upon execution of the Second Amendment and the remaining milestone payment of the balance due upon the successful achievement of specified research and pre-clinical events and the advancement to the third phase of the research plan.

On December 18, 2018, AbbVie and the Company signed an amendment (the “Third Amendment”) to the AbbVie Agreement. The Third Amendment provides that in the event AbbVie determines that it is necessary to enter into license agreements with certain third parties in a particular country or other jurisdiction which, but for such license, would be infringed by the manufacture, use or sale of any product governed by the AbbVie Agreement, AbbVie would be entitled to deduct certain expenses related to such license agreements from particular payments made to the Company.

The Company determined that the Amendment represented a modification to the AbbVie Agreement. The additional research and development services are not distinct from the remaining research and development services under the second phase of the research plan of the AbbVie Agreement. The Amendment was accounted for as part of the original AbbVie Agreement and the services form part of the single performance obligation that was partially satisfied as of the date of the contract modification. As a result, the transaction price for the current performance obligation associated with the second phase of the research plan increased by \$2.0 million. The impact of the contract modification on the transaction price and the measure of progress toward completion of the performance obligation was recognized as an adjustment to revenue upon execution of the Amendment on a cumulative catch-up basis. The cumulative catch-up adjustment to revenue, as a result of the contract modification, was \$1.8 million during 2018.

On February 28, 2019, the JRC concluded that the remaining milestone of \$2.5 million under the Second Amendment was achieved upon the achievement of specified research and pre-clinical events under the second phase of the research plan and the advancement to the third phase of the research plan. Revenue associated with performance obligations under the AbbVie Agreement is recognized as the research and development services are provided using an input method, according to the full-time equivalents incurred. The transfer of control occurs over time and, in management’s judgment, is the best measure of progress towards satisfying the performance obligation. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company’s consolidated balance sheet.

Revenue associated with performance obligations under the AbbVie Agreement are recognized as the research and development services are provided using an input method, according to the full-time equivalents incurred. The research and development activities are expected to be performed over a period of approximately 54 months. The transfer of control occurs over time and, in management’s judgment, is the best measure of progress towards satisfying the performance obligation. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue on the Company’s consolidated balance sheet.

For the three months ended March 31, 2020 and 2019, the Company recognized revenue of \$0.1 million and \$0.3 million, respectively, as collaboration revenue in the Company’s consolidated statements of operations and comprehensive loss. Deferred revenue amounted to \$0.4 million as of March 31, 2020, all of which is included in current liabilities.

**(10) Net Loss per Share**

Basic net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the sum of the weighted-average number of shares of common stock outstanding during the period and if dilutive, the weighted-average number of potential shares of common stock, including unvested restricted common stock and outstanding stock options. In June 2019, the Company sold 6,340,771 shares of common stock and Pre-Funded Warrants to purchase an aggregate of 2,548,117 shares of common stock at an exercise price of \$9.00 per share, with \$8.99 of such exercise price paid at the closing of the offering (see Note 10, *Ginkgo Collaboration*, in the audited financial statements included in the Company’s 2019 Annual Report). The shares of common stock into which the warrants may be exercised are considered outstanding for the purposes of computing net loss per share.

The Company’s potentially dilutive shares, which include outstanding stock options and unvested restricted common stock/units, are considered to be common share equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.



## Notes to Unaudited Consolidated Financial Statements (continued)

The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of the diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an anti-dilutive effect.

	As of March 31,	
	2020	2019
Unvested restricted common stock awards	770,191	87,719
Outstanding options to purchase common stock	3,252,459	2,747,043

**(11) Commitments and Contingencies**

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred. The Company is not currently a party to any material legal proceedings.

The Company's commitments described in the Company's consolidated financial statements as of and for the year ended December 31, 2019 and the notes thereto included in the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2020, have had no material changes during the three months ended March 31, 2020.

**(12) Related-Party Transactions**

In June 2019, the Company expanded its collaboration and entered into an agreement with Ginkgo for the research and development of engineered microbial therapeutic products. As of March 31, 2020, Ginkgo owns 6,340,771 shares of the Company's outstanding common stock. See Note 10, *Ginkgo Collaboration*, in the audited financial statements included in the Company's 2019 Annual Report.

Under the agreement the Company made a prepayment to Ginkgo of \$30.0 million for its foundry services that will be provided to the Company over an initial term of five years. At March 31, 2020, the Company had remaining balances of \$11.3 million and \$12.4 million of current and non-current pre-paid research and development costs related to this transaction, respectively. For the three months ended March 31, 2020, the Company used \$3.6 million of the pre-paid research and development expenses.

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

### Forward-Looking Information

*The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for the year ended December 31, 2019 and 2018 included in our Annual Report on Form 10-K filed with the SEC on March 12, 2020 (the "2019 Annual Report"). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Please see "Risk Factors" beginning on page [15] of this Quarterly Report on Form 10-Q for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. The term "Private Synlogic" refers to Synlogic Operating Company, Inc. (formerly known as Synlogic, Inc.) prior to the consummation of the Merger. Unless otherwise indicated, references to the terms the "combined company", "Synlogic", the "Company", "we", "our" and "us" refer to Private Synlogic prior to the consummation of the Merger and Synlogic, Inc. (formerly known as Mirna Therapeutics, Inc.) and its subsidiaries upon the consummation of the Merger described herein. The term "Mirna" refers to the Mirna Therapeutics, Inc. and its subsidiaries prior to the Merger.*

### Overview

#### Business

We are a clinical-stage biopharmaceutical company focused on advancing our proprietary drug discovery and development platform to create Synthetic Biotic™ medicines. Our Synthetic Biotic medicines apply the principles and tools of synthetic biology to engineer beneficial therapeutic characteristics into microbes, transforming them into efficient and targeted biologic engines. We believe that many patients with serious diseases are underserved today based on the limitations of conventional therapeutic approaches, such as small or large molecules. Synthetic Biotic medicines have the potential to address unmet medical need by performing therapeutic mechanisms not achievable by other drug modalities. Synthetic Biotic medicines are designed to be programmed to metabolize, or consume, a toxic substance, compensate for damaged metabolic pathways in patients, or produce one or more therapeutic factors. Our platform has generated a portfolio of Synthetic Biotic medicines designed to impact both genetic and acquired metabolic diseases, as well as oncology and inflammatory disorders. In a clinical trial with our lead program SYN1618, we have demonstrated consumption of a phenylalanine (Phe), an amino acid that accumulates in a rare metabolic disorder known as phenylketonuria (PKU), and are expanding our pipeline based on learnings from this program.

We believe we have the core competencies in synthetic biology and manufacturing, as well as translational medicine, regulatory experience and clinical development to successfully discover and develop our Synthetic Biotic medicines. In June 2019, we announced an expanded collaboration with Ginkgo Bioworks, Inc. (Ginkgo) to complement our in-house expertise in strain design and development. Ginkgo uses software and automation to program and optimize microbial strains at a large scale. Ginkgo's technology provides us with a synthetic biology-based cell programming platform for testing thousands of microbial strains to accelerate progression of early preclinical leads to drug candidates optimized for clinical development.

While we believe that our Synthetic Biotic platform has potential to address a broad range of diseases, our initial internal pipeline focus is on rare metabolic diseases. We will consider leveraging partnerships to advance programs for other diseases including oncology and inflammatory disorders. Our most advanced programs target rare metabolic diseases that could potentially be treated by oral delivery of Synthetic Biotic medicines. These include conditions caused by a genetic mutation characterized by a dysfunctional metabolic pathway including PKU and maple syrup urine disease (MSUD), as well as acquired metabolic diseases caused by organ dysfunction, such as enteric hyperoxaluria. When delivered orally, Synthetic Biotic medicines are designed to function in the gut to consume a disease-causing toxic metabolite with the intended consequence of reducing its systemic levels. We believe that success in our metabolic disease programs will enable us to demonstrate the potential of our Synthetic Biotic medicines while bringing meaningful change to the lives of patients suffering from these debilitating conditions.

Our most advanced product candidate for the treatment of metabolic dysfunction is SYN1618, an oral therapy intended for the treatment of PKU, a rare metabolic disease in which Phe accumulates in the body as a result of genetic defects. Elevated levels of Phe are toxic to the brain and can lead to neurological dysfunction. SYN1618 is designed to function in the gut of patients to reduce excess Phe, with the goal of lowering levels in the blood and other tissues. SYN1618 has received both Fast Track designation and orphan drug designation for PKU from the U.S. Food and Drug Administration (FDA). We initiated a Phase 1/2a clinical trial of an early liquid formulation of SYN1618 in April 2018 and announced top-line data from healthy volunteers evaluated in this study in September 2018. In July 2019, we announced data that demonstrated that SYN1618 was safe and well-tolerated and achieved proof-of-mechanism of strain activity in both healthy volunteers and patients with PKU. We have also evaluated a new lyophilized formulation of SYN1618 in a bridging study in healthy volunteers. The study of this more patient- and commercialization-

appropriate presentation of SYN1618 demonstrated improved tolerability over the early liquid formulation. The next step for SYN1618 is to conduct a Phase 2 clinical trial. This trial is designed to evaluate safety and tolerability of a solid formulation of SYN1618 as well as its potential to lower blood Phe levels in PKU patients. Synlogic is evaluating clinical program progress as a result of the ongoing COVID-19 pandemic. While Synlogic intends to continue to work with sites to complete preparatory work, in light of the COVID-19 pandemic, it does not expect to be able to enroll subjects into its Phase 2 clinical trial of SYN1618 until it is safe for patients to enter clinical trial sites. Synlogic now expects to initiate a Phase 2 clinical trial of SYN1618 in the second half of 2020.

The strain design and engineering, translational research, clinical and regulatory planning and scalable manufacturing of our PKU program has informed development of future clinical candidates. We are also developing pre-clinical product candidates to address other metabolic conditions including enteric hyperoxaluria and MSUD. Enteric hyperoxaluria is a form of secondary hyperoxaluria caused by increased absorption of oxalate as a result of certain intestinal diseases, including Crohn's disease and short bowel syndrome or as a result of surgical procedures such as bariatric weight-loss surgery. The disorder can lead to a range of conditions of increasing severity from urinary tract infections to recurrent kidney stones and renal failure. MSUD is an inherited, rare metabolic disease characterized by a deficiency of enzymes required to break down certain amino acids. The most common and severe form of the disease is the classic type, which becomes apparent soon after birth and, if left untreated, can lead to seizures, coma, and death. Variant forms of the disorder become apparent later in infancy or childhood and are typically milder, but also lead to delayed development and other health problems if not treated. In our enteric hyperoxaluria program, we expect to move a clinical candidate into IND-enabling studies in 2020.

In August 2019, we announced that we were discontinuing the development of SYN1020, an early stage clinical product candidate for the treatment of hyperammonemia. The decision to discontinue the program was based on top-line data from an interim analysis of a randomized, double-blind, placebo-controlled Phase 1b/2a study of the Synthetic Biotic medicine in 23 patients with cirrhosis and elevated blood ammonia. While SYN1020 was well tolerated in Phase 1b/2a study, the study showed it did not lower blood ammonia in patients with cirrhosis.

We have also developed a portfolio of Synthetic Biotic medicines to treat certain cancers which are designed to modify the tumor microenvironment, activate the immune system and result in tumor reduction. We envision that multiple engineered functions could be combined in one Synthetic Biotic medicine. These Synthetic Biotic medicines could also be used in combination with other cancer therapies such as check-point inhibitors. Our first Synthetic Biotic clinical immuno-oncology (IO) candidate is SYN1891, an intratumorally administered Synthetic Biotic medicine engineered to act as a dual innate and adaptive immune activator. SYN1891 has been designed to activate the immune response in tumors via the E.coli Nissle chassis and production of cyclic di-AMP, an activator of the Stimulator of Interferon Genes, also referred to as the STING pathway. In January 2020, we announced that we had treated the first subject in a Phase 1 clinical trial of SYN1891 in patients with advanced solid tumors and lymphoma. The clinical trial is designed to identify a maximum tolerated dose (MTD) of SYN1891 delivered as a monotherapy. Once an MTD is identified, we will evaluate treatment of patients with a combination of SYN1891 and the checkpoint inhibitor atezolizumab (Tecentriq), provided through a supply agreement with Roche. While we anticipate the Phase 1 clinical trial will remain open and currently enrolled patients will continue on trial, in light of the COVID-19 pandemic, we expect enrollment of new patients to slow which may impact the availability of data in 2020.

We are also leveraging our proprietary technology platform to develop Synthetic Biotic medicines to treat a broader range of human diseases. To achieve this goal, we collaborate with key disease experts who have developed robust models of relevant diseases and to inform our translational medicine strategy. These collaborators bring complementary expertise in preclinical development, clinical development and commercialization. Inflammatory bowel disease (IBD) is an attractive target for our technology as Synthetic Biotic medicines can be designed to locally deliver combinations of complementary therapeutics to potentially address the unmet medical need for maintenance of disease remissions. We have a collaboration with AbbVie S.à.r.l. (AbbVie) to develop Synthetic Biotic medicines for the treatment of types of IBD, including Crohn's disease and ulcerative colitis. We may enter into additional strategic partnerships in the future to maximize the value of our programs and our Synthetic Biotic platform.

In December 2019 an outbreak of a novel strain of coronavirus was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, we are not experiencing significant impact or delays from COVID-19 on our business, operations, except as described herein.

We currently operate in one reportable business segment—the discovery and development of Synthetic Biotic medicines. To date, we have dedicated substantially all of our activities to the research and development of our product candidates. As of March 31, 2020, we have received approximately \$322.8 million in proceeds as we financed our operations through various debt and equity financing arrangements and collaboration agreements, including \$8.5 million in payments received under the AbbVie Agreement, and \$79.9 million in total net proceeds from the sale of our common stock and pre-funded warrants to purchase shares of common stock (the “Pre-Funded Warrants”) in June 2019.

We have not generated any revenue to date from product sales and have incurred significant operating losses since our inception. We have incurred net losses of approximately \$15.8 million and \$12.9 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of approximately \$187.0 million, and we expect to incur losses for the foreseeable future as we develop our product candidates. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

- complete preclinical studies, initiate and complete clinical trials for product candidates;
- contract to manufacture product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, and management personnel;
- expand our existing infrastructure and secure space in a facility to support continued growth in our research and development efforts; and
- add operational and finance personnel to support product development efforts and to support operating as a public company.

We do not expect to generate product revenue unless and until we successfully complete clinical development and obtain regulatory approvals for our product candidates, either alone or in collaboration with third parties. Additionally, we expect to utilize third-party contract research organizations (CROs) and contract manufacturing organizations (CMOs) to carry out our clinical development and manufacturing activities, and we do not yet have a commercial organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Accordingly, we anticipate that we will seek to fund our operations through public or private equity or debt financings, collaborations or licenses, finance lease transactions or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if it will be able to achieve or maintain profitability. Even if we are able to generate product revenue, we may not become profitable.

## **Financial Overview**

### ***Revenue***

Revenue to date is generated from our collaboration agreement with AbbVie. The collaboration agreement contains multiple deliverables, which include an exclusive option for AbbVie to acquire IBDCo and research and development milestones. See Note 10, *Collaboration Agreements: AbbVie Collaboration* in the notes to the unaudited consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a full discussion of the arrangement. We expect our revenue to fluctuate for the foreseeable future as it is principally based on the achievement of research and development milestones under our collaboration agreement with AbbVie.

### ***Research and Development Expense***

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates, including the conduct of preclinical and clinical studies and product development, which are expensed as they are incurred. These expenses consist primarily of:

- compensation, benefits and other employee related expenses;
- supplies to support our internal research and development efforts;

- research and development related facility and depreciation costs; and
- third-party contract costs relating to research, process and formulation development, preclinical and clinical studies and regulatory operations.

The lengthy process of securing regulatory approvals for new drugs requires the expenditure of substantial resources. Any delay or failure to obtain regulatory approvals would materially adversely affect our product candidate development efforts and our business overall. Given the inherent uncertainties of pharmaceutical product development, we cannot estimate with any degree of certainty the likelihood, timing or cost of obtaining regulatory approval and marketing our product candidates and thus, when, if ever, our product candidates will generate revenues and cash flows.

The successful development of our product candidates is highly uncertain and subject to a number of risks. Refer to the risk factors under the heading *Risks Related to the Development of Our Product Candidates* in Part II, Item 1A, found elsewhere in this Quarterly Report on Form 10-Q.

We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as the competitive landscape and ongoing assessments of such product candidate's commercial potential. We expect our research and development costs will be substantial for the foreseeable future. We expect costs associated with our SYN1618 and SYN1891 programs to increase as the programs progress through clinical trials and new programs progress toward IND and into development.

We track direct research and development expenses, consisting principally of external costs, such as costs associated with contract research organizations and manufacturing of preclinical and clinical drug product and other outsourced research and development expenses to specific product programs. Costs related to specific product candidates are tracked upon the selection of a product candidate. We do not allocate employee and consulting-related costs, costs associated with our platform and facility expenses, including depreciation or other indirect costs, to specific product candidate programs because these costs are deployed across multiple product candidate programs under research and development and, as such, are separately classified. The table below summarizes our research and development expenses by categories of costs for the periods presented (in thousands):

	For the three months ended	
	March 31,	
	2020	2019
SYN1020	\$ 122	\$ 1,038
SYN1618	3,634	897
SYN1891	372	1,198
External pre-development candidate expenses and unallocated expenses	2,159	683
Internal research and development expenses	6,390	6,568
	<u>\$ 12,677</u>	<u>\$ 10,384</u>

#### **General and Administrative Expense**

General and administrative expense consists primarily of compensation, benefits and other employee-related expenses for personnel in our administrative, finance, legal, information technology, investor relations, business development and human resource functions. Other costs include the legal costs of pursuing patent protection of our intellectual property, general and administrative related facility and information technology infrastructure costs and professional fees for accounting and legal services. We anticipate increases in expenses related to legal fees, accounting fees, costs for director and officer liability insurance, fees for investor relations services and costs associated with implementing and complying with corporate governance, internal controls and similar requirements applicable to public companies. We charge all general and administrative expenses to operations as incurred.

#### **Other Income (Expense)**

Interest and investment income consists primarily of income earned on investments. Interest expense consists of expense related to our finance leases. Other expense consists primarily of gains and losses on foreign currency invoices.

## Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the U.S. (GAAP). The preparation of these financial statements requires us to make certain estimates and assumptions that affect the reported amounts of assets and liabilities, the reported amounts of revenues and expenses during the reported periods and related disclosures.

Our critical accounting policies are described in our 2019 Annual Report. During the three months ended March 31, 2020, there were no material changes to our critical accounting policies. We believe that these identified policies are critical to fully understanding and evaluating our financial condition and results of operations.

Our estimates and assumptions, including those related to revenue recognition and research and development expenses are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. The estimates and assumptions involved in our revenue recognition policy, particularly (a) assessing the number of performance obligations; (b) determination of transaction price; (c) determining the pattern over which performance obligations are satisfied, including estimates to complete performance obligations, and those estimates and assumptions involved in our contract research accrual process, particularly estimates of work completed to date; involve a greater degree of judgment, and therefore we consider revenue recognition and research and development expenses to be our critical accounting policies. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from our estimates under different assumptions or conditions.

## Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial results.

### Three Months Ended March 31, 2020 Compared to Three Months Ended March 31, 2019

	For the three months ended		Change
	March 31, 2020	March 31, 2019	\$
	(in thousands)		
Revenue	\$ 100	\$ 338	\$ (238)
Operating expenses:			
Research and development	12,677	10,384	2,293
General and administrative	3,821	3,651	170
Total operating expenses	16,498	14,035	2,463
Loss from operations	(16,398)	(13,697)	(2,701)
Other income (expense):			
Interest and investment income	574	757	(183)
Interest expense	(3)	(7)	4
Other expense	(1)	1	(2)
Other income (expense), net	570	751	(181)
Net loss	\$ (15,828)	\$ (12,946)	\$ (2,882)

## Revenue

Revenue was \$0.1 million for the three months ended March 31, 2020 as compared to \$0.3 million for the three months ended March 31, 2019. Revenue for both periods was related to the recognition of deferred revenue from services performed and payments received under the AbbVie collaboration.

## Operating Expenses

### Research and Development Expense

Research and development expense was \$12.7 million for the three months ended March 31, 2020 compared to \$10.4 million in the corresponding period in 2019. The increase in research and development expense was primarily due to an increase of \$2.5 million of nonclinical development costs, mostly for our SYN1618 and MSUD programs, \$0.6 million of clinical development costs for our SYN1618 program, an increase of \$0.3 million in clinical development costs for our SYN1891 program, and an increase of \$0.1 million of research and development support costs. These increases were partially offset by a decrease of \$0.6 million in clinical

development costs for our SYN1020 program, a decrease of \$0.3 million of manufacturing costs for our SYN1891 program and a decrease of \$0.3 million in compensation, benefits and other employee-related expenses. Research and development support costs include increased lease cost related to our lease with Azzur Group, LLC (“Azzur”). Azzur has agreed to provide the Company with access to, and the use of, an approximately 700 square foot cleanroom space to be constructed in Waltham, Massachusetts (the “Azzur Suite”), for a period of 44 months, from May 1, 2019 to December 31, 2022 (the “Term”), as further described under Note 13, *Leases*, in the audited financial statements included in the Company’s 2019 Annual Report.

### **General and Administrative Expense**

General and administrative expense was \$3.8 million for the three months ended March 31, 2020 compared to \$3.7 million for the corresponding period in 2019. The increase was primarily due to increases in professional services and corporate expenses.

### **Other Income (Expense)**

Other income (expense) was \$0.6 million for the three months ended March 31, 2020, compared to \$0.8 million for the corresponding period in 2019. The decrease in other income (expense) of \$0.2 million was related to a decrease in interest and investment income resulting from lower cash balances and lower interest rates generated by our investment account.

### **Liquidity and Capital Resources**

We have incurred losses since our inception on March 14, 2014 and, as of March 31, 2020 we had an accumulated deficit of approximately \$187.0 million. We have financed our operations to date primarily through the sale of preferred stock, common stock, preferred units, warrants, payments received under our AbbVie collaboration agreement, interest earned on investments, and cash received in the Merger. In June 2019, we issued to Ginkgo 6,340,771 shares of common stock and accompanying Pre-Funded warrants to purchase an aggregate of 2,548,117 shares of common stock, at a combined purchase price per share and Pre-Funded Warrant of \$9.00. The Pre-Funded Warrants have an exercise price of \$9.00 per share, with \$8.99 of such exercise price paid at the closing of the offering. The net proceeds to us were approximately \$79.9 million. At March 31, 2020, we had approximately \$114.2 million in cash, cash equivalents, and short-term marketable securities. Our cash and cash equivalents include amounts held in money market funds and corporate debt securities, stated at cost plus unrealized gain and loss, which approximates fair market value. Our available-for-sale securities include amounts held in corporate debt securities and U.S. government agency securities and treasuries. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve liquidity and capital preservation.

During the three months ended March 31, 2020, our cash, cash equivalents and marketable securities balance decreased approximately \$12.8 million. This decrease was primarily due to the cash used to operate our business, including payments related to, among other things, research and development and general and administrative expenses as we continue to invest in our primary drug candidates and support the development of our proprietary platform. We also made capital purchases and made payments on our finance leases.

The following table sets forth the major sources and uses of cash, cash equivalents and restricted cash for each of the periods below (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(in thousands)</b>	
<b>Net cash, cash equivalents and restricted cash (used in) provided by:</b>		
Operating activities	\$ (12,479)	\$ (13,118)
Investing activities	5,817	17,675
Financing activities	(69)	(65)
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	<b>\$ (6,731)</b>	<b>\$ 4,492</b>

### ***Cash Flows from Operating Activities***

Net cash, cash equivalents and restricted cash used in operating activities was approximately \$12.5 million for the three months ended March 31, 2020. The primary use of cash was our net loss of \$15.8 million and an increase in working capital of \$1.2 million, primarily related to increases in prepaid research and development expenses, as result of our June 2019 services agreement with Ginkgo, increases in prepaid expenses and other current assets, decreases in accounts receivable and deferred revenue, decreases in accounts payable and accrued expenses, offset by a decrease in deferred revenue and an increase in operating lease liability. Net loss was partially offset by \$2.1 million of non-cash items primarily including depreciation and equity-based compensation.

Net cash, cash equivalents and restricted cash used in operating activities was \$13.1 million for the three months ended March 31, 2019. The primary use of cash was our net loss of \$12.9 million and a decrease in working capital of \$1.6 million, primarily related to decreases in accounts payable and accrued expenses, and an increase in operating lease liability and accounts receivable offset by an increase in deferred revenue and prepaid expenses and other current assets. Net loss was partially offset by \$1.4 million of non-cash items primarily including depreciation and equity-based compensation.

### ***Cash Flows from Investing Activities***

Net cash provided by investing activities for the three months ended March 31, 2020 was \$5.8 million and resulted primarily from the proceeds from maturity of and redemption of marketable securities of \$20.4 million. This was offset by the purchases of marketable securities of \$14.3 million and property and equipment of \$0.3 million.

Net cash provided in investing activities for the three months ended March 31, 2019 was \$17.7 million and resulted primarily from the proceeds of maturity of marketable securities of \$57.3 million. The increase was partially offset by purchases of marketable securities of \$39.3 million and purchases of property and equipment of \$0.3 million.

### ***Cash Flows from Financing Activities***

Net cash used in financing activities for the three months ended March 31, 2020 and for the corresponding period in 2019, totaled \$0.1 million solely related to payments on our finance leases.

### **Funding Requirements**

To date, we have not commercialized any products and have not achieved profitability. We anticipate that we will continue to incur substantial net losses for the next several years as we further develop our product candidates, invest in our proprietary platform technology and operate as a publicly traded company.

We have generated revenue from our AbbVie collaboration, but have not generated any product revenue since our inception and do not expect to generate any product revenue unless we receive regulatory approval for our product candidates. We believe that our cash, cash equivalents, and short-term marketable securities as of March 31, 2020, will be sufficient to meet our anticipated cash requirements for at least the next 12 months from the date of this filing. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the section entitled "Risk Factors" in this Quarterly Report on Form 10-Q. We have based our estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Due to the numerous risks and uncertainties associated with the development of our product candidates, we are unable to estimate precisely the amounts of capital outlays and operating expenditures necessary to complete the development of, and to obtain regulatory approval for, our product candidates. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the success of our research and development efforts;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the time and costs involved in obtaining regulatory approvals for our product candidates;
- the progress, timing and costs involved in developing manufacturing processes and agreements with third-party manufacturers;
- the rate of progress and cost of our commercialization activities;



- the expenses we incur in marketing and selling our product candidates;
- the revenue generated by sales of our product candidates;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the terms and timing of any additional collaborative, licensing or other arrangements that we may establish;
- the acquisition of businesses, products and technologies;
- our need to implement additional infrastructure and internal systems;
- our need to add personnel and financial and management information systems to support our product development and potential future commercialization efforts, and to enable us to operate as a public company; and
- the extent to which our business is adversely impacted by the effects of the novel coronavirus outbreak or by other health epidemics or pandemics.

As an early-stage company, we are subject to a number of risks common to other life science companies, including, but not limited to, the ability to raise additional capital, development by our competitors of new technological innovations, risk of failure in preclinical studies, the safety and efficacy of our product candidates in clinical trials, the regulatory approval process, the ability to efficiently manufacture our products, market acceptance of our products once approved, lack of marketing and sales history, dependence on key personnel and protection of proprietary technology. Our therapeutic programs are currently pre-commercial, spanning discovery through early development and will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization of any product candidates. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained, that any products developed will obtain necessary regulatory approval or that any approved products will be commercially viable. Even if our product development efforts are successful, it is uncertain when, if ever, we will generate revenue from product sales. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital or obtain financing from other sources, such as strategic collaborations or partnerships. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

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

There have been no material changes to our contractual obligations and commitments set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations- Contractual Obligations and Commitments” in our 2019 Annual Report.

#### **Related Party Transactions**

For a description of transactions with related parties which may fall outside of the reporting period of this section, please see the section entitled “*Related Party Transactions of Directors and Executive Officers of the Combined Organization – Synlogic Transactions*” in our proxy statement filed with the SEC on April 17, 2020.

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

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our performance and the performance of our subsidiaries.

## **JOBS Act**

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

## **Recently Issued Accounting Pronouncements**

For detailed information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 2, *Summary of Significant Accounting Policies* in the notes to the unaudited consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide this information required under this item.

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

### **Definition and limitations of disclosure controls**

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluates these controls and procedures on an ongoing basis.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute assurance, of achieving their objectives.

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

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

### **Changes in Internal Control**

There have not been any changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of such internal control that occurred during our fiscal quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings.

#### 1A. Risk Factors.

*Investing in our common stock involves a high degree of risk. Our business, prospects, financial condition or operating results could be materially adversely affected by the risks identified below, as well as other risks not currently known to us or that we currently consider immaterial. Furthermore, these factors represent risks and uncertainties that could cause actual results to differ materially from those implied by forward-looking statements. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. The following risk factors may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future.*

In the following discussion of risk factors, References to “we”, “us”, “our” and similar terms refer to the combined business of Synlogic, Inc. after the Merger on August 28, 2017.

#### **Risks Related to Our Financial Condition, Capital Requirements and Operating Results**

***We are a clinical-stage biopharmaceutical company with a history of losses, and we expect to continue to incur losses for the foreseeable future, and we may never achieve or maintain profitability.***

We are a clinical-stage biopharmaceutical company focused on the development of Synthetic Biotic medicines and we have incurred significant operating losses since our inception. Our net loss was approximately \$15.8 million and \$12.9 million for the three months ended March 31, 2020 and 2019 respectively. As of March 31, 2020, we had an accumulated deficit of approximately \$187.0 million. To date, we have not generated any product revenue. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We have no products on the market and expect that it will be many years, if ever, before we have a product candidate approved for commercialization.

We have not generated, and do not expect to generate, any product revenue for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials, the regulatory review process for product candidates, and the development of manufacturing and marketing capabilities for any product candidates approved for commercial sale. The amount of our potential future losses is uncertain. To achieve profitability, we must successfully develop product candidates, obtain regulatory approvals to market and commercialize product candidates, manufacture any approved product candidates on commercially reasonable terms, establish a sales and marketing organization or suitable third-party alternatives for any approved product candidates and raise sufficient funds to finance our business activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value could also cause our stockholders to lose all or part of their investment.

***We will require substantial additional funding, which may not be available on acceptable terms, or at all.***

We have used substantial funds to discover and develop our programs and proprietary drug development platform and will require substantial additional funds to conduct further research and development, including preclinical studies and clinical trials of our product candidates, seek regulatory approvals for our product candidates and manufacture and market any products that are approved for commercial sale. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and corporate activities. Because we cannot be certain of the length of time or activities associated with successful development and commercialization of our product candidates, we are unable to estimate the actual funds we will require to develop and commercialize them.

We do not expect to realize any appreciable revenue from product sales or royalties in the foreseeable future, if at all. Our revenue sources will remain very limited unless and until our product candidates complete clinical development and are approved for commercialization and successfully marketed. To date, we have primarily financed our operations through sales of our securities, our third-party collaborations and the Merger. We intend to seek additional funding in the future through collaborations, equity or debt financings, credit or loan facilities or a combination of one or more of these financing sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity or convertible debt securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, may involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of equity securities received any distribution of corporate assets.

If we are unable to obtain funding on a timely basis or on acceptable terms, or at all, we may have to delay, limit or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our product candidates or technologies that we would otherwise pursue on our own.

***Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet the expectations of research analysts or investors, which could cause our stock price to decline.***

Our financial condition and operating results may fluctuate from quarter to quarter and year to year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as factors described elsewhere in this Quarterly Report on Form 10-Q and others:

- our ability to achieve or maintain profitability;
- our ability to develop and maintain Synthetic Biotic technologies;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials, or other product development and approval processes;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect and enforce our intellectual property rights;
- our ability to prevent the theft or misappropriation of our intellectual property, know-how or technologies;
- potential advantages that our competitors and potential competitors may have in securing funding or developing competing technologies or products; and
- our ability to obtain additional capital that may be necessary to expand our business.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

***Our stock price is volatile and our stockholders may not be able to resell shares of our common stock at or above the price they paid.***

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, such as reports by industry analysts, investor perceptions or negative announcements by other companies involving similar technologies or diseases. These factors also include those discussed in this “Risk Factors” section of this Quarterly Report on Form 10-Q and others such as:

- announcements relating to collaborations that we may enter into with respect to the development or commercialization of our product candidates;
- announcements relating to the receipt, modification or termination of government contracts or grants;
- termination or delay of a development program;
- product liability claims related to our clinical trials or product candidates;

- prevailing economic conditions;
- additions or departures of key personnel;
- business disruptions caused by earthquakes or other natural disasters;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- sales of our common stock by the company, our executive officers and directors or our stockholders in the future;
- future sales or issuances of equity or debt securities by us;
- lack of an active, liquid and orderly market in our common stock;
- fluctuations in our quarterly operating results; and
- the issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that have been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

***Our short operating history may make it difficult for stockholders to evaluate the success of our business to date and to assess our future viability.***

We are a clinical-stage biopharmaceutical company with a limited operating history. We commenced active operations in 2014. Our operations to date have been limited to organizing and staffing our company, research and development activities, business planning and raising capital. In April 2018, we announced that we dosed the first patient in our Phase 1b/2a clinical trial of SYN1020 for treatment of hyperammonemia in patients with cirrhosis. Based on the data obtained in this clinical trial, the SYN1020 program was discontinued in August 2019. In April 2018 we dosed our first subject in a Phase 1/2a clinical trial of SYN1618 which is being developed for the treatment of patients with PKU. In light of the COVID-19 pandemic, we do not expect to be able to enroll subjects into our Phase 1/2a clinical trial of SYN1618 until it is safe for patients to enter clinical trial sites. In January 2020 we announced that we had dosed the first subject in our Phase 1 clinical trial of SYN1891 which is being developed for the treatment of patients with solid tumors and lymphoma. In light of the COVID-19 pandemic, we expect enrollment of new patients in the Phase 1 trial of SYN1891 to slow, which has the potential to impact the availability of data in 2020. All of our other therapeutic programs are still in the preclinical development stage. We will need to transition from a company with a research focus to a company capable of supporting clinical development and commercial activities. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes many years to develop one new product candidate from the time it is discovered to the time that it becomes available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may hinder our success in commercializing one or more of our product candidates. Further, drug development is a capital-intensive and highly speculative undertaking that involves a substantial degree of risk. You should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development and clinical trials. Any forward-looking statements regarding our future prospects, plans or viability may not be as accurate as they may be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

## **Risks Related to the Development of Our Product Candidates**

***Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.***

Clinical development of a product candidate is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials we undertake to conduct will be conducted as planned or completed on schedule or at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development of our product candidates include but are not limited to:

- inability to generate satisfactory preclinical or other nonclinical data, including, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;
- failure to permit the conduct of a clinical trial by regulatory authorities, after review of an investigational new drug or equivalent foreign application or amendment;
- delays in recruiting qualified patients in our clinical trials;
- failure by clinical sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by us, clinical sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- patients dropping out of the clinical trials;
- occurrence of adverse events, unacceptable side effects or toxicity issues associated with our product candidates;
- imposition by the FDA of a clinical hold or the requirement by other similar regulatory agencies that one or more clinical trials be delayed or halted;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or performing additional nonclinical studies;
- the ultimate affordability of the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials that may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon such clinical trials and/or clinical trials or development programs in other ongoing or planned indications for a product candidate; and
- delays in identifying or reaching agreement on acceptable terms with third-party manufacturers, delays in developing and transferring a reproducible, scalable manufacturing process, or delays or failure in manufacturing sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional preclinical studies and/or clinical trials, or the results obtained from such new formulation may not be consistent with previous results obtained. Clinical trial delays could also shorten any anticipated periods of patent exclusivity for our product candidates and may allow competitors to develop and bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***The approach we are taking to discover and develop novel therapeutics using synthetic biology to create novel medicines is unproven and may never lead to marketable products.***

The scientific discoveries that form the basis for our efforts to generate and develop our product candidates are relatively recent. The scientific evidence to support the feasibility of developing drugs based on our approach is both preliminary and limited. Synthetic Biotic medicines represent a novel therapeutic modality and their successful development by us may require additional studies and efforts to optimize their therapeutic potential. Any product candidates that we develop may not demonstrate in patients the therapeutic properties ascribed to them in laboratory and other preclinical studies, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. If we are not able to successfully develop and commercialize product candidates based upon this technological approach, we may never become profitable and the value of our capital stock may decline.

***Our Synthetic Biotic product candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.***

We have concentrated our research and development efforts to date on a limited number of product candidates based on our Synthetic Biotic therapeutic platform and identifying our initial targeted disease indications. Our future success depends on our successful development of viable product candidates. There can be no assurance that we will not experience problems or delays in developing our product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved.

The clinical trial and manufacturing requirements of the FDA, the European Medicines Agency and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as Synthetic Biotic medicines may be more expensive and take longer than for other, better known or more extensively studied therapeutic modalities. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates, even if approved for marketing. Approvals by the European Medicines Agency or national regulatory agencies may not be indicative of what the FDA, and vice versa, may require for approval and different or additional preclinical studies or clinical trials may be required to support regulatory approval in each respective jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

***We may not be successful in our efforts to use and expand our development platform to build a pipeline of product candidates.***

A key element of our strategy is to use our targeted focus and experienced management and scientific team to create Synthetic Biotic medicines that can be deployed against a broad range of human diseases in order to build a pipeline of product candidates. Although our research and development efforts to date have resulted in potential product candidates, we may not be able to continue to identify and develop additional product candidates. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, these potential product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position. There is no assurance that we will be successful in our preclinical and clinical development, and the process of obtaining regulatory approvals will, in any event, require the expenditure of substantial time and financial resources.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or terminate our clinical trials or result in a restrictive label or delay regulatory approval by the FDA or comparable foreign authorities. Undesirable side effects and negative results for other indications may negatively impact the development and potential for approval of our product candidates for their proposed indications.

Additionally, even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of or revoke licenses for such products;
- regulatory authorities may require additional warnings on the labels of such products;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

***Our product development program may not uncover all possible adverse events that patients who take our product candidates may experience. The number of subjects exposed to our product candidates during clinical trials and the average exposure time in the clinical development program may be inadequate to detect rare adverse events, or chance findings, that may only be detected once the product is administered to more patients and for greater periods of time.***

Clinical trials by their nature use a sample of the potential patient population. However, with a limited number of patients and limited duration of exposure, we cannot be fully assured that uncommon or severe side effects of our product candidates will be uncovered. Such side effects may only be uncovered with a significantly larger number of patients exposed to the drug. If such safety problems occur or are identified after a product candidate reaches the market, the FDA may require that we amend the labeling of the product or recall the product or may even withdraw approval for the product. Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

***We are heavily dependent on the success of our product candidates. Some of our product candidates have produced results in preclinical settings to date, but none of our product candidates has completed all required clinical trials, and we cannot give any assurance that we will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized.***

We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate.

On August 20, 2019, we announced that we were discontinuing our first therapeutic program to enter clinical trials, SYN1020, an early stage clinical product candidate for the treatment of hyperammonemia. The decision to discontinue the program was based on top-line data from an interim analysis of a randomized, double-blind, placebo-controlled Phase 1b/2a study of the Synthetic Biotic medicine in 23 patients with cirrhosis and elevated blood ammonia. While SYN1020 was well tolerated in Phase 1b/2a study, the study showed it did not lower blood ammonia in patients with cirrhosis. As a result, we have become more dependent on the success of our SYN1618 and SYN1891 programs and new early development programs.

In addition, none of our product candidates has advanced into any pivotal clinical trial, for our proposed indications and it may be years before any pivotal clinical trials are initiated and completed, if at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

***If we fail to obtain or maintain orphan drug exclusivity for some of our products, our competitors may obtain approval to sell competing drugs to treat the same conditions and our revenues will be reduced.***

As part of our business strategy, we have developed and may in the future develop product candidates that may be eligible for FDA and European Commission orphan drug designation. In October 2017, the FDA granted orphan drug designation to SYN1618 for the treatment of PKU. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat, diagnose or prevent rare diseases or conditions that affect fewer than 200,000 people in the United States. In the EU, orphan drug designation may be granted to drugs intended to treat, diagnose or prevent a life-threatening or chronically debilitating disease having a prevalence of no more than five in 10,000 people in the EU. The company that first obtains FDA approval for a designated orphan drug for the associated rare disease receives marketing exclusivity for use of that drug for the stated condition for a period of seven years. Orphan drug exclusive marketing rights may be lost under several circumstances, including a later determination by the FDA that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Similar regulations are in effect in the EU with a ten-year period of market exclusivity.

Because the extent and scope of patent protection for some of our product candidates may be limited, obtaining orphan drug designation is especially important for any product candidates that may be eligible for orphan drug designation. For eligible products, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug designation for our product candidates that do not have broad patent protection, our competitors may then seek to sell a competing drug to treat the same condition and our revenues, if any, may be adversely affected thereby.



Even though we have obtained orphan drug designation for certain of our product candidates and intend to seek orphan drug designation for other product candidates, there is no assurance that we will be the first to obtain marketing approval for any particular rare indication. Further, even though we have obtained orphan drug designation for certain of our product candidates, or even if we obtain orphan drug designation for other potential product candidates, such designation may not effectively protect us from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions and potentially used off-label in the orphan indication. Even after an orphan drug is approved, the FDA can subsequently approve a competing drug for the same condition for several reasons, including, if the FDA concludes that the later drug is safer or more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

***Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results.***

The results from preclinical studies or early clinical trials of a product candidate may not predict the results that will be obtained in subsequent subjects or in later stage clinical trials of that product candidate or any other product candidate. Flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and we may be unable to design and execute clinical trials to support regulatory approval of our product candidates. In addition, preclinical study and clinical trial data are often susceptible to varying interpretations and analyses. Product candidates that seemingly perform satisfactorily in preclinical studies and clinical trials may nonetheless fail to obtain regulatory approval. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could negatively affect our business and operating results.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our costs might be higher than expected and our receipt of necessary regulatory approvals could be delayed or prevented.***

Clinical trials of a new product candidate require the enrollment of a sufficient number of patients suffering from the disease or condition the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the potential patient population, the age and condition of the patients, the stage and severity of disease or condition, the nature and requirements of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease or condition, the perceived risks, benefits and convenience of administration of the product candidate being studied, the patient referral practices of physicians, our efforts to facilitate timely enrollment in clinical trials, and the eligibility criteria for the clinical trial. Delays or difficulties in patient enrollment or difficulties retaining trial participants, including as a result of the availability of existing or other investigational treatments, can result in increased costs, longer development times or termination of a clinical trial.

In addition, our success may depend, in part, on our ability to identify patients who qualify for our clinical trials, or are likely to benefit from any product candidate that we may develop, which will require those potential patients to undergo a screening assay for the presence or absence of a particular genetic sequence or clinical trait. Genetically defined diseases generally, and especially those for which our current product candidates are targeted, may have relatively low prevalence. For example, we estimate there are approximately 16,500 patients that may be diagnosed with PKU in the United States. If we, or any third parties that we engage to assist us, are unable to successfully identify patients with these diseases, or experience delays in doing so, then we may not realize the full commercial potential of any product candidate we develop.

***We may face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our product candidates harms patients, or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, such liability could adversely affect our financial condition.***

The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Patients with the diseases targeted by our product candidates may already be in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial

amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Although we have product liability insurance, which covers any clinical trial we may conduct in the United States, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We will also likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plan to initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage we may require, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates or products causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenues;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations.

***We or the third parties upon which we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

***A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 may materially and adversely affect our business and our financial results.***

The novel coronavirus outbreak has affected segments of the global economy and may materially affect our operations, including potentially significant interruption of our clinical trial activities and pre-commercial launch activities. COVID-19 originated in Wuhan, China, in December 2019 the virus has since spread to multiple countries, including the United States, where we are currently conducting our clinical trials. The continued spread of the coronavirus may result in a period of business disruption, including material delays in our clinical trials. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread globally could also have a material adverse effect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography.

We are closely monitoring the potential impact of the coronavirus outbreak, and the associated restrictions on travel and work that have been implemented, on our business and clinical trials. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, in light of the COVID-19 pandemic, we do not expect to be able to enroll subjects into our Phase 1/2a clinical trial of SYN1618 until it is safe for patients to enter clinical trial sites and we expect enrollment of new patients in the Phase 1 trial of SYN1891 to slow, which has the potential to impact the availability of data in 2020. The coronavirus outbreak may further delay enrollment in our planned or ongoing clinical trials due to prioritization of hospital resources toward the outbreak, the protection of the health of patients and investigators at the clinical trial sites, and restrictions on work and travel. In addition, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. These and other factors could significantly delay our ability to conduct clinical trials or release clinical trial results.

COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials. In addition, we have taken precautionary measures, and may take additional measures, intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We cannot presently predict the extent to which current or future business shutdowns and disruptions may impact or limit our ability or the ability of any of the third parties with which we engage to conduct business in the manner and on the timelines presently planned. Any such impacts or limitations could have a material adverse impact on our business and our results of operation and financial condition. While the potential economic impact brought by and the duration of the coronavirus outbreak may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

**Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters**

***We may seek breakthrough therapy designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.***

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

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

***We may seek Fast-Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.***

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for the condition, a product sponsor may apply for FDA Fast-Track designation. We were awarded Fast-Track designation for SYN1618 in April 2018. Fast-Track designation does not ensure that we will receive marketing approval for the product candidate or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast-Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast-Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast-Track designation alone does not guarantee qualification for the FDA's priority review procedures.

***Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.***

If any of our product candidates are approved for marketing, we will be subject to ongoing regulatory requirements, including with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials, and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (GMP) regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any BLA or marketing authorization application.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and operating results would be adversely affected.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

***Healthcare legislative reform measures may have a material adverse effect on our financial condition or results of operations.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA, was passed, which was intended to substantially change the way health care is financed by both governmental health programs and private insurers, and significantly impact the U.S. pharmaceutical industry. The ACA, among other things, introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program.

The ACA has been under scrutiny by the U.S. Congress almost since its passage, and certain sections of the ACA have not been fully implemented or effectively repealed. As a result, its longevity continues to be uncertain. In addition, ongoing initiatives in the U.S. have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product candidate that we may successfully develop.

It is anticipated that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the reimbursement our customers may receive for our products. Further, there have been judicial and Congressional challenges to certain aspects of the ACA, and it is expected there will be additional challenges and amendments to the ACA in the future, especially with the recent change in administration. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. 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 in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the ACA require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.***

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. We must comply with laws and regulations associated with the international transfer of personal data based on the location in which the personal data originates and the location in which it is processed. Although there are legal mechanisms to facilitate the transfer of personal data from the European Economic Area (EEA), and Switzerland to the United States, the decision of the European Court of Justice that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on safe harbor certification as a legal basis for the transfer of personal data from the European Union to entities in the United States. In February 2016, the European Commission announced an agreement with the Department of Commerce, or DOC, to replace the invalidated safe harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its recent ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission and making commitments on the part of public authorities regarding access to information.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, is subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

Numerous foreign, federal and state laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable health information, including state privacy and confidentiality laws (including state laws requiring disclosure of breaches); federal and state consumer protection and employment laws; HIPAA; and European and other foreign data protection laws. These laws and regulations are increasing in complexity and number, may change frequently and sometimes conflict.

HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, including protected health information, or PHI, by health plans, certain healthcare clearinghouses and healthcare providers that submit certain covered transactions electronically, or covered entities, and their “business associates,” which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. While we are not currently a covered entity or business associate under HIPAA, we may receive identifiable information from these entities. Failure to receive this information properly could subject us to HIPAA’s criminal penalties, which may include fines up to \$250,000 per violation and/or imprisonment. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately concluded with no findings of violations or no penalties imposed, can consume company resources and impact our business and, if public, harm our reputation.

In addition, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California’s patient privacy laws, for example, provide for penalties of up to \$250,000 and permit injured parties to sue for damages. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and our clients and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify.

In addition, the interpretation and application of consumer, health-related, and data protection laws are often uncertain, contradictory, and in flux.

U.S.-based companies may certify compliance with the privacy principles of the Privacy Shield. Certification to the Privacy Shield, however, is not mandatory. If a U.S.-based company does not certify compliance with the Privacy Shield, it may rely on other authorized mechanisms to transfer personal data.

The privacy and data security landscape is still in flux. In October 2016, an action for annulment of the European Commission decision on the adequacy of Privacy Shield was brought before the European Court of Justice by three French digital rights advocacy groups, La Quadrature du Net, French Data Network and the Fédération FDN. This case, Case T738/16, is currently pending before the European Court of Justice. Should the European Court of Justice invalidate the Privacy Shield, it will no longer be possible to transfer data from the European Union to entities in the United States under a Privacy Shield certification, in which case other legal mechanisms would need to be put in place.

In addition, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy regulation (“GDPR”) in 2016 to replace the current European Union Data Protection Directive and related country-specific legislation. The GDPR took effect in May 2018 and governs the collection and use of personal data in the European Union. The GDPR, which is wide-ranging in scope, will impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater.

The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues which may affect our business. Failure to comply with current and future laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business.

In the United States, California recently adopted the California Consumer Privacy Act of 2018, or CCPA, which came into effect beginning in January 2020. The CCPA has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU General Data Protection Regulation. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

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

Our research and development activities and our third-party manufacturers’ and suppliers’ activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers’ facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts, commercialization efforts and business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Given the nature of the research and development work conducted by us, we do not currently carry biological or hazardous waste insurance coverage.

***Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop, implement and maintain costly compliance programs.***

To develop, manufacture and sell certain products outside the United States, we must dedicate resources to comply with numerous laws and regulations in each jurisdiction in which we operate. The Foreign Corrupt Practices Act (FCPA), prohibits any United States individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees may be considered government employees or foreign officials. In other circumstances, certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-United States nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. These laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the U.S., which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA’s accounting provisions and export control laws.



***Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of preclinical or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

***Ethical, legal and social concerns about synthetic biology and genetic engineering could limit or prevent the use of our technologies and limit our revenues.***

Our technologies involve the use of synthetic biology and genetic engineering. Public perception about the safety and environmental hazards of, and ethical concerns over, synthetic biology and genetic engineering could influence public acceptance of our technologies, product candidates and processes. If we and our collaborators are not able to overcome the ethical, legal and social concerns relating to synthetic biology and genetic engineering, our technologies, product candidates and processes may not be accepted. These concerns could result in increased expenses, regulatory scrutiny and increased regulation, trade restrictions on imports of Synthetic Biotic medicines, delays or other impediments to our programs or the public acceptance and commercialization of Synthetic Biotic medicines. Further, there is a risk that Synthetic Biotic medicines made using our technologies could result in adverse health effects or other adverse events, which could also lead to negative publicity. We design and produce product candidates with characteristics comparable or disadvantaged to those found in naturally occurring organisms or enzymes in a controlled laboratory; however, the release of such organisms into uncontrolled environments could have unintended consequences. Any adverse effect resulting from such a release could have a material adverse effect on our business, financial condition or results of operations and we may have exposure to liability for any resulting harm.

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

***We may not be successful in obtaining or maintaining necessary rights to Synthetic Biotic medicines, product candidates and processes for our development pipeline through acquisitions and in-licenses.***

Presently, we have rights to certain intellectual property, through licenses from third parties and under patents and patent applications owned by us. The growth of our business will likely depend in part on our ability to obtain, maintain or enforce our and our licensors' intellectual property rights and to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates or delivery systems that may require the use of additional proprietary rights held by third parties. Our ultimate product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations.

In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by other third parties. We may be unable to develop, acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of other companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These companies could have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have previously and may continue to collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such right of first negotiation for intellectual property, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to it. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

***We intend to rely on patent rights and the status of our product candidates, if approved, as biologics eligible for exclusivity under the Biologics Price Competition and Innovation Act (BPCIA). If Synlogic is unable to obtain or maintain exclusivity from the combination of these approaches, Synlogic may not be able to compete effectively in our markets.***

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Even if we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection, data exclusivity or orphan drug exclusivity, for our product candidates, we believe that our product candidates will be protected by exclusivity that prevents approval of a biosimilar in the United States for a period of twelve years from the time the product to which it claims similarity was first approved. However, The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the Patent Protection and Affordable Care Act, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010, and codified in 42 U.S.C. §262 (the BPCIA), created an elaborate and complex patent dispute resolution mechanism for biosimilars that could prevent us from launching our product candidates in the United States or could substantially delay such launches. Current biosimilars litigation are addressing certain requirements of the BPCIA which is creating uncertainty over how certain terms of the BPCIA should be construed and this, presents uncertainty for both the biologics innovator and biosimilar party. The BPCIA mechanism required for biosimilar applicants may pose greater risk that patent infringement litigation will disrupt our activities and add increased expenses as well as divert management's attention. If a biosimilar version of one of our product candidates were approved in the United States, it could have a negative effect on our business.

***We may not have sufficient patent term protections for our product candidates to effectively protect our business.***

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition. In addition, upon issuance in the United States any patent term can be adjusted based on specified delays caused by the applicant(s) or the USPTO.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We will likely seek patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

As is the case with other biotechnology companies, our success is heavily dependent on patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our proposed markets.***

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent. We also utilize processes for which patents are difficult to enforce. In addition, other elements of our products, and many elements of our product candidate discovery and development processes involve proprietary know-how, information or technology that is not covered by patents. Trade secrets may be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, collaborators, advisors, independent contractors or other third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets, including by maintaining physical and electronic security of our premises and our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, collaborators, advisors, independent contractors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

***Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the area of Synthetic Biotic medicines. We are aware of U.S. and foreign patents and pending patent applications owned by third parties that cover similar therapeutic uses as the product candidates we are developing. We are currently monitoring these patents and patent applications. We may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover our product candidates or technologies, we may not be free to manufacture or market our product candidates as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or

patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patents may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

There have been many lawsuits and other proceedings filed by third parties involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination, post-grant review and equivalent proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

***We depend, in part, on our licensors to file, prosecute, maintain, defend and enforce patents and patent applications that are material to our business.***

While we normally seek and gain the right to fully prosecute the patent applications relating to our product candidates, there may be times when the patent applications enabling our product candidates are controlled by our licensors. If any of our existing or future licensors fail to appropriately and broadly prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

***If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are a party to certain intellectual property license agreements and expect to enter into additional license agreements in the future. Our existing agreements impose, and future license agreements may impose, certain obligations, including the payment of milestones and royalties based on revenues from sales of our products utilizing the technologies licensed from our licensors, and such obligations could adversely affect the overall profitability for us of any products that we may seek to commercialize. In addition, we will need to outsource and rely on third parties for many aspects of the clinical development, sales and marketing of our product candidates covered under our license agreements. Delay or failure by these third parties could adversely affect the continuation of our license agreements with our third-party licensors. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, these agreements may be subject to termination by the licensor which could have a material adverse effect on our business.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we or one of our licensing partners may be required to file patent infringement claims against a third-party to enforce one of our patents which can be expensive, time-consuming and unpredictable. In addition, in an infringement proceeding or a declaratory judgment action against us, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

If we or one of our licensing partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, clarity or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or other jurisdictions, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity, unpatentability and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions or correct inventorship with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation, derivation or interference proceedings may result in a decision adverse to our interests and, even if successful, may result in substantial costs and distract our management and other employees. In addition, we may be unable to raise the funds necessary to conduct our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. Any disclosure of confidential information could adversely affect our business. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

We may in the future be subject to claims that former employees, consultants, collaborators, advisors, independent contractors or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor or other claims challenging the inventorship of our patents or ownership of our intellectual property (including patents and intellectual property that we in-license). Therefore, our rights to these patents may not be exclusive and third parties, including competitors, may have access to intellectual property that is important to our business. In addition, co-owners from whom we do not yet have a license or assignment may raise claims surrounding inventorship or ownership of patents that ultimately issue from this patent family, potentially resulting in issued patents to which we would not have rights under our existing license agreements. Further, in jurisdictions outside the United States, a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. In addition, we may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may be subject to claims that our employees, consultants, collaborators, advisors, independent contractors or other third parties have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at universities, academic research institutions and at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements with and make every effort to ensure that our employees, consultants, collaborators, advisors, independent contractors or other third parties do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to claims that our employees, consultants,

collaborators, advisors, independent contractors or other third parties have inadvertently or intentionally used or disclosed confidential information of these third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may not be able to protect our intellectual property rights throughout the world.***

We have limited intellectual property rights outside the United States. Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the United States can have a different scope and strength and be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties (including competitors) from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patents and other intellectual property rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We have filed for trademark registration of certain marks relating to our current branding. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

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

***We rely, and expect to continue to rely, on third parties to conduct some aspects of our product formulation, research, preclinical, and clinical studies, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such formulation, research or testing.***

We do not independently conduct all aspects of our drug discovery activities, compound development or preclinical studies of product candidates. We currently rely, and expect to continue to rely, on third parties to conduct some aspects of our research and development and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, for

product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our studies that support our clinical trial applications and our clinical trials are conducted in accordance with the study plan and protocols for the trial. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us or our strategic alliance partners to select viable product candidates for clinical trial application submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

***We rely on third-party supply and manufacturing partners for drug supplies for our late-stage clinical activities, and may do the same for any commercial supplies of our product candidates.***

We rely on third-party supply and manufacturing partners to supply the materials and components to manufacture late-stage clinical trial drug supplies. We have not yet manufactured or formulated any product candidate on a commercial scale and may not be able to do so for any of our product candidates. We will work to develop and optimize our manufacturing process, and we cannot be sure that the process will result in therapies that are safe, potent or effective.

There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of any product formulation manufacturer we may engage could require significant effort and expertise because there may be a limited number of qualified replacements.

Synthetic Biotic medicines are complex and difficult to manufacture. We could experience production or technology transfer problems that result in delays in our development or commercialization schedules or otherwise adversely affect our business. Issues with the manufacturing process, even minor deviations from the normal process, could result in insufficient yield, product deficiencies or manufacturing failures that result in lot failures, insufficient inventory, and product recalls.

Many factors common to the manufacturing of most biologics and drugs could also cause production interruptions, including raw materials shortages, raw material failures, growth media failures, equipment malfunctions, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, or acts of god beyond our control. We also may encounter problems in hiring and retaining the experienced specialized personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing processes or facilities could make us a less attractive collaborator for academic research institutions and other parties, which could limit our access to additional attractive development programs, result in delays in our clinical development or marketing schedules and harm our business.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as GMP regulations. Any of our suppliers or manufacturers could fail to comply with such requirements or to perform our obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials could become limited or interrupted for other reasons. Under these circumstances, we may choose or be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, manufacture in collaboration with a third-party at their facilities, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills or technology to another third-party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We may rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third-party's failure to execute on our manufacturing requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development, which may impact our potential economic benefits;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of a collaborator;
- subjecting our product candidates to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

***We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.***

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third-party. With respect to consulting agreements, we indemnify consultants from claims arising from the good faith performance of their services.

Should our obligation under an indemnification provision exceed applicable insurance coverage or should we be denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

***To the extent we are able to enter into collaborative arrangements or strategic alliances, we may be exposed to risks related to those collaborations and alliances.***

We are currently party to agreements with AbbVie and Ginkgo. Biotechnology companies sometimes become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of product candidates. If we elect to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances would subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the relevant product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and



- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

***We may attempt to form collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans.***

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs or platform that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable to us, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaborators and entering into agreements to develop and/or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

#### **Risks Related to Commercialization of Our Product Candidates**

***If any of our product candidates is approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to successfully commercialize any such future products.***

We currently have no sales, marketing or distribution capabilities or experience. If any of our product candidates is approved for marketing and commercialization, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved for marketing and commercialization in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects may be adversely affected.

***If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations and, assuming approval of a product candidate, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.***

Given the small number of patients who have the diseases that we are targeting, our eligible patient population and pricing estimates may differ significantly from the actual market addressable by our product candidates. Our projections of both the number of people who have applicable diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

***We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.***

The development and commercialization of new products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to our product candidates that we may seek to develop or commercialize in the future. For example, BioMarin, Inc., Censa Pharmaceuticals, Inc., Nestlé Health Science S.A. / Codexis, Inc., Homology Medicines, Inc., American Gene Technologies International Inc., Moderna, Inc., Sangamo Therapeutics, Inc., Sanofi S.A., Generation Bio Co., Agios, Inc., Trucode Gene Repair, Inc., SOM Biotech SL and other discovery stage companies have developed or are developing product candidates for the treatment of PKU. Allena Pharmaceuticals, Inc., Novome Biotechnologies, Inc., Oxidien Pharmaceuticals L.L.C. and others are developing product candidates for enteric hyperoxaluria. Acer Therapeutics Inc. has a clinical stage program in MSUD. Aduro Biotech, Inc., Merck & Co. Inc., Spring Bank Pharmaceuticals, Inc., GlaxoSmithKline plc., Bristol Myers Squibb Company have STING agonists in clinical development. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective or less costly than the product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive. In addition to the competition we face from alternative therapies for the diseases we intend to target with our product candidates, we are also aware of several companies that are also working specifically to develop engineered bacteria as cellular drug therapies, such as Precigen, Inc. Further there are several companies working to develop other similar products. Third-party payors, including governmental and private insurers, may also encourage the use of generic products.

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than us, it could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have materially greater name recognition and substantially greater financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors. Failure of our product candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

***The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.***

Even with approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers, patients, and third-party payors accepting our product candidates as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including but not limited to:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the safety and side effect profile of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease targeted;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration;
- the cost of treatment;
- the willingness of the patients and physicians to accept products engineered from bacteria and these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians, patients, and payers, and the willingness of physicians to recommend these therapies to patients based on such risks and benefits;
- the marketing, sales and distribution support for the product;
- the publicity concerning the products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable.

***We may not be successful in any efforts to identify, license, discover, develop, or commercialize additional product candidates.***

Although a substantial amount of our effort will focus on the clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop, or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during development or commercialization so that such a product may become unreasonable to continue to develop or commercialize;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for one or more product candidates, or we may not be able to identify, license, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations.

***Failure to obtain or maintain adequate reimbursement or insurance coverage for products, if any, could limit our ability to market those products and decrease our ability to generate revenue.***

The pricing, coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford expensive treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as ours and what reimbursement codes our product candidates may receive if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue from the sale of our products may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs has and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even if they receive regulatory approval.

### **Risks Related to Our Business Operations and Employees**

***Our failure to attract and retain senior management and key scientific personnel may prevent us from successfully developing our product candidates or any future product candidate, conducting our clinical trials and commercializing any products.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly our president and chief executive officer, chief medical officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of the products we develop.

Although we have not historically experienced significant difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all.

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

We are exposed to the risk that our employees, independent contractors, consultants and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) regulations of regulatory authorities in jurisdictions where we are performing activities in relation to our product candidates, including those laws requiring the reporting of true, complete and accurate information to such authorities; (2) manufacturing regulations and standards; (3) fraud and abuse and anti-corruption laws and regulations; or (4) laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, bias, misconduct, kickbacks, self-dealing and other abusive practices, and these laws may differ substantially from country to country. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting ourselves from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our business including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in subsidized healthcare programs in a given country, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change of control, which could harm our business, financial condition or results of operations.***

Our executive officers are parties to employment agreements providing for aggregate cash payments of up to approximately \$1.2 million at March 31, 2020 for severance and other benefits in the event of a termination of employment in connection with a change of control. The payment of these severance benefits could harm our business, financial condition and results of operations. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

Based on the beneficial ownership of our common stock as of May 1, 2020, our executive officers and directors, together with holders of 5% or more of our common stock outstanding and their respective affiliates, beneficially own approximately 48.7% of our common stock. Accordingly, these stockholders have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

***Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.***

If our existing stockholders or holders of our options sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of May 1, 2020, there were a total of 32,838,515 shares of our common stock outstanding.

***Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of our operating expenses;
- receipt, modification or termination of government contracts or grants, and the timing of payments we receive under these arrangements;

- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make under these arrangements; and
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of the company's stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Provisions of our charter documents or Delaware law could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, and could make it more difficult for you to change management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that our stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our Board of Directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our Board of Directors to elect a director to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director;
- a requirement that special meetings of our Stockholders be called only by our Board of Directors, the chairman of our Board of Directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our Board of Directors to issue preferred stock with such terms as our Board of Directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns or within the last three years has owned 15% or more of the company's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of the company.

In addition, our amended and restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

This 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 any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Provisions in our charter and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

***We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.***

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund our operations. In addition, the terms of any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

***Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges or require us to change our compensation policies.***

Accounting methods and policies for biopharmaceutical companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock-based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this periodic report.

**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.**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Filed with this Report</b>	<b>Incorporated by Reference herein from Form or Schedule</b>	<b>Filing Date</b>	<b>SEC File/Reg. Number</b>
10.1	<a href="#">Amendment No. 1 to the Subscription Agreement dated as of April 1, 2020, by and between the Company and Ginkgo Bioworks, Inc.</a>	X			
31.1	<a href="#">Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>	X			
31.2	<a href="#">Certification of Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).</a>	X			
32.1*	<a href="#">Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).</a>	X			
32.2*	<a href="#">Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).</a>	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			

(\*) 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 Securities and Exchange Commission and are not to be incorporated by reference into any filing of Synlogic, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of such Form 10-Q), irrespective of any general incorporation language contained in such filing.



## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 8, 2020

SYNLOGIC, INC.

By: /s/ AOIFE BRENNAN

Aoife Brennan  
President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ GREGG BELOFF

Gregg Beloff  
Interim Chief Financial Officer  
(Principal Financial Officer and Principal Accounting  
Officer)

**Amendment No. 1 to**  
**Subscription Agreement**

This Amendment No. 1 (this “**Amendment**”) to the Subscription Agreement dated as of June 11, 2019 (the “**Subscription Agreement**”), by and between Synlogic, Inc. (the “**Company**”), a Delaware corporation, and Ginkgo Bioworks, Inc. (the “**Purchaser**”), is made effective as of April 1, 2020, by and between Company and the Purchaser.

W I T N E S S E T H:

WHEREAS, the Purchaser and the Company entered into the Subscription Agreement pursuant to which the Company sold Securities to the Purchaser; and

WHEREAS, the Company and the Purchaser wish to revise Section 5.4 of the Subscription Agreement to clarify the parties’ intent and spirit of the arrangement.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Undefined Terms.** All capitalized terms not otherwise defined herein shall have the respective meanings ascribed to them in the Subscription Agreement.
2. **Amendment to the Subscription Agreement.** The Subscription Agreement is hereby amended as follows:
  - a. Section 5.4 of the Subscription Agreement is hereby amended and restated in its entirety as follows:

**“5.4 Use of Proceeds.** The Company will use the proceeds from the offering to progress and expand its pipeline, including initiating three new programs in the first six months following the Closing Date (the “**Initial Period**”) and six new programs in the 12 months following the Initial Period.”
3. **No Other Changes.** Except as specifically amended and modified hereby, the Subscription Agreement is and shall continue to be in full force and effect, and is hereby in all respects ratified and confirmed.
4. **Effectiveness.** This Amendment shall be effective as of the date first written above.
5. **Counterparts.** This Amendment may be executed in any number of counterparts, each of which shall be deemed to be an original as against any party whose signature appears thereon, and all of which shall together constitute one and the same instrument. This Amendment shall become binding when one or more counterparts thereof, individually or taken together, shall bear the signatures of all of the parties reflected hereon as the signatories.
6. **Captions.** The captions to the sections and paragraphs of this Amendment are for the convenience of the parties only and are not part of this Amendment.

**[Signature Page Follows]**

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**IN WITNESS WHEREOF**, the parties hereto have caused this Amendment to the Subscription Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**SYNLOGIC, INC.**

/s/ AOIFE BRENNAN

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Name: Aoife Brennan  
Title: President & CEO

Address for Notice:  
Synlogic, Inc.  
301 Binney St, Suite 402  
Cambridge, MA 02139

Email: [Contracts@synlogictx.com](mailto:Contracts@synlogictx.com)  
Attention: Legal Department

With a copy to (which shall not constitute notice):

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**PURCHASER:**

**GINKGO BIOWORKS, INC.:**

/s/ JASON KELLY

Name: Jason Kelly

Title: CEO

**CERTIFICATION PURSUANT  
TO RULES 13a-14(a) OR 15d-14(a) UNDER  
THE SECURITIES EXCHANGE ACT OF 1934**

I, Aoife Brennan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Synlogic, Inc. (the “registrant”);
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 registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 8, 2020

/s/ AOIFE BRENNAN

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Aoife Brennan  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

**CERTIFICATION PURSUANT  
TO RULES 13a-14(a) OR 15d-14(a) UNDER  
THE SECURITIES EXCHANGE ACT OF 1934**

I, Gregg Beloff, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Synlogic, Inc. (the “registrant”);
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 registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 8, 2020

/s/ GREGG BELOFF

Gregg Beloff

*Interim Chief Financial Officer*

*(Principal Financial Officer and Principal Accounting Officer)*

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

In connection with the Quarterly Report of Synlogic, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Aoife Brennan, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

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

/s/ AOIFE BRENNAN

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Aoife Brennan  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

May 8, 2020

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

**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 of Synlogic, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gregg Beloff, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

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

/s/ GREGG BELOFF

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Gregg Beloff  
*Interim Chief Financial Officer*  
*(Principal Financial Officer and Principal Accounting Officer)*

May 8, 2020

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.