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 June 30, 2021

☐ **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	**26-1824804**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
301 Binney St., Suite 402 Cambridge, MA	**02142**
(Address of principal executive offices)	**(Zip Code)**

(617) 401-9975
(Registrant's telephone number, including area code)

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

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of August 5, 2021, there were 52,373,311 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.

SYNLOGIC, INC.

QUARTERLY REPORT ON FORM 10-Q

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SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Balance Sheets

(In thousands, except share amounts)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 29,244	$ 32,507
Short-term marketable securities	86,218	67,937
Accounts receivable	1,000	—
Prepaid expenses and other current assets	6,219	6,402
Total current assets	122,681	106,846
Property and equipment, net	9,928	10,776
Right of use asset - operating lease	15,008	15,527
Restricted cash	1,097	1,097
Prepaid research and development, net of current portion	8,164	9,590
Other assets	6	4
Total assets	$ 156,884	$ 143,840
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,121	$ 1,995
Accrued expenses	3,615	3,773
Deferred revenue	904	—
Lease liability - operating lease	2,982	2,531
Finance lease obligations	11	2
Total current liabilities	9,633	8,301
Long-term liabilities:		
Lease liability - operating lease, net of current portion	19,018	20,273
Finance lease obligations, net of current portion	24	—
Other long-term liabilities	131	131
Total long-term liabilities	19,173	20,404
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.001 par value		
250,000,000 shares authorized as of June 30, 2021 and December 31, 2020. 52,375,344 shares issued and outstanding as of June 30, 2021 and 38,183,273 shares issued and outstanding as of December 31, 2020.	52	38
Additional paid-in capital	387,782	345,394
Accumulated other comprehensive income	11	14
Accumulated deficit	(259,767)	(230,311)
Total stockholders' equity	128,078	115,135
Total liabilities and stockholders' equity	$ 156,884	$ 143,840

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

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Revenue	$ 246	$ 445	$ 246	$ 545
Operating expenses:				
Research and development	10,719	12,909	21,899	25,586
General and administrative	4,061	3,473	7,912	7,294
Total operating expenses	14,780	16,382	29,811	32,880
Loss from operations	(14,534)	(15,937)	(29,565)	(32,335)
Other income (expense):				
Interest and investment income	50	406	110	980
Interest expense	(1)	(2)	(1)	(5)
Other expense	—	(2)	—	(3)
Other income (expense), net	49	402	109	972
Net loss	$ (14,485)	$ (15,535)	$ (29,456)	$ (31,363)
Net loss per share - basic and diluted	$ (0.28)	$ (0.44)	$ (0.63)	$ (0.91)
Weighted-average common stock outstanding - basic and diluted	52,049,424	34,967,761	46,876,216	34,604,738
Comprehensive loss:				
Net loss	$ (14,485)	$ (15,535)	$ (29,456)	$ (31,363)
Net unrealized (loss) gain on marketable securities	6	159	(3)	104
Comprehensive loss	$ (14,479)	$ (15,376)	$ (29,459)	$ (31,259)

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

SYNLOGIC, 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				
				For the Three Months Ended June 30, 2021		
Balance at March 31, 2021	40,873,526	$ 41	$ 354,286	$ 5	$ (245,282)	$ 109,050
Proceeds from issuance of common stock, net of issuance costs	11,500,000	11	32,564	—	—	32,575
Exercise of options	31,897	—	64	—	—	64
Restricted stock awards withheld for payment of employees' withholding tax liability	(2,217)	—	(8)			(8)
Cancellation of restricted stock	(27,862)	—	—	—	—	—
Equity-based compensation expense	—	—	876	—	—	876
Unrealized gain (loss) on securities	—	—	—	6	—	6
Net loss	—	—	—	—	(14,485)	(14,485)
Balance at June 30, 2021	52,375,344	$ 52	$ 387,782	$ 11	$ (259,767)	$ 128,078
				For the Three Months Ended June 30, 2020		
Balance at March 31, 2020	32,459,394	$ 33	$ 328,995	$ 55	$ (186,966)	$ 142,117
Proceeds from issuance of common stock in connection with ATM offering, net of issuance costs	1,778,982	1	3,855	—	—	3,856
Cancellation of restricted stock	(93,265)	—	—	—	—	—
Equity-based compensation expense	—	—	1,075	—	—	1,075
Unrealized gain (loss) on securities	—	—	—	159	—	159
Net loss	—	—	—	—	(15,535)	(15,535)
Balance at June 30, 2020	34,145,111	$ 34	$ 333,925	$ 214	$ (202,501)	$ 131,672
				For the Six Months Ended June 30, 2021		
Balance at December 31, 2020	38,183,273	$ 38	$ 345,394	$ 14	$ (230,311)	$ 115,135
Proceeds from issuance of common stock in connection with ATM offering, net of issuance costs	2,447,211	3	8,047	—	—	8,050
Proceeds from issuance of common stock, net of issuance costs	11,500,000	11	32,564			32,575
Exercise of options	32,113	—	64	—	—	64
Issuance of restricted stock	242,454	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	19,061	—	33	—	—	33
Restricted stock awards withheld for payment of employees' withholding tax liability	(18,187)	—	(73)	—	—	(73)
Cancellation of restricted stock	(30,581)	—	—	—	—	—
Equity-based compensation expense	—	—	1,753	—	—	1,753
Unrealized gain (loss) on securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(29,456)	(29,456)
Balance at June 30, 2021	52,375,344	$ 52	$ 387,782	$ 11	$ (259,767)	$ 128,078
				For the Six Months Ended June 30, 2020		
Balance at December 31, 2019	32,266,814	$ 33	$ 327,900	$ 110	$ (171,138)	$ 156,905
Proceeds from issuance of common stock in connection with ATM offering, net of issuance costs	1,778,982	1	3,855	—	—	3,856
Issuance of restricted stock	226,335	—	—	—	—	—
Cancellation of restricted stock	(127,020)	—	—	—	—	—
Equity-based compensation expense	—	—	2,170	—	—	2,170
Unrealized gain (loss) on securities	—	—	—	104	—	104
Net loss	—	—	—	—	(31,363)	(31,363)
Balance at June 30, 2020	34,145,111	$ 34	$ 333,925	$ 214	$ (202,501)	$ 131,672

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

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Cash Flows

(In thousands)

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash flows from operating activities:		
Net loss	$ (29,456)	$ (31,363)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,232	1,326
Equity-based compensation expense	1,753	2,170
Accretion/amortization of investment securities	184	(29)
Reduction in carrying amount of operating lease right of use asset	979	848
Changes in operating assets and liabilities:		
Accounts receivable	(1,000)	—
Prepaid expenses and other current assets	183	582
Prepaid research and development, net of current portion	1,426	8,849
Accounts payable and accrued expenses	(260)	(2,524)
Deferred revenue	904	(544)
Operating lease liabilities	(1,264)	(864)
Other long-term liabilities	—	82
Other assets	(2)	—
Net cash used in operating activities	(25,321)	(21,467)
Cash flows from investing activities:		
Purchases of marketable securities	(74,010)	(35,744)
Proceeds from maturity of marketable securities	54,272	43,732
Proceeds from redemption of marketable securities	1,270	15,247
Purchases of property and equipment	(123)	(320)
Net cash (used in) provided by investing activities	(18,591)	22,915
Cash flows from financing activities:		
Payments on finance lease obligations	(3)	(138)
Proceeds from issuance of common stock, net of issuance costs	32,578	—
Proceeds from issuance of common stock in connection with at-the-market offering, net of issuance costs	8,050	3,856
Proceeds from employee stock purchases and exercise of stock options	97	—
Payment of employee withholding taxes relating to restricted stock awards	(73)	—
Net cash provided by financing activities	40,649	3,718
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,263)	5,166
Cash, cash equivalents and restricted cash at beginning of period	33,604	27,281
Cash, cash equivalents and restricted cash at end of period	$ 30,341	$ 32,447
Supplemental disclosure of non-cash investing activities:		
Assets acquired under operating lease obligation	$ 460	$ —
Property and equipment purchases included in accounts payable and accrued expenses	$ 225	$ 41
Supplemental disclosure of non-cash financing activities:		
Purchase under finance lease	$ 36	$ —
Issuance costs included in accounts payable and accrued expenses	$ 3	$ 10
Cash paid for interest	$ 1	$ 5

The accompanying notes are an integral part of the 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 the drug discovery and development of Synthetic Biotic™ medicines. Synthetic Biotic medicines are generated from Synlogic's proprietary drug discovery and development platform, leveraging a reproducible, modular approach to synthetic biology to develop beneficial microbes, which perform or deliver critical therapeutic functions. Synthetic Biotic medicines are designed to metabolize a toxic substance or compensate for missing or damaged metabolic pathways. Synlogic's goal is to discover, develop and ultimately commercialize Synthetic Biotic medicines. Since incorporation, the Company has devoted substantially all of its efforts to the research and development of its product candidates.

On August 28, 2017, Synlogic, Inc., formerly known as Mirna Therapeutics, Inc. (NASDAQ: MIRN) ("Mirna"), completed a business combination with Synlogic, a private company, pursuant to the Agreement and Plan of Merger and Reorganization, dated as of May 15, 2017 (the "Merger Agreement"), pursuant to which the private Synlogic entity survived 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 June 30, 2021, the Company had approximately $115.5 million in cash, cash equivalents, and short-term marketable securities, $1.1 million of restricted cash and an accumulated deficit of approximately $259.8 million. Since its inception through June 30, 2021, 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.

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, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission ("SEC") on March 25, 2021 (the "2020 Annual Report"), have had no material changes during the three and six months ended June 30, 2021.

Basis of Presentation

The accompanying consolidated financial statements and the related disclosures as of June 30, 2021 and for the three and six months ended June 30, 2021 and 2020 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 2020 and 2019 audited consolidated financial statements and notes included in the Company's 2020 Annual Report. The December 31, 2020 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 and six months ended June 30, 2021 and 2020. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2021 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 Adopted Accounting Pronouncements

In October 2020, the FASB issued an amendment, ASU 2020-08, *Codification Improvements to Subtopic 310-20, Receivables – Nonrefundable Fees and Other Costs*, to the guidance in ASU 2017-08, *Receivables-Nonrefundable Fees and Other Costs (Subtopic 310-20): Premium Amortization on Purchased Callable Debt Securities.* The amendment requires companies to reevaluate whether a callable debt security that has multiple call dates is within the scope of paragraph 310-20-65-2. The amendment shall be effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted the new guidance effective on January 1, 2021 which had an immaterial impact on its consolidated financial statements.

Recently Issued 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.

In May 2021, the FASB issued Accounting Standards Update 2021-04—*Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The standard provides a principles-based framework to determine whether an issuer should recognize the modification or exchange as an adjustment to equity or an expense. The Company is currently evaluating the potential impact ASU 2021-04 will have on its consolidated financial statements and disclosures.

The Company has evaluated other recently issued accounting pronouncements and has concluded that that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

(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 2020 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 June 30, 2021 and December 31, 2020, the Company has classified assets measured at fair value on a recurring basis as follows (in thousands):

		Fair Value Measurements at Reporting Date Using		
Description	June 30, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 29,243	$ 29,243	$ —	$ —
Commercial paper	67,959	—	67,959	—
Corporate debt securities	9,481	—	9,481	—
U.S. government agency securities and treasuries	8,778	8,778	—	—
Total	$ 115,461	$ 38,021	$ 77,440	$ —

		Fair Value Measurements at Reporting Date Using		
Description	December 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	$ 32,506	$ 32,506	$ —	$ —
Commercial paper	40,477	—	40,477	—
Corporate debt securities	18,637	—	18,637	—
U.S. government agency securities and treasuries	8,823	8,823	—	—
Total	$ 100,443	$ 41,329	$ 59,114	$ —

Cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses at June 30, 2021 and December 31, 2020 are carried at amounts that approximate fair value due to their short-term maturities. Finance lease obligations at June 30, 2021 and December 31, 2020 approximate fair value as they bear interest at a rate approximating a market interest rate.

(4) Available-for-Sale Investments

The following tables summarize the available-for-sale securities held at June 30, 2021 and December 31, 2020 (in thousands):

June 30, 2021	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Commercial paper	$ 67,947	$ 13	$ (1)	$ 67,959
Corporate debt securities	9,484	—	(3)	9,481
U.S. government agency securities	8,776	2	—	8,778
Total	$ 86,207	$ 15	$ (4)	$ 86,218

December 31, 2020	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Commercial paper	$ 40,467	$ 11	$ (1)	$ 40,477
Corporate debt securities	18,634	4	(1)	18,637
U.S. government agency securities	8,822	1	—	8,823
Total	$ 67,923	$ 16	$ (2)	$ 67,937

The contractual maturity of all securities held at June 30, 2021 was ten months or less. There were five and eight investments in an unrealized loss position at June 30, 2021 and December 31, 2020, respectively, 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 June 30, 2021 and December 31, 2020 was $15.5 million and $20.1 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 June 30, 2021.

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):

	June 30, 2021	December 31, 2020
Laboratory equipment	$ 7,871	$ 7,793
Computer and office equipment	769	769
Furniture and fixtures	421	421
Leasehold improvements	9,514	9,514
Construction in progress	823	528
	19,398	19,025
Less accumulated depreciation	(9,470)	(8,249)
	$ 9,928	$ 10,776

(6) Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Payroll related	$ 2,248	$ 3,005
Professional fees	475	215
Research and development	647	230
Other	245	323
	$ 3,615	$ 3,773

(7) Stockholders' Equity

In June 2019, the Company issued to Ginkgo Bioworks, Inc. ("Ginkgo") 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. None of the Pre-Funded Warrants have been exercised as of June 30, 2021.

On October 13, 2017 the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") with respect to an at-the-market ("ATM") offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, through Cowen as its sales agent. In an ATM offering, exchange-listed companies incrementally sell newly issued shares into the secondary trading market through a designated broker-dealer at prevailing market prices. During the three months ended June 30, 2021, no shares of common stock were sold pursuant to the ATM. During the six months ended June 30, 2021, 2,447,211 shares of common stock were sold pursuant to the ATM, resulting in net proceeds of approximately $8.1 million.

The Company has reserved for future issuance the following shares of common stock related to the potential exercise of Pre-Funded Warrants, exercise of stock options, and the employee stock purchase plan:

	June 30, 2021
Common stock issuable under pre-funded warrants	2,548,117
Options exercisable to purchase common stock	1,807,951
Employee Stock Purchase Plan	20,480
Total	4,376,548

(8) Equity-based Compensation and Equity Incentive Plans

Equity Plans

The Company currently has three active equity plans.

Pursuant to the evergreen provision of the 2015 Equity Incentive Award Plan (the "2015 Plan"), which allows for an annual increase in the number of shares of common stock available for issuance, the Company added 1,909,163 shares to the 2015 Plan on January 1, 2021.

Pursuant to the evergreen provision of the 2015 Employee Stock Purchase Plan ("ESPP"), which allows for an annual increase in the number of shares of common stock available for issuance, the Company added 381,832 shares to the ESPP on January 1, 2021. There were no options exercised to purchase shares of common stock under the ESPP during the three months ended June 30, 2021 and 19,061 options were exercised during the six months ended June 30, 2021.

As of June 30, 2021, there were an aggregate of 1,633,453 shares available for future grant under the 2017 Stock Incentive Plan (the "2017 Plan") and the 2015 Plan, and 708,433 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 2020 Annual Report.

Stock Options

The following table summarizes stock option activity during the six months ended June 30, 2021.

	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, 2020	3,343,836	$ 6.00	8.4	$ 399
Granted	1,642,296	3.52		
Exercised	(32,113)	2.06		
Cancelled/Forfeited	(348,305)	4.67		
Outstanding at June 30, 2021	4,605,714	5.25	8.5	3,475
Vested or expected to vest at June 30, 2021	4,605,714	5.25	8.5	$ 3,475
Exercisable at June 30, 2021	1,807,951	7.89	7.5	$ 998

(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 June 30, 2021 and December 31, 2020. 3,100,835 and 970,826 options were in the money at June 30, 2021 and December 31, 2020, respectively.

As of June 30, 2021, there was $6.5 million of unrecognized share-based compensation related to unvested stock option grants which is expected to be recognized over a weighted average period of 2.6 years. The total unrecognized share-based compensation cost will be adjusted for actual forfeitures as they occur.

Restricted Common Stock

The following table shows restricted stock activity during the six months ended June 30, 2021:

	Restricted stock awards	
	Number of shares	Weighted average grant date fair value (per share)
Unvested at December 31, 2020	478,207	$ 2.19
Granted	242,454	3.50
Vested	(343,619)	2.39
Forfeited	(30,581)	2.88
Unvested at June 30, 2021	346,461	$ 2.86

As of June 30, 2021, there was approximately $0.9 million of unrecognized share-based compensation related to restricted stock awards granted, which is expected to be recognized over a weighted average period of 3.5 years. The total unrecognized share-based compensation cost will be adjusted for actual forfeitures as they occur.

Employee Stock Purchase Plan

The ESPP is considered a compensatory plan with the related compensation cost expensed over the six-month offering periods. The compensation cost for the three and six months ended June 30, 2021 was $14,000 and $20,000, respectively. The compensation expense related to the ESPP for the three and six months ended June 30, 2020 was $12,000.

Equity Compensation

The Company has recorded total equity-based compensation expense of approximately $0.9 million and $1.8 million during the three and six months ended June 30, 2021, respectively and $1.1 million and $2.2 million during the three and six months ended June 30, 2020, respectively.

The following table summarizes equity-based compensation expense within the Company's consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 359	$ 486	$ 774	$ 927
General and administrative	517	589	979	1,243
	$ 876	$ 1,075	$ 1,753	$ 2,170

The following table summarizes equity-based compensation expense by type of award for the three and six months ended June 30, 2021 and 2020 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	$ 800	$ 890	$ 1,499	$ 1,765
Restricted stock awards	62	173	234	393
Employee stock purchase plan	14	12	20	12
	$ 876	$ 1,075	$ 1,753	$ 2,170

(9) Collaboration Agreements

Roche Collaboration

In June 2021, the Company entered into a Pilot Collaboration and Option Agreement (the "Roche Collaboration and Option Agreement") with F. Hoffmann-La Roche Ltd ("Roche Basel") and Hoffmann-La Roche Inc. ("Roche US", and together with Roche Basel, "Roche"). Under the terms of the Roche Collaboration and Option Agreement, the Company and Roche will seek to collaborate

to research and pre-clinically develop a Synthetic Biotic medicine for addressing an undisclosed novel target for the treatment of inflammatory bowel disease (the "Product Candidate").

Pursuant to the Roche Collaboration and Option Agreement, Roche agreed to pay the Company, an upfront, nonrefundable technology access fee of $1.0 million, which the Company received in July 2021. In addition, the Company is eligible to receive up to $5.0 million in milestone payments upon the achievement of certain success criteria. Following the research period, Roche holds an exclusive option right (the "Option") to negotiate a definitive Collaboration and License Agreement ("CLA") for further development and commercialization of the Product Candidate.

Pursuant to the Roche Collaboration and Option Agreement, during the term of such agreement, each party has granted to the other party a non-exclusive, non-transferrable, non-sublicensable, royalty-free right and license to certain intellectual property and know-how controlled by such party, solely as necessary for the party to perform its obligations under the Roche Collaboration and Option Agreement. The parties will establish a Joint Research Committee ("JRC") to oversee and manage the execution of the underlying study plan for the Roche Collaboration and Option Agreement.

The Roche Collaboration and Option Agreement includes various representations, warranties, covenants, indemnities, and other customary provisions. Roche may terminate the Roche Collaboration and Option Agreement without cause immediately upon written notice where certain success criteria have been met for parts of the study plan, or upon ninety (90) days' prior written notice to the Company. Either party may terminate the Roche Collaboration and Option Agreement in the event of an uncured material breach of the other party.

The research and development will be performed by the Company for approximately 12 to 18 months according to three phases of research as defined in the research plan. The Company is eligible to receive milestone payments from Roche upon the achievement of success criteria for respective milestones.

The Company assessed this arrangement in accordance with ASC 606, *Revenue from Contracts with Customers*, and concluded that the contract counterparty, Roche, is a customer. The Company identified the following material promises made by the Company to Roche 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; (3) implicit renewal options created by Roche's decision not to terminate the contract; (4) the Company's participation on the JRC; and (5) an exclusive right to negotiate a definitive CLA for further development and commercialization of the Product Candidate. The Company determined that the license and research and development activities were not distinct from one another, as the license has limited value without the performance of research and development activities. The Company's participation on the JRC was determined to be quantitatively and qualitatively immaterial and therefore is excluded from performance obligations. As such, the Company determined that the promises associated with the license and research and development services should be combined into a single performance obligation.

The Company next evaluated the milestone payments relating to the three phases of research as defined in the research plan and the option to negotiate and enter into the CLA, to determine whether they provide Roche with any material rights. The Company concluded that the option was 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 Roche 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 Roche Collaboration and Option Agreement, which consists of: (1) the non-exclusive license and (2) the research and development activities.

At the outset of the arrangement, the transaction price included only the $1.0 million up-front consideration received and which was allocated to the single performance obligation. The milestone payments that may be received are excluded from the transaction price until each respective milestone has been achieved. The Company will reevaluate 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 June 2021, the Company began work on the research and development services for the first phase of the research plan and the $1.0 million upfront payment is being recognized over the time of the first phase of the research plan. Upon the Company's completion of these activities and subject to Roche's termination right, the additional milestone payments based on the achievement of specific events outlined in the Roche Collaboration and Option Agreement will become due.

Revenue associated with performance obligations under the Roche Collaboration and Option Agreement are 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.

For the three and six months ended June 30, 2021, the Company recognized revenue of $0.2 million, as collaboration revenue in the Company's consolidated statements of operations and comprehensive loss. Deferred revenue from the collaboration amounted to $0.8 million as of June 30, 2021, all of which is included in current liabilities.

Ginkgo Collaboration

In 2017, the Company established a technology collaboration with Ginkgo. 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 (See Note 7). 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 June 30, 2021 consolidated balance sheet. At June 30, 2021, the Company had remaining balances of $4.5 million and $7.5 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.

AbbVie Collaboration Agreement

In May 2020, we announced the termination of our collaboration with AbbVie to develop Synthetic Biotic medicines for the treatment of types of IBD, including Crohn's disease and ulcerative colitis. Upon termination, we regained all rights to develop these and new IBD Synthetic Biotic medicines for all effectors targeting IBD. This allows us to fully leverage our expertise in strain engineering, quantitative biology, regulatory, and manufacturing to expand our wholly owned GI-based program portfolio to include IBD. We further regained the rights to partner these IBD programs.

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

The Company recognized no revenue for the three months ended June 30, 2021 and $0.4 million for the corresponding period in 2020. There is no deferred revenue on the Company's consolidated balance sheet related to the AbbVie collaboration as of June 30, 2021, as the remainder of the revenue was recognized when the agreement was terminated.

(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 2020 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.

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 June 30,	
	2021	2020
Unvested restricted common stock awards	346,461	669,140
Outstanding options to purchase common stock	4,605,714	3,176,092
Potential shares issuable under the ESPP	10,240	—

(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, 2020 and the notes thereto included in the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2021, have had no material changes during the six months ended June 30, 2021.

(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 June 30, 2021, 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 2020 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 June 30, 2021, the Company had remaining balances of $4.5 million and $7.5 million of current and non-current pre-paid research and development costs related to this transaction, respectively. The Company used $0.7 million and $1.6 million of the pre-paid research and development expenses for the three and six months ended June 30, 2021, respectively.

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, 2020 and 2019 included in our Annual Report on Form 10-K filed with the SEC on March 25, 2021 (the "2020 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 [26] 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

Synlogic is a clinical-stage biopharmaceutical company focused on the discovery and development of Synthetic Biotic™ medicines. Synthetic Biotic medicines are generated from Synlogic's proprietary drug discovery and development platform, leveraging a reproducible, modular approach to synthetic biology to develop beneficial microbes which perform or deliver critical therapeutic functions. Synthetic Biotic medicines are designed to metabolize a toxic substance, compensate for missing or damaged metabolic pathways, or deliver combinations of therapeutic factors. Synlogic's goal is to discover, develop, and ultimately commercialize Synthetic Biotic medicines. Synlogic's proprietary pipeline includes Synthetic Biotic medicines for the treatment of metabolic disorders including Phenylketonuria (PKU) and Enteric Hyperoxaluria. We are building a portfolio of partner-able assets in immunology and oncology.

We have established proof of mechanism in healthy volunteers for both of our co-lead Synthetic Biotic medicines for the treatment of metabolic disorders, SYNB1618 for the treatment of PKU and SYNB8802 for the treatment of Enteric Hyperoxaluria. Studies in patients for both programs are ongoing.

In Phase 1 clinical trials of SYNB1618, we demonstrated consumption of phenylalanine (Phe) and production of strain specific biomarkers of activity in both healthy volunteers and patients. We are currently executing a Phase 2 clinical trial of SYNB1618 in patients with PKU. The buildup of Phe in patients with PKU can lead to serious health problems, including severe neurocognitive complications. Patients have few approved therapies today.

In a Phase 1 clinical trial of SYNB8802, we demonstrated consumption of oxalate in healthy volunteers placed on a high oxalate, low calcium diet to induce temporary Dietary Hyperoxaluria. We are currently executing a clinical trial of SYNB8802 in patients with Enteric Hyperoxaluria. The absorption of oxalate in patients with Enteric Hyperoxaluria leads to dangerously high levels of urinary oxalate and potentially severe renal complications. Patients have no approved therapies today.

Core Capabilities

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 our Synthetic Biotic platform has potential to address a broad range of diseases, our initial pipeline focus is on metabolic diseases. We will consider leveraging partnerships to advance programs for other diseases including oncology and inflammatory disorders. Our most advanced programs target 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, 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 or urinary 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.

Metabolic Programs

Phenylketonuria

Our most advanced product candidate is SYNB1618, an oral therapy intended for the treatment of PKU, a rare metabolic disease in which an amino acid known as phenylalanine (Phe) accumulates in the body. Elevated levels of Phe are toxic to the brain and can lead to neurological and cognitive deficits. SYNB1618 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. SYNB1618 has received both Fast Track designation and orphan drug designation for PKU from the U.S. Food and Drug Administration (FDA).

We completed a Phase 1/2a clinical trial of an early liquid formulation of SYNB1618 and announced top-line data from healthy volunteers evaluated in this study in September 2018. In July 2019, we announced data that demonstrated that SYNB1618 was safe and well-tolerated and achieved proof-of-mechanism of strain activity in both healthy volunteers and patients with PKU. Following the study using the liquid formulation, we developed a lyophilized formulation of SYNB1618. We have evaluated this lyophilized formulation in a bridging study in healthy volunteers. The study of this more patient- and commercialization-appropriate presentation of SYNB1618 demonstrated activity and improved tolerability over the early liquid formulation.

We initiated a Phase 2 clinical trial with SYNB1618 in the third quarter of 2020, referred to as the SynPheny-1 Study. The SynPheny-1 Study is designed to evaluate safety and tolerability of a solid oral formulation of SYNB1618 as well as its potential to lower blood Phe levels in adult PKU patients. The SynPheny-1 Study is constructed to be flexible, with subjects physically coming to the clinic or participating from their homes utilizing home healthcare services.

SYNB1618 is a member of a family of SYNB strains that consume Phe. We have an additional Phe consuming strain for PKU in development, called SYNB1934.

Enteric Hyperoxaluria

Enteric Hyperoxaluria is an acquired metabolic disorder. Enteric Hyperoxaluria is caused by increased absorption of dietary oxalate. The disorder may cause dangerously high levels of urinary oxalate and progressive kidney damage, kidney stone formation, and nephrocalcinosis. Oxalate is present in many healthy foods such as leafy greens, nuts, and chocolate, making it difficult to control with dietary interventions. Enteric Hyperoxaluria often occurs as a result of a primary insult to the bowel, such as inflammatory bowel disease, short bowel syndrome, or surgical procedures such as Roux-en-Y bariatric weight-loss surgery. There are no approved treatments.

In May 2020, we announced the nomination of a clinical candidate for Enteric Hyperoxaluria, SYNB8802. We initiated a Phase 1 clinical trial of SYNB8802 in the fourth quarter of 2020. This study will assess the safety, tolerability and kinetics of SYNB8802 as well as the effect SYNB8802 has on changes in plasma and urine biomarkers of strain activity, and the potential to reduce urinary oxalate. The study has two parts: Part A is a multiple ascending dose study in healthy volunteers in whom we will induce temporary hyperoxaluria via diet; and Part B is a placebo controlled, cross-over design study in patients with Enteric Hyperoxaluria following Roux-n-Y gastric bypass surgery.

We announced results of Part A of the Phase 1 study in March 2021. SYNB8802 achieved proof of mechanism and was advanced to Part B of the study. SYNB8802 was generally well tolerated in healthy volunteers. There were no serious or systemic adverse events. Dose responsive changes in urinary oxalate levels were observed with a significant reduction in urinary oxalate relative to placebo across three dose levels, one of which was selected as the Part B dose. Full results of the study will be presented at a future medical meeting.

Other Metabolic Programs

We are leveraging the capabilities built in the development of our PKU and Enteric Hyperoxaluria programs to design and pre-clinically develop Synthetic Biotic medicines for other inherited and acquired metabolic disorders with high levels of unmet medical need.

Immuno-modulation Programs

Oncology

We have also developed a portfolio of Synthetic Biotic medicines designed to modify the tumor microenvironment and result in tumor reduction, intended for use in combination with other cancer therapies such as checkpoint inhibitors. Our first immuno-oncology ("IO") candidate is SYNB1891, an intratumorally administered Synthetic Biotic medicine. SYNB1891 is 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 (STING) pathway. In January 2020, we treated the first subject in a Phase 1 clinical trial of SYNB1891 in patients with advanced solid tumors and lymphoma. The clinical trial is designed to identify a maximum tolerated dose (MTD) of SYNB1891 delivered as a monotherapy and a recommended Phase 2 dose in combination therapy with the checkpoint inhibitor atezolizumab (Tecentriq), provided through a supply agreement with Roche. We released interim data from the ongoing monotherapy arm of this trial in December 2020, which demonstrated target engagement and production of biomarkers consistent with STING activation. In December 2020, we also initiated the combination arm of the Phase 1 clinical trial.

Auto-Immune Disorders

We are also designing and developing Synthetic Biotic medicines to treat auto-immune and inflammatory disorders. To achieve this goal, we plan to collaborate with leading drug development organizations.

Inflammatory bowel disease (IBD) is an attractive target for our technology as Synthetic Biotic medicines can be designed to locally deliver to the gut therapeutic effectors or combinations of effectors to potentially address the unmet medical need in patients suffering from IBD. In May 2020, we announced the termination of our collaboration with AbbVie S.à.r.l. ("AbbVie") to develop Synthetic Biotic medicines for the treatment of IBD. Upon termination, we regained all rights to develop these and new IBD Synthetic Biotic medicines for all effectors targeting IBD.

In June 2021, we entered into entered into a Pilot Collaboration and Option Agreement (the "Roche Collaboration and Option Agreement") with F. Hoffmann-La Roche Ltd ("Roche Basel") and Hoffmann-La Roche Inc. ("Roche US", and together with Roche Basel, "Roche"). Under the terms of the Roche Collaboration and Option Agreement, we and Roche will seek to collaborate to research and pre-clinically develop a Synthetic Biotic medicine for addressing an undisclosed novel target for the treatment of inflammatory bowel disease (the "Product Candidate").

Pursuant to the Roche Collaboration and Option Agreement, Roche agreed to pay us, an upfront, nonrefundable technology access fee of $1.0 million, which we received in July 2021. In addition, we are eligible to receive up to $5.0 million in milestone payments upon the achievement of certain success criteria. Following the research period, Roche holds an exclusive option right (the "Option") to negotiate a definitive Collaboration and License Agreement (CLA) for further development of the Product Candidate.

Pursuant to the Roche Collaboration and Option Agreement, during the term of such agreement, each party has granted to the other party a non-exclusive, non-transferrable, non-sublicensable, royalty-free right and license to certain intellectual property and know-how controlled by such party, solely as necessary for the party to perform its obligations under the Roche Collaboration and Option Agreement. The parties will establish a Joint Research Committee (JRC) to oversee and manage the execution of the underlying study plan for the Roche Collaboration and Option Agreement.

We continue to design and develop additional Synthetic Biotic medicines in IBD, utilizing our expertise in strain engineering, quantitative biology, regulatory, and manufacturing. We retain all rights to these programs and may enter into additional strategic partnerships in the future to maximize the clinical and commercial value of our programs and our Synthetic Biotic platform.

Summary

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 June 30, 2021, we have received approximately $377.3 million in proceeds as we financed our operations primarily through the sale of preferred stock, common stock, preferred units, warrants, payments received under the AbbVie collaboration agreement, interest earned on investments, and cash received in the Merger.

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 $14.5 million and $29.5 million for the three and six months ended June 30, 2021, respectively and $15.5 million and $31.4 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of approximately $259.8 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 or manufacture product candidates internally;
- 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, commercial, 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.

Impact of the COVID-19 pandemic on our business

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, and 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. Our ability to enroll our clinical trials will be dependent on many factors, including the progression of the pandemic and its impact on patients and the investigators at our clinical trial sites. We are actively working with sites and investigators to mitigate these risks. We continue to carefully monitor the situation with respect to each of our clinical trials and follow guidance from local and federal health authorities.

Financial Overview

Revenue

Revenue for the three months ended June 30, 2021 was generated from our collaboration agreement with Roche. In June 2021, we announced that we entered into the Roche Collaboration and Option Agreement for the discovery of a novel Synthetic Biotic medicine for the treatment of inflammatory bowel disease (IBD). The collaboration agreement contains multiple deliverables, which include an exclusive option for Roche to negotiate a definitive collaboration and license agreement (CLA) for further development of the Product Candidate and acquire research and development milestones. See Note 9, *Collaboration Agreements: Roche 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.

Revenue generated prior to June 30, 2021 was from our collaboration agreement with AbbVie. In May 2020, we announced the termination of our collaboration with AbbVie. Upon termination of the collaboration with AbbVie, we regained all rights to develop the IBD Synthetic Biotic medicines previously developed with AbbVie as well as new IBD Synthetic Biotic medicines for all effectors targeting IBD. Due to the termination of this Agreement, we do not expect further revenue from AbbVie. See Note 9, *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.

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;
- leased manufacturing space; 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 drug development candidates 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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
SYNB1618	$ 1,035	$ 2,068	$ 2,012	$ 5,702
SYNB1891	593	472	1,355	844
SYNB8802	673	107	2,414	107
SYNB1934	407	—	497	—
External pre-development candidate expenses and unallocated expenses	1,135	4,489	2,167	6,770
Internal research and development expenses	6,876	5,773	13,454	12,163
	$ 10,719	$ 12,909	$ 21,899	$ 25,586

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 general and administrative costs include the legal costs of pursuing patent protection of our intellectual property, facility and information technology infrastructure costs and professional fees for accounting and legal services. We anticipate that our general and administrative expenses will increase in the future as we support our continued research and development activities. We also anticipate continued expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services, costs for director and officer liability insurance, and costs associated with 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 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 2020 Annual Report. During the six months ended June 30, 2021, 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 June 30, 2021 Compared to Three Months Ended June 30, 2020

	For the Three Months Ended		Change
	June 30, 2021	June 30, 2020	$
	(in thousands)		
Revenue	$ 246	$ 445	$ (199)
Operating expenses:			
Research and development	10,719	12,909	(2,190)
General and administrative	4,061	3,473	588
Total operating expenses	14,780	16,382	(1,602)
Loss from operations	(14,534)	(15,937)	1,403
Other income (expense):			
Interest and investment income	50	406	(356)
Interest expense	(1)	(2)	1
Other expense	—	(2)	2
Other income (expense), net	49	402	(353)
Net loss	$ (14,485)	$ (15,535)	$ 1,050

Revenue

Revenue was $0.2 million for the three months ended June 30, 2021, as compared to $0.4 for the three months ended June 30, 2020. Revenue for the three months ended June 30, 2021 was related to services performed under the Roche collaboration. Revenue for the three months ended June 30, 2020 was related to services performed under the AbbVie collaboration. In May 2020, we announced the termination of our collaboration with AbbVie.

Operating Expenses

Research and Development Expense

Research and development expense was $10.7 million for the three months ended June 30, 2021 compared to $12.9 million in the corresponding period in 2020. The decrease in research and development expense was primarily due to a decrease of $5.0 million of nonclinical development costs, primarily related to SYNB1618. These decreases were partially offset by increases of $1.5 million of clinical development costs for our clinical programs, primarily related to SYNB8802, SYNB1618 and SYNB1934 and an increase of $1.0 million of compensation, benefits and other employee-related expense.

General and Administrative Expense

General and administrative expense was $4.1 million for the three months ended June 30, 2021 compared to $3.5 million for the corresponding period in 2020. The increase was primarily due to increases in professional services and corporate expenses.

Other Income (Expense)

Other income (expense) was $0.1 million for the three months ended June 30, 2021, compared to $0.4 million for the corresponding period in 2020. The decrease in other income (expense) of $0.3 million was related to lower interest income generated by our investment account.

Six Months Ended June 30, 2021 Compared to Six Months Ended June 30, 2020

	For the Six Months Ended		Change
	June 30, 2021	June 30, 2020	$
	(in thousands)		
Revenue	$ 246	$ 545	$ (299)
Operating expenses:			
Research and development	21,899	25,586	(3,687)
General and administrative	7,912	7,294	618
Total operating expenses	29,811	32,880	(3,069)
Loss from operations	(29,565)	(32,335)	2,770
Other income (expense):			
Interest and investment income	110	980	(870)
Interest expense	(1)	(5)	4
Other expense	—	(3)	3
Other income (expense), net	109	972	(863)
Net loss	$ (29,456)	$ (31,363)	$ 1,907

Revenue

Revenue was $0.2 million for the six months ended June 30, 2021 as compared to $0.5 million for the six months ended June 30, 2020. Revenue for the six months ended June 30, 2021 was related to services performed under the Roche collaboration. Revenue for the six months ended June 30, 2020 was related to services performed under the AbbVie collaboration. In May 2020, we announced the termination of our collaboration with AbbVie.

Operating Expenses

Research and Development Expense

Research and development expense was $21.9 million for the six months ended June 30, 2021 compared to $25.6 million in the corresponding period in 2020. The decrease in research and development expense was primarily due to a decrease of $8.3 million of nonclinical development costs, primarily related to SYNB1618, and decreases in clinical development costs of $0.2 million for SYNB1618. These decreases were partially offset by increases of $1.2 million of compensation, benefits and other employee-related expenses, and increased clinical development costs of $3.3 million for SYNB8802, SYNB1891and SYNB1934.

General and Administrative Expense

General and administrative expense was $7.9 million for the six months ended June 30, 2021 compared to $7.3 million for the corresponding period in 2020. The increase was primarily due to increases in consulting expenses, offset by decreases in compensation, benefits and other employee-related expenses, and headcount-related expenses.

Other Income (Expense)

Other income (expense) was $0.1 million for the six months ended June 30, 2021, compared to $1.0 million for the corresponding period in 2020. The decrease in other income (expense) of $0.9 million was related to a decrease in interest and investment income resulting from lower interest income generated by our investment account.

Liquidity and Capital Resources

We have incurred losses since our inception on March 14, 2014 and, as of June 30, 2021 we had an accumulated deficit of approximately $259.8 million. We have financed our operations to date primarily through the sale of preferred stock, common stock, preferred units, warrants, payments received under the AbbVie collaboration agreement, payments received under the technology collaboration with Ginkgo, interest earned on investments, and cash received in the Merger. At June 30, 2021, we had approximately $115.5 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, commercial paper 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 six months ended June 30, 2021, our cash, cash equivalents and marketable securities balance increased approximately $15.0 million. This increase was primarily due to the sale of our common stock in an underwritten public offering in April 2021 and proceeds from the sale of our common stock in the ATM offering program. These increases were offset by 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.

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):

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Net cash, cash equivalents and restricted cash (used in) provided by		
Operating activities	$ (25,321)	$ (21,467)
Investing activities	(18,591)	22,915
Financing activities	40,649	3,718
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (3,262)	$ 5,166

Cash Flows from Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was approximately $25.3 million for the six months ended June 30, 2021. The primary use of cash was our net loss of $29.5 million, which was partially offset by $4.1 million of non-cash items primarily including depreciation, equity-based compensation, and the right of use asset. There was a decrease in working capital, primarily related to decreases in prepaid research and development expenses, as a result of the work being completed on the Ginkgo collaboration, decreases in prepaid expenses and other current assets, decreases in accrued expenses, offset by increases in accounts payable, operating lease liability, and deferred revenue.

Net cash, cash equivalents and restricted cash used in operating activities was approximately $21.5 million for the six months ended June 30, 2020. The primary use of cash was our net loss of $31.4 million, which was partially offset by $4.3 million of non-cash items primarily including depreciation and equity-based compensation. There was an increase in working capital of $5.6 million, primarily related to decreases in prepaid research and development expenses, as a result of our June 2019 services agreement with Ginkgo, decreases in prepaid expenses and other current assets, decreases in accounts payable and accrued expenses, a decrease in operating lease liability, offset by a decrease in deferred revenue.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 was $18.6 million and resulted primarily from the proceeds from maturity of marketable securities of $54.3 million and proceeds from redemption of marketable securities of $1.3 million. This was offset by the purchases of marketable securities of $74.0 million and property and equipment of $0.1 million.

Net cash provided by investing activities for the six months ended June 30, 2020 was $22.9 million and resulted primarily from the proceeds from maturity of marketable securities of $43.7 million and proceeds from redemption of marketable securities of $15.2 million. This was offset by the purchases of marketable securities of $35.7 million and property and equipment of $0.3 million.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 totaled $40.6 million, primarily related to net proceeds of $32.6 million from the sale of our common stock in an underwritten public offering in April 2021, $8.0 million from the sale of our common stock in the ATM offering program and proceeds of $0.1 million from exercise of stock options and ESPP contributions, offset by payments of withholding taxes for employees relating to restricted stock awards.

Net cash provided by financing activities for the six months ended June 30, 2020 totaled $3.7 million related to net proceeds of $3.9 million from the sale of our common stock in the ATM offering program, offset by 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 are currently generating revenue from our Roche collaboration and have historically generated revenue from our AbbVie collaboration (which was terminated in May 2020), 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 June 30, 2021, 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 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 2020 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 "*Certain Relationships and Related Person Transactions"* in our proxy statement filed with the SEC on April 27, 2021.

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.

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-K, 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 June 30, 2021 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.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

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

- A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 may materially and adversely affect our business and our financial results.
- Even if we obtain regulatory approval for a product candidate, we will remain subject to ongoing regulatory requirements.
- 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.
- 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.
- 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 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.
- Ethical, legal and social concerns about synthetic biology and genetic engineering could limit or prevent the use of our technologies and limit our revenues. 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.
- We may not have sufficient patent term protections for our product candidates to effectively protect our business.
- 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.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- 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.
- We may be subject to claims challenging the inventorship of our patents and other intellectual property.
- We may not be able to protect our intellectual property rights throughout the world.
- 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 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 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.
- 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.
- We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than us.
- 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.
- 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 principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.
- Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.
- 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.
- 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.

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 $14.5 million and $29.5 million for the three and six months ended June 30, 2021, respectively and $15.5 million and 31.4 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2021, we had an accumulated deficit of approximately $259.8 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 SYNB1020 for treatment of hyperammonemia in patients with cirrhosis. Based on the data obtained in this clinical trial, the SYNB1020 program was discontinued in August 2019. In April 2018, we dosed our first subject in a Phase 1/2a clinical trial of SYNB1618 which is being developed for the treatment of patients with PKU. In January 2020, we announced that we had dosed the first subject in our Phase 1 clinical trial of SYNB1891 which is being developed for the treatment of patients with solid tumors and lymphoma. In November of 2020, we announced that we had initiated the Phase 2 clinical study of SYNB1618 and the Phase 1 study of SYNB8802. All of our other therapeutic programs are still in the preclinical or clinical development stage. We will need to transition from a company with a focus on research and clinical development to a company capable of 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 and clinical 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, SYNB1020, 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 SYNB1020 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 SYNB1618, SYNB8802 and SYNB1891 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 SYNB1618 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 coronavirus outbreak has affected segments of the global economy and may materially affect our operations, including potentially significant interruption of our clinical trial activities. 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 on 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 pre-clinical 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. Over the coming weeks and months, we will continue to carefully monitor the situation with respect to each of our clinical trials and follow guidance from local and federal health authorities.

COVID-19 may also affect employees of third-party contract research organizations and contract manufacturing 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, potentially 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 price 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 SYNB1618 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.

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., Nestlé Health Science S.A. (Codexis, Inc.), Homology Medicines, Inc., American Gene Technologies International Inc., Sangamo Therapeutics, Inc., Sanofi S.A., Generation Bio Co., Agios Pharmaceuticals, 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., Federation Bio, Inc., Oxidien Pharmaceuticals L.L.C. and others are developing product candidates for Enteric Hyperoxaluria. Merck & Co. Inc., Spring Bank Pharmaceuticals, Inc., GlaxoSmithKline plc., Bristol Myers Squibb Company, and Silicon Therapeutics have STING agonists in clinical development. Companies developing other modalities which target STING or similar mechanisms include companies such as Roche (Genentech) and Pfizer Inc. / Merck KgaA. Multiple companies develop and market antibodies called checkpoint inhibitors including Pfizer Inc., Roche (Genentech), Merck, Bristol-Myers Squibb Company, Eli Lilly & Co, and others. 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.

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 August 5, 2021, our executive officers and directors, together with holders of 5% or more of our common stock outstanding and their respective affiliates, beneficially own approximately 47.1% 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.

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 August 5, 2021, there were a total of 52,373,311 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.

Employees surrendered 18,187 shares to us, at purchase prices ranging from $3.50 to $4.12, during the six months ended June 30, 2021, for the payment of the minimum tax liability withholding obligations upon the vesting of shares of restricted stock. We do not consider this a share buyback program.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.1	License and Services Agreement and Statement of Work, dated April 28, 2021, by and between Synlogic Operating Company, Inc. and Azzur Cleanrooms-On-Demand – Boston, LLC.	X			
10.2	Pilot Collaboration and Option Agreement, dated June 16, 2021, among Synlogic Operating Company, Inc. and Hoffman-La Roche Inc.	X			
31.1	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).	X			
31.2	Certification of Interim Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).	X			
32.1*	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).	X			
32.2*	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).	X			
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Date File because XBRL tags are embedded within the Inline XBRL document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

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: August 12, 2021

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)

EXHIBIT 10.1

Confidential
Execution Copy

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

THE PARTIES HERETO ACKNOWLEDGE AND AGREE THAT THIS AGREEMENT IS NOT A LEASE AND IS A MERE LICENSE AND CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN LICENSEE'S FAVOR. THE PARTIES HERETO FURTHER ACKNOWLEDGE THAT ALL INTELLECTUAL PROPERTY, WHETHER PATENTABLE OR NOT, CREATED, CONCEIVED OR REDUCED TO PRACTICE BY LICENSEE SHALL BE THE SOLE PROPERTY OF AND SHALL VEST IN LICENSEE.

LICENSE AND SERVICES AGREEMENT

This License and Services Agreement (the "Agreement") is made as of the 28th day of April, 2021 ("Effective Date"), by and between AZZUR CLEANROOMS-ON-DEMAND - BOSTON, LLC, a Massachusetts limited liability company (the "Licensor"), and Synlogic Operating Company, Inc. 301 Binney St. Suite 402 Cambridge, MA 02142, a Delaware corporation (the "Licensee").

WITNESSETH:

WHEREAS, pursuant to certain agreements (as may be amended, modified, and/or restated from time to time, the "Lease") between Licensor and DBCI, Inc. (the "Landlord"), Licensor leases the buildings wherein it provides services to the Licensee (the "Premises").

WHEREAS, Licensor desires to license to Licensee, and Licensee desires to license from Licensor and use, a portion of the Premises for the sole purpose of early phase clinical or preclinical manufacturing and related activities, together with other business activity related thereto; and

WHEREAS, Licensor and Licensee are willing to enter into such license, and for Licensee to engage Licensor to perform such support services, all under the terms, covenants and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein the parties, intending to be legally bound, hereby agree as follows:

ARTICLE I.

DEFINITIONS

Section 1.01 The following terms used herein shall have the meaning set forth in the corresponding section set forth in the table below:

Defined Term	Section
Agreement	Preamble
Cleanroom(s)	2.01
Common Space	2.01
Confidential Information	9.01
Dedicated Space	2.01
Effective Date	Preamble
Equipment	3.03
Fees	7.01
Landlord	Recitals
Lease	Recitals
Licensed Space	2.01
License	2.01
Licensee	Preamble
License Fee	7.01
Licensor	Preamble
Licensor's FF&E	2.02
Losses	11.02
Office Space	2.01
Premises	Recitals
Products	3.01
Intellectual Property	8.01
Regulatory Approval	6.02
Regulatory Authority	5.03
SOPs	2.03
SOW	2.01
Support Services	4.01
Term	12.01

ARTICLE II.

GRANT OF LICENSE

Section 2.01 Grant of License. Subject to the terms and conditions of this Agreement, Licensor does hereby grant to Licensee a limited license (the "License") to occupy cleanroom space and associated office space all of which are identified in an individual Scope of Work ("SOW") executed by the parties (respectively, the Cleanroom and the Office Space, collectively, the "Dedicated Space"), together with a non-exclusive right in common with the Licensor and Licensor's invitees, guests, customers, and other licensees at the Premises to access and use the following, including but not limited to: gown-in and gown-out areas, access corridors, main lobby, necessary hallways, shared breakrooms, shared rest-rooms, shared parking areas, stairs and ingress and egress points (the "Common Space", and collectively with the Dedicated Space, the "Licensed Space").

Section 2.02 Licensor Equipment. The foregoing License grant contained in this Agreement provides Licensee with the exclusive use of the Licensor's equipment, furniture and other property located in the Dedicated Space and, subject to the SOPs, non-exclusive use of the equipment, furniture and other property located in the Common Space, each as described on an applicable SOW. Unless otherwise specified in an applicable SOW, all personal property, including furniture and equipment installed in or located in the Licensed Space prior to Licensee's use of the Licensed Space is the property of Licensor and is to be described in the applicable SOW (collectively, the "Licensor's Fixtures, Furniture & Equipment" or "Licensor's FF&E").

Section 2.03 Standard Operating Policies ("SOPs"). The Licensee shall comply fully with the Licensor's required SOPs as from time to time in effect with respect to the Premises, including the SOPs for use of and cleaning the Cleanroom. These SOPs shall be made available to the Licensor for training purposes, as specified in the applicable SOW. Licensor shall have the right, exercisable in its sole and absolute discretion to revise, amend, modify, and/or restate the SOPs at any time, and such revised, amended, modified, and/or restated SOPs shall be deemed to be automatically and immediately incorporated herein. The Standard Operating Procedures for the Premises and/or Licensed Space applicable to Licensee, as revised, amended, modified and/or restated from time to time by Licensor, in Licensor's sole discretion, are referred to herein as, the "SOPs."

ARTICLE III.

USE OF LICENSED SPACE

Section 3.01 Use of Space. Licensee shall use the Licensed Space for the sole purpose of early phase clinical or pre-clinical manufacturing and related activities ("Activities") for Licensee's product (collectively, the "Products"), together with all other business activities related thereto including producing Products or engaging in Activites on behalf of third-parties and/or collaborators. Notwithstanding anything herein to the contrary, throughout the Term (defined in Article 12), Licensee shall use and occupy the Licensed Space solely in accordance with, and as permitted under, the terms of the Lease.

Section 3.02 Access. Except in the case of emergencies, or exceptions specified in the applicable SOW, Licensee and its duly authorized, trained employees shall have access to the Dedicated Space and to Common Space between the standard working hours of 06:30 to 18:00, Monday through Friday. Work being performed outside standard working hours/days shall require reasonable advance notification to, and approval from the Licensor. Licensee's duly-authorized agents, invitees, or guests may enter the Licensed Space in accordance with access and security procedures as set forth in applicable SOPs provided in writing to Licensee by Licensor.

Section 3.03 Equipment. Except as to any equipment that does not impact Licensor's current mechanical, electrical and plumbing ("MEP") as well as SOPs Licensee shall not be permitted to install or bring into the Dedicated Space any new equipment or accessories that were not previously defined in the applicable SOW, unless approved in writing (i.e. Change Order) by Licensor, which writing shall be attached as an amendment to the applicable SOW. Licensee shall work with the Licensor to define, as necessary, any additional costs of installation, calibration and preventive maintenance, or monitoring of such approved Equipment, and define the appropriate responsibility in the Change Order.

ARTICLE IV.

SUPPORT SERVICES

Section 4.01 Support Services. During the Term, Licensor shall provide to Licensee certain support services as set forth in an applicable SOW (the "Support Services") and include on-site personnel support, project management, controlled temperature storage of materials, use of process gases, gowning supplies, consumables, liquid nitrogen, dry ice, coordination and management of third party activities such as shipping, calibration etc. The costs of such Support Services are included in the License Fee and detailed in the applicable SOW.

Section 4.02 Training. Licensee (and its duly-authorized employees, consultants or contractors needed for any of Licensee's activities on the Premises) shall participate in certain training as defined in the Licensor's SOPs as reasonably required by Licensor. Such required training modules may include: (i) training before occupying and using Licensed Space; (ii) updated training as applicable; and (iii) training as procedures change and periodic refresher training including as to life safety matters as Licensor may direct from time to time. Training shall be provided in a manner and at times that are mutually agreed by the parties. Training costs shall be listed in the applicable SOW. Licensee employee discipline shall be the responsibility of the Licensee, and Licensor shall direct any complaints with respect to a Licensee employee to the attention of Licensee's **Facility Director**, or designee who may be named in an applicable SOW.

Section 4.03 Utilities. As part of the Support Services and included in the License Fees described in any SOW, Licensor shall provide routine monitoring of environmental conditions (temperature, pressure, humidity, as defined in the applicable SOW) for the Licensed Space and Licensor's FF&E twenty-four hours a day/seven days a week. Licensor shall provide services to back-up electrical equipment to allow for activities and materials storage, at the necessary temperatures, to continue in the event of a power outage at the Licensed Space.

Section 4.04 Security. Licensee acknowledges that Licensor is a lessee of the Premises and does not provide, nor is responsible for providing, security services at the Premises, or any portion of the Licensed Space. Licensee shall comply with all security procedures and requirements including all applicable SOPs related to security.

Section 4.05 Parking. Licensee and its employees will park in the areas around the Premises so designated from time to time by Licensor as the parking areas for Licensee. Such parking areas will be non-exclusive. Licensee's guests and invitees shall park in the parking areas around the Premises so designated from time to time by Licensor as the parking areas for visitors.

Section 4.06Use of Subcontractors. The Support Services may not be subcontracted by Licensor without prior written notice to, and approval by, the Licensee (with such approval including the subcontracted actions being outlined in the applicable SOW).

Section 4.07 Other Licensee Operations, Activities and Requirements. Except, and only to the extent of the Support Services expressly provided for in this Agreement, Licensor shall not have any obligations or otherwise be responsible or liable for any other operations, activities or requirements of Licensee or any services in support of the same, whether arising out of the processing or other activity at the Licensed Space or otherwise, including equipment, supplies, services and facilities.

Section 4.08 Quality Agreement. The parties will also agree upon a Quality Agreement containing quality assurance provisions for the Licensed Space and Support Services ("Quality Agreement"). In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, the provisions of the Quality Agreement shall govern.

ARTICLE V.

LEASE; REPAIRS AND MAINTENANCE

Section 5.01 Incorporation of Lease Obligations by Reference; Licensee's Obligations to Maintain Dedicated Space. The rules, restrictions and obligations that regard occupancy and use imposed upon Licensor (in its capacity as the tenant) pursuant to the Lease are incorporated herein by reference and imposed upon Licensee mutatis mutandis, except to the extent they are expressly deleted or modified by the provisions of this Agreement. Without limiting the generality of the foregoing, Licensee shall not make any alterations, improvements or additions to the Dedicated Space unless Licensee obtains Licensor's prior written consent, which shall not be withheld unreasonably (provided that any such withholding on account of the Landlord similarly withholding such consent shall be deemed "reasonable"). Licensee shall maintain the Designated Space in a good, neat, and orderly condition, and in such a condition as is required of Licensor as tenant under the Lease; provided that Licensee shall not make any repairs to the Designated Space, such repair right and obligation being held solely by Licensor (subject to any indemnification obligations Licensee may have with respect to the event, cause, or circumstances giving rise to such repair right or obligation). Licensee shall inform Licensor if Licensor's FF&E in the Dedicated Space requires maintenance or repair in order to keep the same in good order and repair and Licensor shall maintain and repair Licensor's FF&E. Licensee shall not permit the Designated Space to be overloaded, damaged, contaminated by hazardous materials, stripped, or defaced, nor suffer any waste. Notwithstanding anything herein to the contrary, the whole of the Premises remains Licensor's property and in Licensor's possession and control. Licensee acknowledges that this Agreement creates no tenancy interest, leasehold estate or other real property interest in Licensee's favor.

Section 5.02 Subordination to Lease; No Privity. This Agreement is subject and subordinate to the Lease. Nothing in this Agreement shall be construed to create privity of estate or privity of contract between Licensee and Landlord. Nor shall anything herein contained be deemed to create any partnership or joint venture between the parties hereto, and the relationship of the parties shall be solely that of independent contractors.

Section 5.03 Licensor Access to Licensed Space. Notwithstanding any non-disclosure, confidentiality, or other like-restrictive covenant agreement(s) executed by Licensor in favor of Licensee, Licensor and its employees, contractors and agents shall have the right from time to time and at any time throughout the Term to enter (with reasonable advance notice) any portion of the Licensed Space (including, without limitation, each Cleanroom, the Office Space, and the Common Space) to examine and inspect the same to make such repairs, alterations, improvements or additions to the Dedicated Space or any other portion of the Premises; provided that (1) Licensor's employees, contractors, agents and business invitees shall be required to sign a Licensee's standard form of visitor confidentiality agreement prior to being allowed access to the Dedicated Space, and (2) Licensor shall use reasonable efforts to minimize disruption to the business and operations of Licensee. Additionally, notwithstanding any non-disclosure, confidentiality, or other like-restrictive covenant agreement(s) executed by Licensor in favor of Licensee, Licensor shall be permitted to allow into the Premises and any portion of the Licensed Space (including, without limitation, each Cleanroom, the Office Space, and the Common Space) any governmental or Regulatory Authority (as defined below) for any purpose whatsoever upon reasonable notice or after good faith efforts to provide such notice. The term "Regulatory Authority" shall include but is not limited to international country regulatory agencies, the United States FDA, United States state regulatory agencies,

and voluntary regulatory agencies such as the American Association of Tissue Banks (AATB), and other similar agencies, as these Regulatory Authorities apply to the Licensee's activities.

ARTICLE VI.

REGULATORY

Section 6.01 Facility Qualification / Standards. Licensor does not guarantee, certify, represent, or warrant that any portion of the Dedicated Space (including, without limitation, any Cleanroom) is certified by the International Organization for Standardization ("ISO" or any other third-party standardization or certification organization or entity). No portion of the Designated Space is registered or otherwise licensed by the United States FDA, or any other governmental authority or Regulatory Authority as a manufacturing, preparing, propagating, compounding, or processing establishment. Licensor is responsible for qualifying the Cleanroom(s) and support systems for their intended use, as per the applicable SOW.

Section 6.02 Regulatory Registrations and Approvals. Licensee shall be solely responsible for obtaining and maintaining all Regulatory Approvals (as defined herein) necessary for the research, development, processing, manufacturing or licensing activities associated with their Product(s). Notwithstanding anything to the contrary - for example, separate agreements between the Licensee and Licensor - the Licensor shall have no obligation to assist Licensee in obtaining and/or maintaining any Regulatory Approvals, and shall have no obligation to make any addition, modification, alteration, or renovation to any portion of the Licensed Space and/or Support Services. The term "Regulatory Approval" means any and all approvals, licenses, registrations, accreditations or authorizations of the relevant Regulatory Authority, including all approvals and permits necessary for the processing, development, manufacture, use, storage, import, or transport of product.

Section 6.03 Inspections and Audits. To the extent permitted by applicable law, each party shall promptly advise the other party if an authorized agent of a governmental authority or Regulatory Authority visits or intends to visit the Premises for the purpose of performing an audit or inspection. Notwithstanding the foregoing, Licensee and Licensor each acknowledge and agree that Licensor shall have no responsibility or other obligation to communicate or interact with any governmental authority or Regulatory Authority with respect to the research, development, processing, manufacturing or licensing activities or requirements of the product(s), or the Licensed Space's or the Support Services' suitability, registration, or licensure for aforementioned, in regard to the Licensor's product(s). Licensee shall be responsible, and act as the sole point of contact, for communications with Regulatory Authorities in connection with the research, development, processing, manufacturing or licensing activities or requirements of the Product(s).

ARTICLE VII.

FEES

Section 7.01 Fees. Licensee shall pay to Licensor a license fee for Licensed Space (the "License Fee"). Licensee shall also be assessed a monthly charge to cover variable costs services such as third party shipping costs, overages on support services on a monthly basis and minor out of scope items ("Variable Budget"). The License Fee, Variable Budget and payment terms shall be set forth on the fee schedule attached to an applicable SOW.

Section 7.02 Payments. All Fees shall be paid in accordance with the fee schedule defined in the applicable SOW and paid in lawful money of the United States of America by electronic transfer of funds to the account of Licensor set forth in a written notice from Licensor or by another method agreed between the parties.

Section 7.03 Taxes. Licensor shall be responsible for the payment of any and all taxes levied on account of Fees paid to Licensor by Licensee under this Agreement.

ARTICLE VIII.

INTELLECTUAL PROPERTY

Section 8.01 Intellectual Property. Licensor agrees not to claim any rights, title or ownership in the Licensee's Confidential Information (as defined herein) or any Intellectual Property (as defined herein), and that the rights, title and ownership in the Confidential Information and Intellectual Property shall, as between the parties, vest in Licensee. Licensor further agrees not to use any trademark of Licensee, or any other identifier for any advertising, promotion or any other purpose without the prior written consent of Licensee. "Intellectual Property" means all intellectual property, whether patentable or not, created, conceived or reduced to practice by Licensee, either alone or in combination with others, in carrying out any services hereunder or otherwise in connection with this Agreement, including inventions, discoveries, modifications, and/or improvements, patents, patent applications, trademarks, trade names, service marks, copyrights, creative works, derivative works, moral rights, trade secrets, proprietary information, rights to use, industrial designs, proprietary materials, including chemical and biological materials, compositions, methods of use, methods of administration, or methods of treatment.

Section 8.02 Assistance. Upon the written request of Licensee, Licensor and Licensee shall negotiate in good faith the entry into a mutually agreeable consulting agreement between Licensor and Licensee pursuant to which Licensor would provide consulting services to Licensee with respect to preparing, filing, prosecuting, and maintaining rights to any Intellectual Property. To the extent any provision of a consulting agreement expressly conflicts with any provision of this Agreement, the provisions of such consulting agreement shall govern.

ARTICLE IX.

CONFIDENTIALITY

Section 9.01 Mutual confidentiality terms and conditions were defined and approved in the previously executed agreement dated 07, May 2018 and any amendments (the "CDA"), which is incorporated by reference, the term of which extends to cover confidential disclosures made hereunder and pursuant to any obligations as set forth in the CDA.

ARTICLE X.

REPRESENTATIONS AND WARRANTIES

Section 10.01 Representations and Warranties by each Party. Each party represents, warrants and covenants that:

(a) Organization and Good Standing. Such party is and will remain a legal entity duly organized, validly existing and in good standing under the laws of its jurisdiction of organization;

(b) Authorization. The execution and delivery of this Agreement has been authorized by all requisite action. This Agreement is and will remain a valid and binding obligation of such party, enforceable in accordance with its terms, subject to any applicable laws with respect to bankruptcy, insolvency and the relief of debtors;

(c) No Broker. Neither party has dealt with a broker, agent or finder in connection with this Agreement;

(d) No Conflict. Such party is authorized to enter into this Agreement and that the respective signatories hereto have been authorized to sign this Agreement, and such party does not require consent from and is not violating any contractual obligation with any other party by entering into this Agreement; and

(e) Compliance with Laws. Such party shall comply with all applicable laws, regulations and ordinances and the permits, orders and requirements of all government authorities in connection with its grant of and use of the Licensed Space, Support Services, and testing of the Product. Without limiting the preceding sentence, Licensee acknowledges that its obligations will include maintaining appropriate material safety data sheets and other records and provide the same to Licensor to enable Licensor to comply with its obligations.

Section 10.02 Representations and Warranties by Licensor. All Support Services furnished by Licensor will be performed by adequately trained personnel in a professional manner and in accordance with the highest industry standards. Throughout the Term, Licensor shall comply with all Lease terms and maintain the Designated Space as is required of Licensor as tenant under the Lease.

Section 10.03 Restrictions on Licensor and Licensee Activities. Licensor and Licensee acknowledge that each of them and their officers, employees and agents will during the Term gain substantial knowledge of the business of the other party. Accordingly, Licensor and Licensee each on behalf of itself, its officers and employees hereby covenants that, during the Term and for a period of two (2) years after the expiration or termination of this Agreement, it will not, without the prior written consent of the other party hire, employ, solicit or attempt to solicit or induce any person employed by the other party to leave such employment or to break his or her non-competition agreement, non-disclosure agreement or any other agreement with the other party (the Parties acknowledge that general advertisements and job postings shall not be violations of this Section).

Section 10.04 Hazardous Materials. Licensee represents, warrants and covenants that it, its employees, and agents shall not generate, store, install, dispose of or otherwise handle in the Common Space or the Office Space any hazardous material other than those permitted on site. Unless otherwise specified in an SOW, Licensee shall be responsible for proper labeling and storage of all hazardous materials generated, stored, installed, disposed of or otherwise handled in the Licensed Space by Licensee and its employees, or in or around the Premises, by Licensee.

Section 10.05 Absence of Debarment. Licensor represents, warrants and covenants that Licensor's personnel (i) has not been debarred and are not subject to a pending debarment, and will not use in any capacity in connection with any services hereunder any person who has been debarred or is subject to a pending debarmentpursuant to 21 USC § 335a or excluded pursuant to 42 U.S.C. § 1320a-7, or equivalent actions under the Regulatory Authorities in any jurisdiction, (ii) has not been convicted of any crime or engaged in any conduct that would reasonably be expected to result in debarment under 21 USC § 335a or exclusion pursuant to 42 U.S.C. § 1320a-7 or equivalent actions under the applicable laws in any jurisdiction, and (iii) has not been convicted of, charged with or investigated for any violation of law related to fraud, theft, embezzlement, breach of fiduciary duty, financial misconduct, controlled substances or obstruction of an investigation.

ARTICLE XI.

INSURANCE, INDEMNIFICATION & LIMITATION OF LIABILITY

Section 11.01 Insurance. Each party shall obtain and maintain throughout the Term, at its sole cost and expense, the following types of insurance coverage and limits of liability:

(a) Commercial General Liability including Umbrella Insurance coverage with limits of insurance of not less than $[***] per occurrence and $[***] in the aggregate;

(b) Workers' Compensation and Employers Liability coverage that meet applicable state (and federal, where applicable) statutory limits; and

(c) such and other commercially reasonable forms of insurance agreed to by the parties.

Each insurance policy shall be maintained with insurers reasonably acceptable to the other party. Each party shall provide the other party with a certificate of insurance suitable to the other party evidencing such insurance policy/ies and stating that such policy/ies are in full force and effect and shall remain in effect throughout the Term, unless the insurance carrier provides not less than [***] prior written notice of expiration or cancellation. Upon receipt of any such notice from an insurance carrier, such party shall promptly provide such notice to the other party. Licensor and Licensee agree to have their respective insurance companies issuing property damage insurance waive any rights of subrogation that such companies may have against Licensor or Licensee, as the case may be, so long as the insurance carried by Licensor and Licensee, respectively, is not invalidated thereby. As long as such waivers of subrogation are contained in their respective insurance policies, Licensor and Licensee hereby waive any right that either may have against the other on account of any loss or damage to their respective property to the extent such loss or damage is insurable under property damage insurance.

Section 11.02 Indemnification by Licensor. Subject to Section 11.04, Licensor shall save, defend, indemnify and hold Licensee, its affiliates and their respective officers, directors, member-managers, managers, employees, contractors, invitees and agents ("Licensee Representatives") harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a third party ("Claims") resulting or otherwise arising from or in connection with any negligence or willful misconduct of Licensor or any of the Licensor Representatives in fulfillment of Licensor's obligations under this Agreement, except to the extent any of the foregoing results from the negligence or willful misconduct of Licensee or any of the Licensee Representatives.

Section 11.03 Indemnification by Licensee. Subject to Section 11.04, Licensee shall save, defend, indemnify and hold Licensor, its affiliates and their respective officers, directors, member-managers, managers, employees, contractors, invitees and agents ("Licensor Representatives") harmless from and against any and all Losses resulting or otherwise arising from or in connection with Claims relating to: (a) any negligence or willful misconduct of Licensee or any of the Licensee Representatives; (b) Licensee's use of the Licensed Space, all except to the extent any of the foregoing results from the negligence or willful misconduct of Licensor or any of the Licensor Representatives; and (c) Licensee's breach of this Agreement.

SECTION 11.04 LIMITATION OF LIABILITY.

(a) NOTWITHSTANDING ANYTHING TO THE CONTRARY, EXCEPT FOR DAMAGES RESULTING FROM LICENSOR'S ADJUDICATED NEGLIGENCE OR GROSS MISCONDUCT OR BREACH OF CONFIDENTIALITY SECTION 9.01, IN NO EVENT SHALL LICENSOR OR ANY OF ITS DIRECTORS, MEMBERS, MANAGERS, OFFICERS, SHAREHOLDERS, INVESTORS, EMPLOYEES, ADVISERS, OR AGENTS BE LIABLE OR RESPONSIBLE FOR INTERRUPTION OR LOSS OF BUSINESS (SPECIFICALLY INCLUDING ANY INTERRUPTION RESULTING FROM THE NEED TO CONDUCT REPAIRS OR MAINTENANCE ON ANY OF THE PREMISES OR ANY OF THE EQUIPMENT PROVIDED BY LICENSOR), INCOME OR PROFITS, OR ANY CONSEQUENTIAL, INDIRECT OR SPECIAL DAMAGES, AND INCLUDING (a) THE FAILURE OF INABILITY OF THE TESTING OR THE PRODUCT TO OBTAIN ANY LEVEL OF LICENSURE, CERTIFICATION, OR APPROVAL FROM ANY GOVERNMENTAL AUTHORITY OR REGULATORY AUTHORITY; AND/OR (b) THE MARKETING, ADVERTISING, SALE, DISTRIBUTION, TRANSPORTATION, CONSUMPTION, USE, OR APPLICATION OF ANY OF THE TESTING AND/OR THE PRODUCT(S) AND/OR THE EFFECTS OF ANY OF THE FOREGOING.

(b) IN NO EVENT SHALL LICENSOR'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE, GROSS NEGLIGENCE, OR WILLFUL MISCONDUCT) OR OTHERWISE, EXCEED THE AGGREGATE FEES PAID OR PAYABLE TO LICENSOR PURSUANT TO THIS AGREEMENT IN THE THREE (3) YEAR PERIOD PRECEDING THE EVENT GIVING RISE TO THE CLAIM.

Section 11.05 DISCLAIMER OF WARRANTIES. EXCEPT AS SET FORTH IN SECTION 10.01, 10.02 AND THE APPLICABLE SOW, THE PARTIES HEREBY EXPRESSLY DISCLAIM ANY AND ALL OTHER EXPRESS OR IMPLIED WARRANTIES REGARDING THE PREMISES, THE LICENSED SPACE (OR ANY PORTION THEREOF), THE SUPPORT SERVICES AND ANY OTHER MATERIALS OR SUPPLIES PROVIDED UNDER THIS AGREEMENT.

ARTICLE XII.

LICENSE TERM, TERMINATION, CHANGES AND EXTENSIONS

Section 12.01 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated, shall continue for a period of five (5) years or the expiration of any SOW hereunder, whichever comes first (the "Term"). The Term shall be set forth in the applicable SOW. The parties may extend the term of Licensed Space, provided the specific Cleanroom is available for the duration of the extension and provided that Licensee notifies Licensor of its intent to extend at least [***] prior to the end of the Cleanroom term specified in the applicable SOW. All extensions will require a new SOW and Fees may be adjusted based on market conditions. **Licensor does not guarantee availability of the Cleanroom beyond current Term in the applicable SOW.**

Section 12.02 Termination. This Agreement may be terminated as follows:

(a) If either Licensee or Licensor breaches or defaults in the performance or observance of any of its respective obligations under this Agreement, and such breach or default is not cured within [***] after the giving of written notice by the other party specifying such breach or default.

(b) If either party is generally unable to meet its debts when due, or makes a general assignment for the benefit of its creditors, or there shall have been appointed a receiver, trustee or other custodian for such party for or a substantial part of its assets, or any case or proceeding shall have been commenced or other action taken by or against such party in bankruptcy or seeking the reorganization, liquidation, dissolution or winding-up of such party or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law, and any such event shall have continued for [***] undismissed, unstayed, unbonded and undischarged, then the other party may, upon notice to such party, terminate this Agreement, such termination to be effective upon such party's receipt of such notice.

(c) If a substantial portion of the Licensed Space is damaged as a result of fire or other casualty or is taken by means of eminent domain, Licensor may terminate this Agreement upon notice to Licensee.

(d) "Early Termination". If, at any time during the Term of the Agreement, the Licensee desires early termination of this Agreement or otherwise discontinue use of the Designated Space, it will provide formal written notice of intent to vacate to Licensor at least three (3) months in advance of the early termination date. If Licensee terminates early, the Licensor will take good faith measures to contract with an alternate licensee to occupy the Licensee's Dedicated Space for the balance of any unused Term. Provided an alternate licensee is available and willing to occupy the space, Licensor will refund the relevant pre-paid License Fee for the duration the alternate licensee is occupying the same Cleanroom. If Licensor is unable to find an alternate licensee to occupy the Cleanroom, Licensor will continue to charge Licensee the License Fee, excluding all costs related to Personnel Support, Consumables and Variable Budget, provided however, if such costs are incurred by Licensee, then, Licensee shall pay such costs on an hourly basis as agreed to by the parties until the three (3) months of advance notice is complete.

(e) Termination prior to Term start. After pre-payment of Fees to reserve the Cleanroom and support services, per a related SOW, up until [***] of the start date of the Term, Licensee can terminate this Agreement with written notice to Licensor. Any pre-payments of Fees per related SOW will be refunded to Licensee. Terminations prior to Term start within [***] of the start date of the Term will be address per Section 12.02(d) above.

Section 12.03 Effects of Expiration and Termination. Unless otherwise specified in Section 12.02 or any of the provisions of the applicable SOW, upon expiration or termination of this Agreement:

(a) The License, the Support Services, and any other licenses and rights granted or afforded by Licensor to Licensee hereunder shall terminate as set forth herein or as specified in an applicable SOW.

(b) Licensee shall vacate and decommission to commercially reasonable standards the Dedicated Space, leave the Licensed Space broom clean and in the same general order and condition as the Licensed Space on the Effective Date, except for reasonable wear and tear, and promptly provide a copy of all decommissioning documentation to Licensor. Licensee shall after such termination or expiration: (1) remove all of Licensee's personal property and all other property and effects of Licensee and all persons claiming through or under Licensee from the Licensed Space and the Premises, (2) remove all Equipment, and (3) repair all damage to the Licensed Space and the Premises, if any, occasioned by such removal, reasonable wear and tear excepted. Licensor shall provide Licensee with full access and the right to remove the foregoing property (including Equipment) from the Licensed Space following expiration or termination of this Agreement.

Section 12.04 Survival. The termination or expiration of this Agreement shall not relieve the parties of any obligations accruing prior to such termination, and any such termination shall be without prejudice to the rights of either party against the other. The provisions of Sections 7.01, 7.02, 7.03, 12.03, 12.04 and Articles VIII, IX, X, XI, and XIII shall survive any termination or expiration of this Agreement.

Section 12.05 Changes in Scope of Services or Fees. ANY and ALL changes that materially impact the scope of services or fees as described in the applicable SOW must be addressed per formal, mutually-approved Change Orders to the SOW. Licensor reserves the right to grant a conditional approval - so that work may commence in good faith - provided there is written notification (via email or letter), while formal approval of the Change Order is pending.

Section 12.06 Transition of License and Support Services. In the event of assignment of this Agreement by Licensee, Licensor shall reasonably assist in the transition of the License and Support Services.

ARTICLE XIII.

MISCELLANEOUS

Section 13.01 Notices.

(a) Any notice or communications given or required to be given pursuant to this Agreement shall be effective only if rendered or given in writing, sent by (1) registered or certified mail, return receipt requested, (2) a nationally recognized courier service such as Federal Express or UPS, or (3) hand delivery (with a duplicate copy sent via either method described in (1) or (2) immediately above) addressed:

If to Licensee, to:

Synlogic Operating Company, Inc.
301 Binney St. Suite 402
Cambridge, MA 02142
ATTN: Tony Awad, COO

If to Licensor, to:

Azzur Cleanrooms-on-Demand - Boston LLC
411 Waverley Oaks #129
Waltham, MA 02452
Attn: Ravi Samavedam, President Azzur COD

(b) Any such demand, notice, communication or report shall be deemed to have been given pursuant to this Agreement upon delivery or refusal of delivery. Either party may at any time change its address for notification purposes by providing written notice stating the change and setting forth the new address.

Section 13.02 Entire Agreement; Amendment.

(a) Entire Agreement. Except as expressly otherwise provided herein, this Agreement together with the exhibits and schedules attached hereto, which are incorporated herein by this reference, embodies and constitutes the entire understanding between the parties with respect to the licensing transaction contemplated herein and supersede any conflicting terms in the Master Services Agreement entered into by the parties on or about [***]. In the event of conflict, discrepancy, or inconsistency between the terms of this Agreement and any SOW, purchase order, or other document or form used by the parties, the terms of this Agreement will control except to the extent that such other document specifically states an intent to supersede this Agreement on a specific matter.

(b) Amendment. This Agreement may not be modified, amended or terminated, and Licensee's obligations hereunder shall in no way be discharged, except as expressly provided in this Agreement or by written instrument executed by the parties hereto. This Agreement shall not be construed in any way to grant Licensee any leasehold or other real property interest in the Licensed Space. This Agreement merely grants Licensee this License to enter upon, occupy and use the Licensed Space during the Term in accordance with the terms and conditions hereof.

Section 13.03 Assignment. This Agreement is personal to Licensee, and Licensee may not assign its rights or delegate its duties under this Agreement (whether by operation of law or otherwise) without the prior written consent of Licensor which shall not be unreasonably conditioned, delayed or withheld; provided, however, Licensor's consent shall not be required in the event Licensee assigns this Agreement to a successor in interest to all or substantially all of its business or assets. Licensor will provide reasonable notice to Licensee in the event Licensor assigns any of its rights and/or delegates any of its duties under this Agreement. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective permitted legal representatives, successors and assigns.

Section 13.04 Recording. Neither Licensor nor Licensee shall have the right to record this Agreement or any memorandum thereof.

Section 13.05 Force Majeure. Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than a default in the payment of any Fees) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, pestilence, pandemic, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by the other party or the Landlord.

Section 13.06 Governing Law; Jurisdiction; Venue. This Agreement and all related documents including all schedules attached hereto and all matters arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, for all purposes shall be governed by and construed in accordance with the laws of the State of Massachusetts, without giving effect to any conflict of laws principles that would cause the laws of any other jurisdiction to apply. Any action or proceeding by either of the parties to enforce this Agreement shall be brought only in any state or federal court located in the State of Massachusetts, Middlesex County. The parties hereby irrevocably submit to the exclusive jurisdiction of these courts and

waive the defense of inconvenient forum to the maintenance of any action or proceeding in such venue. No provision herein shall be construed as precluding a party from bringing an action for injunctive relief or other equitable relief at any time. In the event of litigation or any dispute relating to the enforcement of this Agreement, the prevailing party shall be entitled to recover its reasonable attorneys' fees and costs from the non-prevailing party.

Section 13.08 Severability. If and solely to the extent that any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal or unenforceable, the court shall modify this Agreement to effect the original intent of the parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 13.09 Waivers. Any term or condition of this Agreement may be waived at any time by the party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the party or parties waiving such term or condition. Neither the waiver by any party of any term or condition of this Agreement nor the failure on the part of any party, in one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

Section 13.10 Interpretation. The term "business days" as used in this Agreement shall exclude Saturdays, Sundays and holidays, the term "Saturdays" as used in this Agreement shall exclude holidays and the term "holidays" as used in this Agreement shall mean all days observed as legal holidays by either the State of Ohio or the United States of America. The terms "Person" and "persons" as used in this Agreement shall be deemed to include natural persons, firms, corporations, partnerships, limited liability entities, unincorporated associations, and any other private or public entities, whether any of the foregoing are acting on their own behalf or in a representative capacity. Whenever the words "including", "include" or "includes" are used in this Agreement, they shall be interpreted in a nonexclusive manner.

Section 13.11 Execution and Counterparts. This Agreement shall not be binding or effective until this Agreement is executed and delivered by Licensor and Licensee. This Agreement may be executed in several counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same instrument. The execution of this Agreement may be effected by electronically transmitted (email) or facsimile signatures, all of which shall be treated as originals.

Section 13.12 Attachments. All the attachments are integral parts of this Agreement and are attached hereto. The attachments are listed in the table below:

(a) Exhibit A: Scope of Work P-9717.

[signatures on next page]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Effective Date.

LICENSEE:

SYNLOGIC OPERATING COMPANY, INC.

By: /s/ GREGG BELOFF
Name: Gregg Beloff
Title: Interim Chief Financial Officer

LICENSOR:

AZZUR CLEANROOMS-ON-DEMAND – BOSTON, LLC

By: /s/ RAVI SAMAVEDAM
Name: Ravi Samavedam
Title: President

CONFIDENTIAL

EXHIBIT A

Scope of Work (SOW)

Scope of Work P-9717 for

Scope of Work for Cleanroom 3 Use (May 1, 2021 to December 31, 2022)

Section 1 - Background/Scope

Azzur Cleanrooms On Demand ("COD") facilities are designed for clients to utilize controlled clean areas and services related to early phase cGMP manufacturing. This Scope of Work ("SOW") is for 21 months, subject to terms and conditions specified in the **LICENSE AND SERVICES AGREEMENT**, of cleanroom use ("CR3") and support related services at the COD facility located at 411 Waverley Oaks Rd., #126, Waltham, MA 02452. This SOW replaces P-6671 for the duration of May 2021 to Dec 2022. This SOW is entered into by and COD ("Licensor") and Synlogic ("Licensee") effective as of the approval date of this SOW. Upon execution of this SOW, this SOW will be incorporated into a mutually approved License and Services Agreement ("LSA") that contains additional terms and conditions of the COD Cleanrooms and support services use.

A Purchase Order ("PO") for the license fees for the duration of 21 months and the first monthly pre-payment of the license fees, as identified this SOW, will be due no later than 30 days after the execution of this SOW and the related LSA.

Section 2 – License and Technical Requirements

Commencing on the Effective Date and subject to the terms and conditions of the LSA, Licensor grants to Licensee a license to access and use the cleanroom with specification described in Section 3. Licensor will provide the support services described in this Section 3 using Licensor personnel. Licensor personnel will perform the services in a timely, professional and workmanlike manner and in accordance with all applicable laws, regulations and guidelines. Licensor will maintain all permits, licenses or other approvals necessary for the operation of the Cleanroom in accordance with the requirements set forth herein. Specifically, Licensor will perform Services in accordance with the following:

Licensor personnel will be experienced with FDA facility compliance expectations. Licensor has based this Statement of Work upon the following documents.

- Code of Federal Regulations Title 21 Part 210 – Current Good Manufacturing Practice in the Manufacturing, Processing, Packing, or Holding of Drugs; General
- Code of Federal Regulations Title 21 Part 211 – Current Good Manufacturing Practice for Finished Pharmaceutical
- ISPE Good Practice Guide – Science and Risk-Based Approach for the Delivery of Facility Systems and Equipment
- ISPE Good Practice Guide – Good Engineering Practices
- PDA Technical Report 56 – Application of Phase Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance

Licensee personnel using the classified areas are to be trained on Licensor SOPs on gowning, personnelmovement, material control, gowning training, safety training etc.

Section 3 – Detailed Scope

This SOW provides details of the licensed cleanroom space, office space, support services and the related inclusions.

a) Cleanroom

- Dedicated CR3 cleanroom space for a duration of 21 months with a start date of May 2021.
  - All entry/exit door to controlled or classified spaces will be access controlled via badge accessand security controls
  - Cleanroom entry/exit doors will be interlocked with access only to Licensee and Licensor personnel.
  - Room differential pressures which will meet [***].
  - Room differential pressures which will meet [***].
  - Temperature specification range of [***] with operational control of [***]
  - Differential pressure, temperature and humidity will be continually monitored and alarmed.

    Remote alarm management is performed by Licensor.
  - The [***] will be furnished with a [***]. Additional room furnishings can be installed upon request, the costs for which are not included in this SOW.
- [***] in the cleanroom
  - [***] certification/maintenance

NOTE: [***] ***and disinfection during routine use is*** **Licensee*****'s responsibility.***

- Cleanroom Cleaning
  - Weekly – Horizontal and vertical surfaces including wiped using [***], floors vacuumed andmopped using the latest version of the following approved cleaning solution [***] rotated on a monthly basis).
  - Monthly – Same as weekly cleaning followed by second cleaning using approved cleaningsolution on all surfaces ([***] rotated on a monthly basis).
  - Quarterly (once every 3 months) – Same as monthly cleaning (approved cleaning solutionused will be [***])

NOTE: Changes in cleaning regimen including type of agents and frequency as well as enhanced cleaning for changeover can be implemented, the costs for which are not included in this SOW.

- Routine Environmental Monitoring (EM)
  - Weekly TAP, Viable Air and Surface Monitoring
  - Data review and quality support (in-case of any deviation)
  - Trending and reporting of EM data on a periodic basis

NOTE: Changes in environmental monitoring including additional in-process monitoring costs are included in table 2 of section 4 of this SOW.

- Access to consumable including gowning materials, cleaning supplies (wipes, alcohol) and dry ice. Licensor personnel will stock and re-stock such materials on a routine basis.

b) Facility Infrastructure/ Quality Management (Licensor owned assets)

- Security and access control for cGMP areas. Issuance and management of badges.
- Back-up power for entire facility with all controlled assets (both Licensor and client owned)
- Pest control, housekeeping and non-gmp cleaning
- Waste removal and disposal (Biological, Hazardous, Non-Hazardous)
- Licensor owned asset management including installation, calibration, qualification, routine monitoring, maintenance, alarm management and documentation.
- Quality management of all Licensor owned assets including incident management.

c) Material Storage for 21 months in Licensor owned assets in dedicated qualified, controlled, monitored and maintained environments in the following Standard Minimum Units (SMU) monthly amounts. The monthly SMU amounts are determined based on the usage rates in 2020.

- [***]

d) Personnel Support ([***] per month)

- Materials management including receipt, inspection, labeling, inventory management, segregation, movement, staging/kitting and raw materials quality release based on CofA.
- Routine project meetings for scheduling, reporting, budget updates and issue resolution.
- On-site support on an on-going basis.
- Coordination/scheduling of shipment pickup and drop-off activities, packaging and labeling of samples, product shipments etc. Reconciliation of temperature monitors used for shipments.

e) Dedicated office space for Licensee personnel with access to telephone, printer/scanner, wireless internet, television/Monitor, office supplies and cafeteria.

Section 4 – Fees

a) License Fee

The License Fee will be pre-paid on a monthly basis and includes items listed under the relevant category in Table 1 below, provided, however, the License Fee shall exclude from pre-pay or account for (as credit back to Licensee) any reduction in Personnel Support or Consumables during times when the Cleanroom is not utilitzed due to any renovation or shutdowns. A monthly Variable Budget for support services overage compared to SMU amounts and out of scope activities has been established at [***] per month. Specifically, the variable budget will cover the following known items, as needed:

- Overages compared to monthly SMU amounts (personnel, material storage).
- Training (General and Gowning Training). All Licensee individuals requiring access to the facility will undergo general safety, biohazards and Licensor facility compliance SOPs. Training will be documented and monitored by Licensor personnel.
- Third-party costs paid by Licensor for activities including equipment/furniture purchase,shipping costs etc. will be passed through with a [***] upcharge.

Table 2 below shows the costs related to support services for monthly overages and other services to be covered by the Variable Budget, if required. Note that the unit costs of overages are higher than unit costs included in the License Fees as unplanned activities result in additional costs such as offsite storage, material movement and personnel time.

Table 1: Project Costs

[***]

Total PO amount (2021+2022)	$2,302,448

[***]

Section 5 – Payments and Invoicing

All invoices are due net +30 days from the invoice date. Fixed amounts for the monthly License Fee will be generated at the start of each month. Monthly invoices for variable amounts will be generated out at the end of each month, if required based on actual usage.

The total amount for CR3 use and related services for 21 months starting May 2021 to Dec 2022 including a variable budget allocation of $[***] per month is **$2,302,448**. A Purchase Order ("PO") for the total amount is required for the reservation of the cleanroom and related services specified in this SOW. In addition, a pre-payment of [***] for the first month (May 2021) of license fees will be required for the reservation of the cleanroom and related services specified in this SOW.

Section 6 – Approvals

SOW Generated by (COD):
Date: 22APR21

Name: /s/ RAVI SAMAVEDAM
Ravi Samavedam
Title: President, Azzur COD

Email: ravi.samavedam@azzur.com

SOW Accepted by (Synlogic):

NAME: /s/ GREGG BELOFF
Gregg Beloff
TITLE: Interim Chief Financial Officer
DATE: 29 April 2021

EXHIBIT 10.2

Confidential
Execution Copy

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

Pilot Collaboration and Option Agreement

This pilot collaboration and option agreement is entered into as of the Effective Date (as defined below) by and between **Hoffmann-La Roche Inc.**, with an office and place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, U.S.A. ("**Roche US**") and **F. Hoffmann-La Roche Ltd**, located at Grenzacherstrasse 124, 4070 Basel, Switzerland ("**Roche Basel**", Roche Basel and Roche US together referred to as "**Roche**"), on the one hand, and **Synlogic Operating Company, Inc.**, located at 301 Binney St., Suite 402, Cambridge, MA 02142 (hereafter referred to as "**Synlogic**"), on the other hand.

WHEREAS, Synlogic has expertise and capabilities to discover and to develop clinical drug candidates using [***]; and

WHEREAS, Roche has expertise and capabilities in the discovery, development and commercialization of innovative therapeutics in inflammatory bowel diseases; and

WHEREAS, the Parties are interested to enter into a pilot collaboration and option agreement to research and pre-clinically develop potential novel [***] inflammatory bowel diseases, as further outlined herein; and

WHEREAS, Roche may elect to commence negotiations for a definitive collaboration and license agreement based on the license term sheet attached to this pilot collaboration agreement and as further outlined herein.

NOW THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

1 Definitions

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 Accounting Standards

The term "Accounting Standards" shall mean, with respect to a Party or its Affiliate, GAAP or IFRS, as such Party or its Affiliate uses for its financial reporting obligations, in each case, consistently applied.

1.2 Acquirer
The term “Acquirer” shall mean, with respect to a Party, the person or entity, or group of persons or entities, that is the acquirer of, or a successor to, a Party in connection with a Change of Control, together with Affiliates of such persons or entities that are not Affiliates of such Party immediately prior to the completion of such Change of Control of such Party.

1.3 Affiliate
The term “Affiliate” shall mean any individual, corporation, association or other business entity that directly or indirectly controls, is controlled by, or is under common control with an individual, corporation, association or other business entity in question. As used in this definition of “Affiliate,” the term “control” shall mean the direct or indirect ownership of more than fifty percent (>50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation, association or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise. Anything to the contrary in this paragraph notwithstanding, Chugai Pharmaceutical Co., Ltd, a Japanese corporation (“Chugai”) and/or its subsidiaries (if any) shall not be deemed as Affiliates of Roche unless Roche provides written notice to Synlogic of its desire to include Chugai and/or its respective subsidiaries (as applicable) as Affiliate(s) of Roche.

1.4 Agreement
The term “Agreement” shall mean this document including any and all appendices and amendments to it as may be added and/or amended from time to time in accordance with the provisions of this Agreement.

1.5 Applicable Law
The term “Applicable Law” shall mean all applicable laws, statutes, rules, regulations and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, agency or other body, domestic or foreign, including any applicable rules, regulations, guidelines, or other requirements of the Regulatory Authorities that may be in effect from time to time, including the United States Federal Food, Drug, and Cosmetic Act, as amended, GCP, GLP and GMP, anti-bribery laws, such as the United States Anti-Kickback Statute, Foreign Corrupt Practices Act and UK Bribery Act, as well as all applicable data protection and privacy laws, rules and regulations, including the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act, as amended, and the Health Information Technology for Economic and Clinical Health Act and the EU General Data Protection Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, along with other country-level data protection laws, as may be applicable.

1.6 Change of Control
The term “Change of Control” shall mean, with respect to a Party: (a) the acquisition by any Third Party, together with its Affiliates, if applicable, of beneficial ownership of fifty percent (50%) or more of the then outstanding equity securities or combined voting power of such Party, other than acquisitions by employee benefit plans sponsored or maintained by such Party; (b) the consummation of a business combination involving such Party with a Third Party, unless, following such business combination, the stockholders of such Party immediately prior to such business combination beneficially own directly or indirectly more than fifty percent (50%) of the then outstanding securities or combined voting power of the surviving entity or the parent of the surviving entity immediately after such business combination; or (c) the sale of all or substantially

all of such Party's and its Affiliates', if applicable, assets or business relating to the subject matter of this Agreement.

1.7 CLA

The term "CLA" shall mean the collaboration and license agreement between the Parties for which Roche may elect to commence negotiations in accordance with Article 2.11.

1.8 Commercially Reasonable Efforts

The term "Commercially Reasonable Efforts" shall mean such level of efforts consistent with the efforts Roche or Synlogic, as applicable, devotes at the same stage of research, development or commercialization, as applicable, for its own internally discovered or developed pharmaceutical products in a similar area with similar market potential, at a similar stage of their product life taking into account the existence of other competitive products in the market place or under research or development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors. It is understood that such product potential may change from time to time based upon changing scientific, business, marketing, and return on investment considerations.

1.9 Competitive Product

The term "Competitive Product" shall mean any compound or product that specifically regulates, through activation of or agonizing, the Target. For clarity, a Product Candidate is a Competitive Product.

1.10 Confidential Information

The term "Confidential Information" shall mean any and all information, data or know-how (including Know-How), whether technical or non-technical, oral or written, that is disclosed by one Party or its Affiliates ("**Disclosing Party**") to the other Party or its Affiliates ("**Receiving Party**"). Confidential Information shall not include any information, data or know-how that:

(i) was generally available to the public at the time of disclosure, or becomes available to the public after disclosure by the Disclosing Party other than through fault (whether by action or inaction) of the Receiving Party or its Affiliates,

(ii) can be evidenced by written records to have been already known to the Receiving Party or its Affiliates prior to its receipt from the Disclosing Party,

(iii) is obtained by the Receiving Party or its Affiliates at any time lawfully from a Third Party under circumstances permitting its use or disclosure,

(iv) is developed independently by the Receiving Party or its Affiliates other than through knowledge of Confidential Information as evidenced by written records, or

(v) is approved in writing by the Disclosing Party for release by the Receiving Party.

The terms of this Agreement shall be considered Confidential Information of the Parties.

1.11 Control

The term "Control" shall mean (as an adjective or as a verb including conjugations and variations such as "Controls" "Controlled" or "Controlling") (a) with respect to Patent Rights and/or Know-How (including a Party's interest in any jointly-owned Patent Right or Know-How), the possession by a Party of the ability to grant an assignment, a license or sublicense, as applicable, of such Patent Rights and/or Know-How (other than pursuant to this Agreement) without violating the terms of any agreement or arrangement between such Party and any other party and (b) with respect to proprietary materials, the possession by a Party of the ability to supply such proprietary materials to the other Party as provided herein without violating the terms of any agreement or

arrangement between such Party and any other party, in each case, (a) and (b), without being obligated to pay any royalties or other consideration therefor to any Third Parties.

1.12 Deliverables
The term “Deliverables” shall mean the deliverables as defined in the Study Plan and all data packages, reports, data, samples, or other materials generated under the Study Plan.

1.13 [***].

1.14 Effective Date
The term “Effective Date” shall mean the date of the last signature on this Agreement.

1.15 [***].

1.16 [***].

1.17 [***].

1.18 Executive Officer
The term “Executive Officer” shall mean with regard to Synlogic, the chief executive officer, or his or her designee, and with regard to Roche, the head of Pharma Partnering Alliance Management, or his or her designee.

1.19 Expert
The term “Expert” shall mean a person with [***]. Such person shall be fluent in the English language.

1.20 Force Majeure Event
The term “Force Majeure Event” shall mean an event beyond the reasonable control of the affected Party not caused by the fault or negligence of such Party, such as an embargo, war, act of war (whether war be declared or not), act of terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, fire, flood, earthquake, epidemic, pandemic or other act of God or act, omission or delay in acting by any governmental authority.

1.21 FTE
The term “FTE” shall mean [***], which number of hours will be pro-rated based on the number of days when used for periods of less than [***] months, devoted to or in support of research or development activities under the Rescue Plan that is carried out by one or more qualified scientific or technical employees (excluding Third Party contractors) of a Party or its Affiliates, as applicable. Notwithstanding the foregoing, the time of a single individual will not account for more than one (1) FTE for a given Calendar Year (or applicable pro-rata portion of an FTE during any Calendar Quarter or other period of less than a Calendar Year).

1.22 FTE Costs
The term “FTE Costs” shall mean, for any period, the FTE Rate multiplied by the number of FTEs who perform a specified activity under this Agreement. FTEs will be pro-rated on a daily basis if necessary.

1.23 FTE Rate
The term “FTE Rate” shall mean, with respect to research or development activities under the Rescue Plan, $[***] per FTE. The FTE Rate includes (a) all wages and salaries, employee

benefits, bonus, travel and entertainment, supplies and other direct expenses and (b) indirect allocations, including all general and administrative expenses, human resources, finance, occupancy and depreciation, in each case ((a) and (b)), expended in connection with relevant activities.

1.24 GAAP
The term “GAAP” shall mean United States generally accepted accounting principles, consistently applied.

1.25 GCP
The term “GCP” shall mean good clinical practices, which are the then-current standards for Clinical Trials for pharmaceuticals, as set forth in the FD&C Act, ICH Guideline Q7A, or other Applicable Law, and such standards of good clinical practice as are required by the Regulatory Authorities of the European Union and other organizations and governmental authorities in countries for which the applicable Product Candidate or Product is intended to be developed, to the extent such standards are not less stringent than United States standards or ICH Guidelines.

1.26 GLP
The term “GLP” shall mean the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or the successor thereto, or comparable regulatory standards in jurisdictions outside of the United States as they may be updated from time to time, to the extent such standards are not less stringent than United States standards.

1.27 GMP
The term “GMP” shall mean the then-current Good Manufacturing Practices as specified in Applicable Law, including the United States Code of Federal Regulations, ICH Guideline Q7A, or equivalent laws, rules or regulations of an applicable Regulatory Authority at the time of manufacture.

1.28 Governmental Authority
The term “Governmental Authority” shall mean any applicable government authority, court, council, tribunal, arbitrator, agency, department, bureau, branch, office, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city, or other political subdivision thereof, or (c) any supranational body.

1.29 Insolvency Event
The term “Insolvency Event” shall mean circumstances under which a Party (i) has a receiver or similar officer appointed over all or a material part of its assets or undertaking; (ii) passes a resolution for winding-up (other than a winding-up for the purpose of, or in connection with, any solvent amalgamation or reconstruction) or a court makes an order to that effect or a court makes an order for administration (or any equivalent order in any jurisdiction); (iii) enters into any composition or arrangement with its creditors (other than relating to a solvent restructuring); (iv) ceases to carry on business; or (v) is unable to pay its debts as they become due in the ordinary course of business.

1.30 IFRS
The term “IFRS” shall mean International Financial Reporting Standards.

1.31 JOT
The term “JOT” shall mean the joint operation team described in Section 3.2.

1.32 JRC
The term “JRC” shall mean the joint research committee described in Section 3.1.

1.33 Know-How
The term “Know-How” shall mean any inventions, discoveries, data, knowledge, information and materials, including samples, chemical manufacturing data, toxicological data, pharmacological data, preclinical and clinical data, results, formulas, trade secrets, techniques, methods, processes, procedures, technology, practices, chemical structures, nucleic and amino acid sequences, assays, platforms, formulations, specifications and quality control testing data.

1.34 Material Delay
The term “Material Delay” shall mean any unanticipated delay of greater than [***] consecutive days in the timeline for a Party to conduct its respective activities under the Rescue Plan or Study Plan for Part B2, including but not limited to (i) non-scientific events, including for example, a Force Majeure Event, or (ii) scientific events independent of the performance of Product Candidate features, but which materially impacts the ability to assess the data package for Part B2, including for example, failure of the positive/negative control to work as expected or failure of the experimental model.

1.35 Materials
The term “Materials” means all biological materials, chemical compounds and other materials provided by such Party to the other Party for use by the other Party to conduct activities pursuant to this Agreement.

1.36 Out-of-Pocket Costs
The term “Out-of-Pocket Costs” means, with respect to a Party, costs and expenses paid by such Party or its Affiliates to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards), other than employees of such Party or its Affiliates.

1.37 Patent Rights
The term “Patent Rights” shall mean all rights under any patent or patent application, in any country worldwide, including any provisional, non-provisional, substitution renewal, divisional, continuation or continuation-in-part and all patents granted thereon, and all reissues, re-examinations, extensions, confirmations, revalidations, registrations and patents of addition thereof, including patent term extensions and supplementary protection certificates, international patent applications filed under the Patent Cooperation Treaty (PCT) and any foreign equivalents to any of the foregoing.

1.38 Party
The term “Party” shall mean Synlogic or Roche, as the case may be, and “Parties” shall mean Synlogic and Roche collectively.

1.39 Product Candidate
The term “Product Candidate” shall mean [***].

1.40 Product
The term “Product” shall mean any product, including any combination product, containing a Product Candidate as an active ingredient regardless of their finished form, formulation or dosage.

1.41 Regulatory Authority
The term “Regulatory Authority” shall mean, with respect to a given country, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the EMA), regional, state or local regulatory agency, department, bureau, board, commission, council or other Governmental Authority that holds responsibility for development, commercialization or manufacturing of, and the granting of marketing approval for a pharmaceutical product in such country or region.

1.42 Rescue Plan Costs
The term Rescue Plan Costs” shall mean FTE Costs and Out-of-Pocket Costs incurred by or on behalf of a Party or its Affiliates in the conduct of research and development activities in accordance with any Rescue Plan.

1.43 Synlogic Platform Technology
The term “Synlogic Platform Technology” shall mean [***].

1.44 Synthetic Biotic Medicines
The term “Synthetic Biotic Medicines” shall mean [***].

1.45 Target
The term “Target” shall mean [***].

1.46 Third Party
The term “Third Party” shall mean a person or entity other than (i) Synlogic or any of its Affiliates or (ii) Roche or any of its Affiliates.

1.47 Additional Definitions
Each of the following definitions is set forth in the Section of this Agreement indicated below:

Definition	Section
Alliance Director	3.4
Acquired Party	7.2
Auditing Party	5.5.1
Audited Party	5.5.1
Breaching Party	12.2.1
Chairperson	3.1.2
CLA Term Sheet	2.11
Collaboration Know-How	9.1.2
Collaboration Patent Rights	9.1.2
Collaboration Technology	9.1.2
Development Budget	5.2.1
Disclosing Party	1.11
Expert Committee	3.3
Filing Party	6.2
ICC	13.11
Indemnified Party	11.3
Indemnifying Party	11.3
Losses	11.1
Members	3.1.2
Non-Breaching Party	12.2.1

Non-Filing Party	6.2
Non-Publishing Party	6.4
Option Exercise Deadline	4
Option Right	4
Other Acquired Program	8
Part	2.1
Part A Payment Trigger Date	2.7.2
Part B1 Payment Trigger Date	2.7.2
Part B2 Payment Trigger Date	2.7.2
Payment Trigger Dates	2.7.2
Peremptory Notice Period	12.2.1
Pilot Collaboration	2.1
Provision Date	2.7.1
Publishing Party	6.4
Receiving Party	1.11
Re-Negotiation Period	2.10
Re-Negotiation Request	2.10
Representatives	6.1
Rescue Plan	2.8
Rescue Plan Decision Period	2.8
Roche Indemnitees	11.1
Sensitive Information	7
Sharing Date	6.3
Study Plan	2.2
Success Criteria	2.2
Success Criteria Failure Expiration	2.8
Synlogic Acquisition	7.3
Synlogic Acquisition Program	7.3
Synlogic COC Program	7.2
Synlogic Indemnitees	11.2
Third Party Acquisition	8
Third Party Claims	11.1

2 Conduct of the Pilot Collaboration

2.1 Scope

The goals of the collaboration under this Agreement ("**Pilot Collaboration**") are for the Parties to research and pre-clinically develop Product Candidates by [***]. The Pilot Collaboration is divided into three parts, which shall each be defined in the Study Plan: "**Part A**", "**Part B1**" and "**Part B2**" (each a "**Part**").

2.2 Study Plan

The detailed study plan for the Pilot Collaboration is attached hereto as Appendix 1 ("**Study Plan**"). The Parties will conduct the Pilot Collaboration in accordance with the Study Plan with oversight by the JRC. Subject to Section 3.1.4 (g), the Study Plan may only be modified by written agreement of the Parties; provided that the Study Plan shall at all times set forth (a) the three Parts of the Pilot Collaboration and a list of defined success criteria ("**Success Criteria**") for each Part, (b) the work to be performed by Synlogic and/or Roche, (c) the Material(s) to be provided by Roche to Synlogic and by Synlogic to Roche, respectively, (d) the expected Deliverables, including data packages, to be provided by each Party during the Pilot Collaboration.

2.3 Transfer of Materials

To facilitate the conduct of activities under the Study Plan (and Rescue Plan, as applicable), each Party will provide such Materials specified in the Study Plan (and Rescue Plan, as applicable) to the other Party in reasonable quantities to permit such other Party to conduct its respective activities under the Study Plan (and Rescue Plan, as applicable). All Materials transferred pursuant to this Section 2.3: (a) will be provided according to DAP (address of the receiving Party) Incoterms® 2020, (b) will remain the sole property of the supplying Party, (c) will be used only in the fulfilment of the receiving Party's obligations or exercise of rights under this Agreement, (d) will remain solely under the control of the receiving Party, (e) will not be used or delivered by the receiving Party to or for the benefit of any Third Party (other than a subcontractor permitted in accordance with Section 8.3) without the prior written consent of the supplying Party, and (f) will not be used in research or testing involving human subjects, unless expressly agreed in writing. The receiving Party will use the Materials in compliance with Applicable Laws and the terms and conditions of this Agreement, and will not reverse engineer or chemically analyse such Materials, except as specified in the Study Plan or Rescue Plan. All Materials supplied under this Section 2.3 that are not Deliverables are supplied "as is", with no warranties of fitness for a particular purpose and must be used with prudence and appropriate caution in any experimental work, as not all of their characteristics may be known.

2.4 Diligent Efforts

Roche and Synlogic shall each use Commercially Reasonable Efforts to perform their respective tasks and obligations in conducting all activities ascribed to it in the then-current Study Plan and any Rescue Plan, as applicable, in accordance with the time parameters and the Rescue Plan Costs set forth therein.

2.5 Records

Each Party will maintain, and cause its Affiliates and subcontractors to maintain, records of the activities undertaken pursuant to the Study Plan or Rescue Plan in sufficient detail and in good scientific manner appropriate for scientific, patent and regulatory purposes, which will be complete and accurate in all material respects and will fully and properly reflect all work done, data and developments made, and results achieved.

2.6 Reporting

Each Party will furnish to the JRC, within [***] days after the end of each calendar quarter, to the extent applicable to such Party, an update on such Party's progress under the Study Plan or Rescue Plan during the relevant calendar quarter, including a summary of any results and data generated by such Party under such Study Plan or Rescue Plan. Such Party will provide the JRC with such other information, results and data with respect to the research activities under the Study Plan or Rescue Plan as any member of the JRC may reasonably request that are in such Party's possession or control.

2.7 Provision of Data Packages; Achievement of Success Criteria

2.7.1 Provision of Data Packages

With respect to each of Part A, Part B1, and Part B2 of the Study Plan or Rescue Plan, as applicable, upon the JOT's reasonable belief (as determined in good faith) that the Success Criteria for such Part has been achieved, Synlogic will provide a data package with all data and results for its respective activities for such Part as required under the Study Plan or the applicable Rescue Plan (the date such data package is provided, the "**Provision Date**"). After the Provision Date for a given Part, the JRC will meet within [***] days after the Provision Date to review the full data package and determine whether or not the Success Criteria have been met for such Part.

2.7.2 Achievement of Success Criteria

Upon the JRC's determination that the Success Criteria for Part A have been met (including after any Rescue Plan, if applicable) (the "**Part A Payment Trigger Date**"), Roche will pay Synlogic the milestone payment set forth in Section 5.1.2. Upon the JRC's determination that the Success Criteria for Part B1 have been met (including after any Rescue Plan, if applicable) (the "**Part B1 Payment Trigger Date**"), Roche will pay Synlogic the milestone payment set forth in Section 5.1.3. Upon the JRC's determination that the Success Criteria for Part B2 have been met (including after any Rescue Plan, if applicable) (the "**Part B2 Payment Trigger Date**", and, together with the Part A Payment Trigger Date and the Part B1 Payment Trigger Date, the "**Payment Trigger Dates**"), Roche will pay Synlogic the milestone payment set forth in Section 5.1.4.

2.8 Rescue Plan

With respect to each of Part A, Part B1, and Part B2 of the Study Plan, if, following the Provision Date, the JRC determines that the Success Criteria have not been met for such Part (a "**Success Criteria Failure Determination**"), then within [***] days after the Provision Date ("**Rescue Plan Decision Period**"), Roche may request in writing for the JRC to discuss an additional plan for such Part for additional optimization or experiments to be performed by the Parties with the goal of achieving the Success Criteria for such Part. In the event that the Parties mutually agree on the activities to be conducted pursuant to an additional plan for such Part, then the Parties will document such additional activities in a "**Rescue Plan**" for such Part, including (i) a list of activities to be conducted by the Parties, (ii) an estimated timeline to conduct such activities, and (iii) the Rescue Plan Costs for such activities, broken down by Party.

2.9 Success Criteria Failure Expiration

2.9.1 Without Rescue Plan

(a) A Success Criteria Failure Determination occurs with respect to Part A or Part B1 on the earlier of, as applicable, (i) the date that the Parties conclude they are unable to agree upon a Rescue Plan, after Roche has made a timely request for a Rescue Plan in accordance with Section 2.8, or (ii), if Roche has failed to make a timely request for a Rescue Plan in accordance with Section 2.8 the expiration of the Rescue Plan Decision Period; provided, however, that Roche may issue the Re-Negotiation Request before the occurrence of the Success Criteria Failure Expiration pursuant to Article 3.

(b) A Success Criteria Failure Determination occurs with respect to Part B2 on the expiration of the Rescue Plan Decision Period (or such earlier time as Roche notifies Synlogic that it will not initiate negotiations of the CLA), if Roche has not initiated negotiations of the CLA, on the expiration of the Rescue Plan Decision Period), and Roche shall not have the right to issue a Re-Negotiation Request.

(c) A Success Criteria Failure Determination occurs with respect to Part B2 on the date that the Parties conclude they are unable to agree upon a Rescue Plan under Section 2.8, if Roche requests a Rescue Plan prior to the end of the Rescue Plan Decision Period.

2.9.2 With Rescue Plan

If Roche timely requests a Rescue Plan with respect to either Part A or Part B1 and the Parties agree upon a Rescue Plan, and thereafter it is determined in accordance with Section 2.7.1 that

the Success Criteria for such Part are not met upon completion of the applicable Rescue Plan, then Success Criteria Failure Expiration shall be deemed to have occurred with respect to such Part on the date that the JRC determines that the Success Criteria have not been met under such Rescue Plan. Notwithstanding the foregoing, if Roche issues a Re-Negotiation Request within [***] days thereafter, then Section 2.10 shall apply.

2.10 Re-Negotiation Request

Roche has a [***] right prior to the Option Exercise Deadline to issue a written request to re-negotiate the scope of this Agreement (a "**Re-Negotiation Request**"). If Roche issues a Re-Negotiation Request, then for a period of [***] days thereafter (or until such time as Roche informs Synlogic that it desires to terminate such negotiations, if earlier) (the "**Re-Negotiation Period**"), the Parties will negotiate in good faith a new pilot collaboration agreement or other agreement, including a potential change of scope for targets other than the Target, the scope of the transaction and the associated economics for such transaction. If the Parties are unable to mutually agree to a new pilot collaboration agreement or other agreement during the [***] day period following the date of the Re-Negotiation Request, then the Parties will have no further obligation under this Section 2.10.

2.11 CLA Negotiations

At any time after the Effective Date but no later than [***] days after the Payment Trigger Date for Part B2 (including provision of any applicable Rescue Plan), Roche may elect to initiate negotiations of the CLA. If Roche initiates such negotiations, the Parties shall negotiate with each other in good faith, which good faith requires adherence to the terms included in the CLA term sheet attached hereto as Appendix 2 (the "**CLA Term Sheet**"). If the CLA is not executed by the Parties prior to the Option Exercise Deadline, then the Parties will have no further obligations to negotiate with each other (unless Roche has issued a Re-Negotiation Request in accordance with Section 2.10).

3 Governance

3.1 Joint Research Committee

3.1.1 Establishment of JRC

As of the Effective Date, the Parties shall establish a JRC to oversee and manage the Pilot Collaboration, Study Plan and/or Rescue Plan, as applicable.

3.1.2 JRC Members

The JRC shall be composed of [***] ("**Members**"). Roche and Synlogic each shall be entitled to appoint [***] Members with appropriate seniority and functional expertise. Each Party may replace any of its Members and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a Member shall notify the other Party at least [***] days prior to the next scheduled meeting of the JRC. Both Parties shall use reasonable efforts to keep an appropriate level of continuity in representation. Both Parties may invite a reasonable number of additional experts and/or advisors to attend part or the whole JRC meeting with prior notification to the JRC. The Alliance Director of each Party may attend the JRC meetings as a permanent participant. Members may be represented at any meeting by another person designated by the absent Member. The JRC shall be chaired by a [***] ("**Chairperson**"), unless agreed otherwise by the JRC.

3.1.3 Meetings.

The format (virtual or in person) and venue for the meetings shall be agreed by the JRC. The JRC will meet at least once every [***] months or as agreed by the JRC to plan, review and discuss the progress of the Pilot Collaboration. Notwithstanding the foregoing, in any case where a matter within the JRC's authority arises, the JRC will convene a meeting, either virtually or in person, and consider such matter as soon as reasonably practicable, but in no event later than [***] days after the matter is first brought to the JRC's attention (or, if earlier, at the next regularly scheduled JRC meeting). Alternatively, the JRC may decide to take decisions by email.).

3.1.4 Responsibilities of JRC.

The JRC shall have the responsibility and authority to:

(a) review and oversee the execution of the Study Plan and/or Rescue Plan, as applicable, for the Pilot Collaboration, including the Success Criteria for each Part, the work to be performed by Synlogic and/or Roche, the Material(s) to be provided by Roche to Synlogic and by Synlogic to Roche, respectively, and the expected deliverables and data packages to be provided by each Party during the Pilot Collaboration;

(b) review the efforts of the Parties under the Pilot Collaboration;

(c) discuss appropriate resources necessary to conduct the Rescue Plan, as applicable;

(d) establish, oversee and set expectations and mandates for the JOT;

(e) recommend action items to each Party's respective decision making bodies;

(f) attempt to resolve any disputes on an informal basis; and

(g) make minor consensual changes to the Study Plan, provided that such changes do not affect Deliverables, Success Criteria and timelines and budget.

The JRC shall have no responsibility and authority other than that expressly set forth in this Section 3.1.4.

3.2 Joint Operation Team

The JRC shall establish a JOT with respect to the day-to-day conduct of certain activities under the Study Plan or any Rescue Plan. The JOT shall be composed of representatives designated by each Party. Representatives must be appropriate for the tasks then being undertaken and the stage of research or pre-clinical development, in terms of their seniority, availability, function in their respective organizations, training and experience. Each Party shall designate one of its representatives as its primary JOT contact. Each Party may replace its representatives from time to time upon written notice to the other Party; *provided*, *however*, if a Party's representative is unable to attend a meeting, such Party may designate a knowledgeable alternate to attend such meeting and perform the functions of such representative. The JOT will be responsible for overseeing the day-to-day execution of the Study Plan and for reviewing the Parties' progress thereunder, subject to the oversight by the JRC. The JOT shall meet at least monthly by audio or video teleconference or as otherwise agreed by the JOT. For the avoidance of doubt, the JOT is not a decision-making body.

3.3 Dispute Resolution

The JRC shall operate by consensus, with each of the [***] of each Party having collectively [***]. In the event consensus cannot be reached, the following rules shall apply:

(a) in the event of a dispute over whether the Part A or Part B1 Success Criteria have been met, then Roche shall have the final say, which shall be made in good faith;

(b) in the event of a dispute over whether the Part B2 Success Criteria have been met, then the matter will be escalated to the respective designated Executive Officer for each Party for a good faith resolution.

If the Executive Officers are unable to resolve the matter within [***] days of such referral, then such dispute shall be resolved by the Expert Committee as follows: Roche will select one (1) Expert, Synlogic will select one (1) Expert, and those two (2) Experts shall select the Expert, who shall then be chairman of a committee of the three (3) Experts (the "**Expert Committee**"), each with a single deciding vote. The Expert Committee will promptly hold a meeting to review the issue under review, at which meeting it will consider memoranda based on the data package for Part B2 submitted by each Party at least [***] days before the meeting, as well as reasonable additional arguments that each Party may present at the meeting. The Expert Committee shall then within [***] days after the meeting, make a determination on such dispute. The determination of the Expert Committee as to the dispute under review will be binding on both Parties. The Parties will share equally in the costs of the Expert Committee. Unless otherwise agreed to by the Parties, the Expert Committee may not decide on issues outside the scope mandated under terms of this Agreement.

(c) Other than a dispute over whether the Success Criteria have been met,

(i) [***], and

(ii) [***].

3.4 Alliance Director

Each Party shall appoint one person to be its point of contact with responsibility for facilitating communication and collaboration between the Parties (each, an "**Alliance Director**"). The Alliance Directors shall be permanent participants of the JRC meetings (but not members of the JRC) and may attend JOT meetings as appropriate. The Alliance Directors shall facilitate resolution of potential and pending issues and potential disputes to enable the JRC to reach consensus and avert escalation of such issues or potential disputes.

3.5 Limitations of Authority

The JRC, the JOT or any other committee shall have no authority to amend or waive any terms of this Agreement, nor shall the JRC, the JOT or any other committee have the authority to determine whether a Party is in breach of this Agreement.

3.6 Expenses

Each Party shall be responsible for its own expenses including travel and accommodation costs incurred in connection with the JRC, the JOT or any other committee.

3.7 Lifetime

The JRC shall exist until the completion of the Pilot Collaboration, unless otherwise agreed in the CLA. The JOT shall exist until the completion of the Pilot Collaboration.

4 Option Right

Synlogic hereby grants Roche an exclusive option right ("**Option Right**") which, if exercised by Roche, shall grant to Roche the rights and licenses set forth in the definitive CLA negotiated and

executed in accordance with Section 2.11. Roche may exercise its Option Right at any time prior to the Option Exercise Deadline. "**Option Exercise Deadline**" shall mean the earliest of:

(a) the expiration or termination of this Agreement, or

(b) the [***] anniversary of the Effective Date if the Success Criteria for Part A have not been achieved by such date, or

(c) the [***] anniversary of the date of the Payment Trigger Date for Part A if the Success Criteria for Part B1 have not been achieved by such date, or

(d) (i) [***] days after the Provision Date for Part B2 (including provision of any applicable Rescue Plan), [***] days after the end of the Rescue Plan Decision Period for Part B2 where (A) the Success Criteria have not been met for Part B2 and (B) prior to the end of the Rescue Plan Decision Period, if Roche has not yet requested a Rescue Plan but has initiated negotiations of the CLA, or

(e) the date Roche informs Synlogic that it will not initiate negotiations of the CLA or desires to terminate negotiations of the CLA, or

(f) On the [***] anniversary of the Payment Trigger Date for Part B1, provided that if the Study Plan timelines for Part B2 have not been met because of any Material Delay, the Option Exercise Deadline will be extended by the additional days needed to enable the Party performing the relevant activities to remedy such Material Delay and to complete its activities for Part B2 for the applicable Rescue Plan or Study Plan. The duration of such timeline extension shall be agreed upon by the JRC in good faith. In the event of a dispute over whether a timeline extension is appropriate, the Party performing the activities for which the time extension is necessary, shall have the final say, which must be made in good faith.

5 Payments by Roche

In consideration of Synlogic's contribution to the Pilot Collaboration, Roche shall make the following payments:

5.1 Upfront and Milestone Payments

5.1.1 Upfront

Roche shall pay an upfront of one million US dollars (US$ 1,000,000), due [***] days from the Effective Date and receipt of an invoice from Synlogic.

5.1.2 Part A Milestone Payment

Roche shall make a milestone payment of [***] for Part A of the Study Plan, due [***] days after the Part A Payment Trigger Date and receipt of an invoice from Synlogic.

5.1.3 Part B1 Milestone Payment

Roche shall make a milestone payment of [***] for Part B1 of the Study Plan, due [***] days after the Part B1 Payment Trigger Date and receipt of an invoice from Synlogic.

5.1.4 Part B2 Milestone Payment

Roche shall make a milestone payment of [***] for Part B2 of the Study Plan, due [***] days after the Part B2 Payment Trigger Date and receipt of an invoice, unless there is a dispute as to

whether the Success Criteria have been met which is resolved in Synlogic's favour, in which case the payment will be deferred until [***] days after resolution of the dispute and receipt of an invoice.

5.1.5 General
Each payment under this Section 5.1 will be non-refundable and non-creditable.

5.2 Research Funding

5.2.1 Cost Sharing Responsibilities.
[***]. For any Rescue Plan, Roche will fund [***] percent ([***]%) and Synlogic will fund the remaining [***] percent ([***]%) of all Rescue Plan Costs under the budget related to the activities described under such Rescue Plan (the "**Rescue Plan Budget**"); provided that such Rescue Plan Costs are incurred pursuant to the Rescue Plan as approved by the JRC. Synlogic shall invoice Roche on a calendar quarterly basis for all Rescue Plan Costs payable to Synlogic by Roche pursuant to the Rescue Plan Budget. Roche shall pay each such invoice within [***] days of receipt thereof.

5.2.2 Excess Rescue Plan Costs.
Each Party will use Commercially Reasonable Efforts to ensure that the Rescue Plan Costs for a given Calendar Year do not exceed [***] ([***]%) of the agreed Rescue Plan Budget with respect to that year. If either Party's Rescue Plan Costs exceed [***] ([***]%) of the agreed Rescue Plan Budget for the activities for which such Party is responsible under the Rescue Plan, then such Party shall be solely responsible for any such excess Rescue Plan Costs.

5.3 Invoices
All invoices shall be issued to the following address (or other address as Roche may later provide):

F. Hoffmann-La Roche Ltd
Accounts Payable
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

Each invoice shall contain:

- Synlogic's name, address, VAT number;
- billing details: invoice date, reference to the contract, applicable payment term and a description of the activities for which payment is sought, in reasonable detail;
- the invoice amount and currency;
- Purchase Order number if provided by Roche;
- bank account information to which payment shall be made; and
- the name of Roche's contract manager.

Failure to provide invoices as directed may result in payment delays.

All payments according to this Article 5 made by Roche to Synlogic are net of all present or future taxes, levies, imposts, deductions, charges or withholdings, and all liabilities with respect thereto. According to this, all taxes, fees, duties etc. due by Synlogic shall be paid solely by Synlogic.
The payments to be made under this Agreement shall not include value added tax (VAT), if any is due and payable thereon.

If any Applicable Law requires the withholding of taxes of any type, levies or other charges with respect to any amounts payable under this Agreement to Synlogic, then Roche shall promptly pay such tax, levy or charge for and on behalf of Synlogic to the proper governmental authority, and shall promptly furnish Synlogic with receipt of payment. Roche shall be entitled to deduct any such tax, levy or charge actually paid from royalty or other payment due to Synlogic or be promptly reimbursed by Synlogic if no further payments are due to Synlogic. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

5.4 Late Payments

Any payment under this Agreement that is not paid on the thirtieth business day after the date such payment is due shall bear interest, to the extent permitted by Applicable Law, at [***] percentage points above the average one-month Euro Interbank Offered Rate (EURIBOR) (if EURIBOR ceases to exist, then other such short term inter-bank interest rate as deemed suitable by the Parties), as reported by Reuters from time to time, calculated on the number of days such payment is overdue.

5.5 Auditing

5.5.1 Auditing

Each Party shall keep, and shall require its Affiliates and subcontractors to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all Rescue Plan Costs under this Agreement. Such books of accounts shall be kept at their principal place of business. Each Party (the "**Auditing Party**"), at its sole cost and expense, shall have the right to engage an internationally recognized independent public accountant reasonably acceptable to the other Party (the "**Audited Party**") to perform, on behalf of the auditing Party, an audit of such books and records of such member that are deemed necessary by the independent public accountant to report on the Rescue Plan Costs incurred for the period or periods requested by the auditing Party and the correctness of any financial report or payments made under this Agreement.

Upon timely request and at least [***] working days' prior written notice from the auditing Party, such audit shall be conducted for those countries for which the auditing Party has specifically requested, during regular business hours in such a manner as to not unnecessarily interfere with the audited Party's normal business activities. Such audit shall be limited to results in the [***] Calendar Years prior to audit notification, and if the auditing Party requests an audit for a given Calendar Year, no additional audits may be conducted for such Calendar Year. If the auditing Party does not request an audit of a given country in a given Calendar Year on or before the [***] anniversary of the end of such Calendar Year, then the auditing Party will be deemed to have accepted the royalty payments and reports for such country in such Calendar Year.

Such audit shall not be performed more frequently [***] Calendar Year nor more frequently than once with respect to records covering any specific period of time.

All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying Rescue Plan Costs, shall be treated as the audited Party's Confidential Information subject to the obligations of this Agreement and need neither be retained more than [***] after completion of an audit hereof, if an audit has been requested; nor more than [***] from the end of the Calendar Year to which each shall pertain; nor more than [***] after the date of termination of this Agreement.

5.5.2 Audit Reports

The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The auditors shall share all draft audit findings with the audited Party before sharing such findings with the auditing Party and before the final audit report is issued. The final audit report shall be shared with the audited Party at the same time it is shared with the auditing Party.

5.5.3 Over- or Under-Payment

If the audit reveals an overpayment, the auditing Party shall reimburse the audited Party for the amount of the overpayment within [***] days. If the audit reveals an underpayment, the audited Party shall reimburse the auditing Party for the amount of the underpayment within [***] days. The audited Party shall pay for the audit costs if the underpayment of the audited Party exceeds [***] percent ([***]%) of the aggregate amount of Rescue Plan Costs owed for the period of the audit.

6 Confidential Information

6.1 Obligation Not to Disclose Confidential Information

During the term of this Agreement and for a period of [***] years thereafter, the Receiving Party agrees to (i) treat such Confidential Information as confidential with the same standard of care it would its own proprietary information of a like nature, but no less than a reasonable standard of care; (ii) take commercially reasonable precautions to prevent the disclosure of such Confidential Information to any Third Party, and (iii) not use such Confidential Information other than for the purpose of fulfilling its obligations or exercising its rights under this Agreement, without the prior written consent of the Disclosing Party.

Each Receiving Party shall only disclose the Disclosing Party's Confidential Information to those of its and its Affiliates' employees, agents, representatives, advisors, Third Party contract research organizations, and potential and actual *bona fide* investors (collectively, "**Representatives**") who (i) with respect to Disclosing Party's employees and Third Party contract research organizations, have need to know the Confidential Information for the performance of the Study Plan, (ii) are apprised of the confidential nature of the Confidential Information and (iii) are bound to written confidentiality and nondisclosure obligations (or in the case of professional advisors, ethical duties) which are no less restrictive than the terms of this Agreement (but which may be of a shorter duration, if customary). Each Party shall be responsible for any breach of any of the terms of this Agreement by any of its Representatives.

6.2 Permitted Disclosure

In the event that Confidential Information of a Disclosing Party is required to be disclosed by a Receiving Party pursuant to law or regulation, by subpoena, judicial or administrative order, the party required to make disclosure shall give timely prior notice (in no event less than [***] days) to the other party to allow that party to assert any exclusions or exemptions that may be available to it under such law or regulation and shall provide reasonable cooperation and assistance to such party in seeking to obtain protection of such Confidential Information. If either Party reasonably concludes that a copy of this Agreement or any disclosure regarding this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, then such Party (the "**Filing Party**") will provide the other Party (the "**Non-Filing Party**") with a draft of such disclosure at least [***] prior to its intended publication for the Non-Filing Party's review if such disclosure is being made in connection with any regularly filed report, including any quarterly (10-Q) or annual (10-K) report, or at least [***] business days prior to its intended publication for all other disclosures. During such period, the Non-Filing Party shall (i) approve the draft disclosure and permit the Filing Party to

issue it, or (ii) contact the Filing Party to discuss modification to the draft disclosure. If the Non-Filing Party asks for modification, then the Filing Party shall make such modification unless the Non-Filing Party is advised by its outside legal counsel in good faith that such disclosure must be made without such modification to comply with applicable law.

6.3 Sharing Date

Synlogic may not share the results of the Pilot Collaboration with Third Parties prior to the Sharing Date. After the Sharing Date, Synlogic may share the results of the Pilot Collaboration with Third Parties under obligations of confidentiality, however such results may not mention Roche or Roche Affiliates. "**Sharing Date**" means the later of (i) expiration or termination of this Agreement, (ii) the Re-Negotiation Period, if applicable, and (iii) [***] days after the Option Exercise Deadline pursuant to clause (e) of Article 4, provided, however, that in either of (i) or (ii), if the Parties initiate negotiations for the CLA prior to the end of the Sharing Date and eventually successfully enter into the CLA, then the terms of the CLA shall govern when Synlogic may share such results, which point in time shall be no earlier than the end of the [***] (unless mutually agreed by the Parties under the CLA).

6.4 Publication

With respect to any paper or presentation proposed for disclosure (a) by Roche which includes Confidential Information of Synlogic, or (b) during this Agreement term, by either Party which utilizes information, data, and/or results generated under the Pilot Collaboration or (c) Synlogic, which includes Confidential Information of Roche (such publishing Party in each of clauses (a)-(c), the "**Publishing Party**"), the other Party (the "**Non-Publishing Party**") shall have the right to review any such proposed paper or presentation. The Publishing Party shall submit to the Non-Publishing Party the proposed publication or presentation (including posters, slides, abstracts, manuscripts, marketing materials and written descriptions of oral presentations) at least [***] calendar days prior to the date of submission for publication or the date of presentation, whichever is earlier, of any of such submitted materials. The Non-Publishing Party shall review such submitted materials and respond to the Publishing Party as soon as reasonably possible, but in any case within [***] calendar days ([***] calendar days for abstracts) of receipt thereof. At the option of the Non-Publishing Party, the Publishing Party shall (A) delete from such proposed publication or presentation any Confidential Information of the Non-Publishing Party, and/or (B) delay the date of such submission for publication or the date of such presentation for a period of time sufficiently long (but in no event longer than an additional [***] calendar days) to permit the Non-Publishing Party to prepare and file a patent application for any patentable subject matter in accordance with Section 9.2. Once a publication has been approved by the Non-Publishing Party, the Publishing Party may make subsequent public disclosure of the contents of such publication without the further approval of the Non-Publishing Party; *provided*, such content is not presented with any new data or information or conclusions and/or in a form or manner that materially alters the understanding of the subject matter therein. Notwithstanding the foregoing, in the case of proposed publication or presentation by a Party during this Agreement term under clause (b) above, neither Party shall submit such publication or make such presentation without the other Party's prior written consent.

6.5 Return or Destruction of Confidential Information.

Upon the written request of the Disclosing Party, the Receiving Party shall return or destroy all copies of the Confidential Information, provided however, that the Receiving Party may retain one copy of such information in its files for archival purposes. Any electronic back-up tapes or other electronic back-up files that have been created solely by their automatic or routine archiving and back-up procedures shall not be subject to this Section. For clarity, Roche may retain all results and data arising from the performance of the Study Plan.

7 Exclusivity; Change of Control

7.1 Exclusivity Covenants

During the term of this Agreement, Synlogic will not [***], in each case [***] other than as requested by Synlogic and agreed by Roche in its sole discretion. For clarity, [***].

7.2 Change of Control

If there is a Change of Control, then the Party experiencing such Change of Control ("**Acquired Party**") shall provide written notice to the other Party ("**Non-Acquired Party**") at least [***].

Following consummation of the Change of Control, the Non-Acquired Party and the Acquirer shall adopt in writing reasonable procedures, including the separation of personnel, to prevent the disclosure of the Non-Acquired Party's Confidential Information beyond the Acquired Party's personnel who need to know the Confidential Information solely for the purpose of fulfilling the Acquired Party's obligations under this Agreement.

Notwithstanding anything herein to the contrary, after any Change of Control of a Party, no Know-How, Patent Rights or proprietary materials of any Affiliate of such Party that becomes an Affiliate after such Change of Control of such Party shall become (i) in the case of Synlogic, "licensed to Roche under Section 8.1 or (ii) in the case of Roche, licensed to Synlogic under Section 8.1, in each case (i)-(ii), unless such Know-How, Patent Rights or proprietary materials are thereafter intentionally used by such Party in such Party's performance of its activities under this Agreement.

7.2.1 Synlogic Change of Control

Notwithstanding Section 7.1, if a Change of Control occurs with respect to Synlogic or its parent Affiliate with an Acquirer, and the Acquirer (or any of such Acquirer's successors or assigns, other than Synlogic and its Affiliates as of the Change of Control) as of the Change of Control, or later, has a program or product (or rights thereto) that would otherwise violate Section 7.1 (each, a "**Synlogic COC Program**"), then (a) Section 7.1 will not apply with respect to such Synlogic COC Program, and (b) such Third Party, or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, as applicable, will be permitted to pursue, and continue such Synlogic COC Program after such Change of Control and such pursuit and continuation will not constitute a violation of Section 7.1; provided that (i) none of the Collaboration Technology and Patent Rights and Know-How licensed to Synlogic by Roche hereunder will be used in the Synlogic COC Program and (ii) the research activities required under this Agreement will be conducted separately from any research activities directed to such Synlogic COC Program, including the non-use of Roche's Confidential Information, maintenance of separate lab notebooks and records and separate personnel working on each of the activities under this Agreement and the activities covered under such Synlogic COC Program.

Upon [***] days' prior written notice from Roche, Roche, at its sole cost and expense, shall have the right to [***].

7.2.2 Synlogic Acquisition

In addition, notwithstanding Section 7.1, if (a) Synlogic or its Affiliate acquires a Third Party (by merger, sale, consolidation, reorganization, or otherwise) so that such Third Party becomes an Affiliate over which Synlogic or its Affiliate has control, or (b) Synlogic or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (a) and (b), a "**Synlogic Acquisition**"), and, in each case, the Third Party (or any of such

Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Synlogic and its Affiliates as of the Synlogic Acquisition) already has, or the acquired assets contain, as applicable, a program or product that existed prior to the Synlogic Acquisition that would otherwise violate any of Section 7.1 (a "**Synlogic Acquisition Program**"), then Synlogic or such Affiliate will elect whether to (i) divest its rights to such Synlogic Acquisition Program, or (ii) cease the pre-clinical and clinical development and commercialization of such Synlogic Acquisition Program, and will provide Roche written notice of the existence of such Synlogic Acquisition Program and such decision within [***] days after the closing of such Synlogic Acquisition. If Synlogic provides notice as described in clause (i) of the preceding sentence, then Synlogic, and its Affiliates if applicable, will divest such Synlogic Acquisition Program within [***] years after the closing of the applicable Synlogic Acquisition, and if Synlogic provides notice that it will terminate such Synlogic Acquisition Program as described in clause (ii) of the preceding sentence, then Synlogic, and its Affiliates if applicable, will cease the clinical development and commercialization of such Synlogic Acquisition Program as soon as reasonably practicable and in any event within [***] days of the closing of the applicable Synlogic Acquisition, giving due consideration to ethical concerns and requirements under Applicable Law and any agreements with Third Parties.

8 Licenses; Subcontracting

8.1 License Grants

8.1.1 Research License

During the term of this Agreement, each Party hereby grants to the other Party a non-exclusive, non-transferable, non-sublicensable (except in accordance with Section 8.2), royalty-free right and license under such Party's respective Patent Rights and Know-How Controlled by such Party as of the Effective Date or during the term of this Agreement that are necessary or reasonably useful to research and pre-clinically develop Product Candidates solely to enable the other Party to conduct the activities assigned to the other Party in the Study Plan or any Rescue Plan.

8.1.2 Collaboration IP

Synlogic hereby grants to Roche a non-exclusive, perpetual, irrevocable, sublicensable right and license, for any and all purposes whatsoever, under the Collaboration Patent Rights claiming inventions made under the Study Plan or the Rescue Plan where such Collaboration Patent Rights (a) do not specifically relate to the Synlogic Platform Technology or to any Product Candidates or Products, or their use or manufacture, and (b) where at least one inventor is an employee or agent of Roche or Roche's Affiliates. Such non-exclusive grant to Roche shall be fully paid-up (subject to any applicable payment obligations under this Agreement and the CLA, if the Parties enter into the CLA).

8.2 Sublicensing

Each Party shall have the right to grant sublicenses under its rights granted under Section 8.1.1 to its Affiliates and to subcontractors permitted in accordance with Section 8.3, without prior approval of the other Party. In addition, Roche shall have the right to grant sublicenses under the license granted pursuant to Section 8.1.2 to Third Parties without the prior consent of Synlogic. Each such sublicense pursuant to this Section 8.2 shall be consistent with all applicable terms and conditions of this Agreement, and each Party shall remain responsible for its rights and obligations hereunder, including the payment of all amounts due hereunder.

8.3 Subcontracting

The Parties will be entitled to utilize the services of Third Parties to perform their respective activities under the Pilot Collaboration; provided, that (a) each Party will require that such Third Party operates in a manner consistent with the terms of this Agreement, and (b) each Party will remain at all times fully liable for its respective responsibilities contracted to such Third Party. Each Party will require that any such Third Party agreement entered into pursuant to this Section 8.3 (a) include confidentiality and non-use provisions that are no less stringent than those set forth in Section 6 (but of duration customary in confidentiality agreements entered into for a similar purpose); and (b) obtain ownership of, or a fully sublicensable license (or an exclusive option to obtain such license) under and to, any Know-How and Patent Rights that are developed by such Third Party in the performance of such agreement. For clarity, the foregoing requirement to obtain ownership of, or a fully sublicensable license (or an exclusive option to obtain such license) will not apply to any background or foundational Know-How or Patent Rights owned or in-licensed by a Third Party or its Affiliates (including any improvements thereto). The Party utilizing the services of a Third Party service provider will be solely responsible for direction of and communications with such Third Party.

9 Intellectual Property and Publications

9.1 IP Ownership

9.1.1 Pre-Existing IP

Each Party shall remain the owner of all Patent Rights, Know-How, inventions, data and other intellectual property rights (i) owned or Controlled by such Party or its Affiliates as of the Effective Date or (ii) that such Party generates independently of this Agreement.

9.1.2 Collaboration IP

Synlogic shall own all Know-How generated solely by or on behalf of either Party or jointly by or on behalf of both Parties under the Study Plan and any Rescue Plan (the "**Collaboration Know-How**") regardless of inventorship, and any Patent Rights that cover or claim such Know-How (the "**Collaboration Patent Rights**", and, together with the Collaboration Know-How, the "**Collaboration Technology**") subject to Section 9.1.1 above. Inventorship will be determined under US patent law as if such Know-How were made in the United States. Roche and its Affiliates will, and hereby does, assign to Synlogic or one or more of its designated Affiliates, its and its Affiliates' right, title and interest in, to and under the Collaboration Technology, as may be necessary to effectuate the allocation of ownership of Know-How set forth in this Section 9.1.2. Roche agrees that it will promptly disclose all Collaboration Technology to Synlogic as it arises and shall take all actions and provide Synlogic with all reasonably requested assistance to effect such assignment and will execute any and all documents necessary to perfect such assignment.

9.2 Patent Prosecution

During the term of this Agreement Synlogic shall be responsible (at its own expense) for filing and prosecution of patent applications claiming Collaboration Know-How. During the term of this Agreement. Synlogic will consult with Roche on the filing and prosecution of Collaboration Patent Rights that might trigger payments from Roche to Synlogic under the definitive CLA and will furnish Roche, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and documents received from outside counsel in the course of prosecuting such Patent Rights, or copies of documents filed with the relevant patent offices with respect to such Patent Rights. Synlogic will consider in good faith any timely comments from Roche thereon.

In the event that, other than in the customary process of patent prosecution, Synlogic intends to abandon any Collaboration Patent Rights that claim any Product Candidates or the use or

manufacture thereof and could potentially be licensed to Roche under the CLA, Synlogic shall notify Roche at least [***] days before any such Patent Right would become abandoned and will offer to assign such Collaboration Patent Rights to Roche.

9.3 Enforcement and Defense
As between the Parties, [***].

10 Representations and Warranties; Covenants

10.1 Synlogic's Representations and Warranties; Covenants
Synlogic hereby represents, warrants and covenants the following to Roche:

(a) Synlogic has the full right, power and authority, and has obtained all approvals, licenses, permits or consents necessary, to enter into this Agreement, to perform all of its obligations hereunder and to grant the licenses granted hereunder.

(b) Synlogic has not as of the Effective Date entered into, and shall not following the Effective Date enter into, any agreement that conflicts with this Agreement or Synlogic's obligations hereunder.

(c) Synlogic has not prior to the Effective Date agreed to grant in the future, and shall not following the Effective Date grant, any license, sublicense or other right to exploit any intellectual property rights that conflicts with the licenses granted to Roche under this Agreement.

(d) All of Synlogic's employees, officers and consultants have executed agreements requiring assignment to Synlogic of all Know-How made by such individuals during the course of and as a result of their association with Synlogic.

(e) Synlogic represents and warrants that neither Synlogic nor Synlogic's employees have ever been debarred under 21 U.S.C. §335a, disqualified under 21 C.F.R. §312.70 or §812.119, sanctioned by a Federal Health Care Program (as defined in 42 U.S.C §1320 a-7b(f)), including without limitation the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any other similar Federal or state agency or program. In the event Synlogic or an employee of Synlogic receives notice of debarment, suspension, sanction, exclusion, ineligibility or disqualification under the above-referenced statutes, Synlogic shall immediately notify Roche in writing and Roche shall have the right, but not the obligation, to terminate this Agreement for breach.

(f) Synlogic and its Affiliates and subcontractors will conduct the research under the Study Plan and each Rescue Plan in a good scientific manner and in accordance with all Applicable Laws.

10.2 Roche Representations and Warranties; Covenants
Roche hereby represents, warrants and covenants the following to Synlogic:

(a) Roche has the full right, power and authority, and has obtained all approvals, licenses, permits or consents necessary, to enter into this Agreement and to perform all of its obligations hereunder and to grant the licenses granted hereunder.

(b) Roche has not as of the Effective Date entered into, and shall not following the Effective Date enter into, any agreement that conflicts with this Agreement or Roche's obligations hereunder.

(c) Roche has not as of the Effective Date agreed to grant in the future, and shall not following the Effective Date grant, any license, sublicense or other right to exploit any intellectual property rights that conflicts with the licenses granted to Synlogic under this Agreement.

(d) Roche and its Affiliates and subcontractors will conduct the research under the Study Plan and each Rescue Plan in a good scientific manner and in accordance with all Applicable Laws.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, (A) NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO MATERIALS OR INFORMATION SUPPLIED BY IT TO THE OTHER PARTY HEREUNDER AND (B) EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

11 Indemnification

11.1 Indemnification by Synlogic

Synlogic hereby agrees to defend, indemnify and hold harmless, Roche, its Affiliates and their respective directors, officers, employees and agents and the successors and assigns of any of the foregoing (collectively, the "**Roche Indemnitees**") from any liabilities, damages, penalties, fines, costs, or expenses (including attorney's fees) (collectively, "**Losses**") arising out of or in connection with any Third Party claims, suits, actions, demands or judgments ("**Third Party Claims**") arising out of (a) Synlogic's performance under this Agreement, or (b) Synlogic's negligence or wilful misconduct; except and to the extent, in each case (a) and (b), that any such Loss is due to the negligence or wilful misconduct of any Roche Indemnitee.

11.2 Indemnification by Roche

Roche hereby agrees to defend, indemnify and hold harmless, Synlogic, its Affiliates and their respective directors, officers, employees and agents and the successors and assigns of any of the foregoing (collectively, the "**Synlogic Indemnitees**") from any Losses arising out of or in connection with any Third Party Claims arising out of (a) Roche's performance under this Agreement, or (b) Roche's negligence or wilful misconduct; except and to the extent, in each case (a) and (b), that any such Loss is due to the negligence or wilful misconduct of any Synlogic Indemnitee.

11.3 Indemnification Procedure

In the event of a Third Party Claim against a Party entitled to indemnification under this Agreement ("**Indemnified Party**"), the Indemnified Party shall promptly notify the other Party ("**Indemnifying Party**") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defence of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

11.4 Insurance

Subject to this Section 11.4, each Party shall obtain and maintain comprehensive general liability insurance customary in the industry for companies of similar size conducting similar business, and in any case sufficient to cover its obligations.

Upon either Party's request, each Party shall provide the other Party with its certificate of insurance evidencing the insurance coverage set forth this Section 11.4. Each Party shall provide to the other Party at least [***] days prior written notice of any cancellation, non-renewal or material change in any of such insurance coverage.

In the event that either Party is an entity which, [***], the obligations set forth in this Section 11.4 above shall not apply with respect to such Party, if such Party notifies the other Party in writing that it elects to provide coverage through a commercially reasonable program of self-insurance; provided, however, that the obligations set forth in this Section 11.4 above shall resume with respect to such Party and its Affiliates, or successor-in-interest and its Affiliates, if such program of self-insurance is terminated or discontinued for any reason.

11.5 Limitation of Liability

NEITHER PARTY WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT, OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF (A) A PARTY'S GROSS NEGLIGENCE OR WILFUL MISCONDUCT, (B) A BREACH OF SECTION 9, (C) A BREACH OF SECTION 6. NOTHING IN THIS SECTION 11.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT.

12 Term and Termination

12.1 Term

This Agreement shall become effective as of the Effective Date. Provided that this Agreement is not earlier terminated in accordance with Section 12.2, it shall continue in force until any of the following:

(a) a Success Criteria Failure Expiration;

(b) the date Roche exercises its Option Right and the Parties enter into the CLA; or

(c) the day after the Option Exercise Deadline.

12.2 Termination

12.2.1 Termination for Breach

A Party ("**Non-Breaching Party**") shall have the right to terminate this Agreement in the event the other Party ("**Breaching Party**") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach. The Breaching Party shall have a period of [***] days after such written notice is provided ("**Peremptory Notice Period**") to cure such breach. If the Breaching Party delivers written notice to the Non-Breaching Party of the Breaching Party's determination

that such material breach cannot be cured within the [***] days and demonstrates that the breaching Party is working diligently to cure such breach, the Peremptory Notice Period shall be extended up to a maximum of [***] days, subject to the remainder of this Section 12.2.1. If the Breaching Party has a bona fide dispute as to whether such breach occurred or has been cured, it will so notify the Non-Breaching Party during the Peremptory Notice Period, and the expiration of the Peremptory Notice Period shall be tolled until such dispute is resolved pursuant to Section 13.11. Upon a determination of breach or failure to cure, the Breaching Party may have the remainder of the Peremptory Notice Period to cure such breach. If such breach is not cured within the Peremptory Notice Period, then absent withdrawal of the Non-Breaching Party's request for termination, this Agreement shall terminate in its entirety or such identified countries effective as of the expiration of the Peremptory Notice Period.

12.2.2 Termination for Scientific Reasons
In case the JRC mutually agrees that the Pilot Collaboration is no longer scientifically viable, the Parties may mutually terminate for lack of scientific viability.

12.2.3 Insolvency
A Party shall have the right to terminate this Agreement upon [***] days' written notice, if the other Party incurs an Insolvency Event; provided, however, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if the Party that incurs the Insolvency Event consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] days after the filing thereof.

12.2.4 Change of Control
Roche shall have the right to terminate this Agreement upon written notice, if such written notice of termination is issued within [***] days after Synlogic has informed Roche of such Change of Control.

12.2.5 Termination by Roche without Cause
Roche may terminate without cause (a) immediately upon written notice where the Success Criteria have been met for either Part A or Part B1 of the Study Plan, commencing on the applicable Provision Date and ending [***] thereafter, or (b) upon ninety (90) days' prior written notice to Synlogic.

12.3 Consequences of Expiration and Termination
Except as otherwise set forth in this Section 12.3 and in Section 12.4, all rights and obligations of the Parties hereunder will terminate as of the effective date of such termination, and all licenses granted under Section 8.1 will terminate unless expressly provided otherwise in Section 8.1.

After the expiration date or effective date of termination, neither Party will have any additional payment obligations to the other Party hereunder other than payments due or accrued prior to such expiration date or effective date of termination but unpaid thereunder (including any milestone payment that is due as a result of the Success Criteria having been met prior to the expiration date or the date of termination).

If this Agreement is terminated or expires without Roche having exercised its Option Right, Synlogic shall, at its own expense, immediately return to Roche all of the Materials and Confidential Information supplied by Roche (including any modified remnants thereof), or destroy all such Material and Confidential Information if so requested by Roche, and Roche shall, at its own expense, immediately return to Synlogic all of the Materials and Confidential Information

supplied by Synlogic (including any modified remnants thereof), or destroy all such Materials and Confidential Information if so requested by Synlogic.

12.4 Survival

Article 1 (Definitions, to the extent necessary to interpret this Agreement), Article 5 (Payments by Roche as applicable), Article 6 (Obligation Not to Disclose Confidential Information), Article 9 (Intellectual Property and Publication), Article 11 (Indemnification), Article 13 (Miscellaneous) as well as Sections 8.1 (License Grant), 12.3 (Consequences of Expiration and Termination) and 12.4 (Survival) shall survive expiration or termination of this Agreement and continue to be enforceable.

13 Miscellaneous

13.1 Force Majeure

Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent, and for so long as, such failure or delay is caused by or results from one or more Force Majeure Events; provided that the affected Party gives the other Party prompt written notice of any such Force Majeure Event and the cessation thereof; and provided further that the affected Party promptly undertakes and continues to use Commercially Reasonable Efforts to cure such failure or delay resulting from the Force Majeure Event as soon as practicable and to mitigate its effects, and promptly resumes performance whenever such Force Majeure Event is removed. Any deadline or time period affected by such a Force Majeure Event or a Party's failure to perform resulting therefrom shall be extended automatically by [***]. If a Force Majeure persists for more than [***] days, the Parties will negotiate in good faith any modifications of the terms of this Agreement that may be necessary to arrive at an equitable solution, unless the Party giving such notice has set out a reasonable timeframe and plan to resolve the effects of such force majeure and executes such plan within such timeframe.

13.2 Independent Contractor

No employee or representative of either Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without said Party's prior written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Synlogic legal relationship to Roche under this Agreement shall be that of independent contractor, and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

13.3 Unenforceable Provisions and Severability

If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions that will achieve as far as possible the economic business intentions of the Parties. However the remainder of this Agreement will remain in full force and effect, provided that the material interests of the Parties are not affected, i.e. the Parties would presumably have concluded this Agreement without the unenforceable provisions.

13.4 Waiver

Failure of a party to require the other party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement.

13.5 Headings
The captions to the Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections hereof.

13.6 Assignment
Neither party may assign this Agreement or any part thereof to any Third Party without the prior written consent of the other party. Notwithstanding the foregoing, subject to Section 7.2, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a party that acquires, by or otherwise in connection with, merger, sale of assets, or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates. The assigning Party will remain responsible for the performance by its assignee of any obligation hereunder so assigned. Any purported assignment in violation of this Section 13.7 will be null, void, and of no legal effect.

13.7 Interpretation
Except where the context expressly requires otherwise:

(a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa),

(b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation",

(c) the word "will" shall be construed to have the same meaning and effect as the word "shall",

(d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein),

(e) any reference herein to any Party or Third Party or person shall be construed to include the Party's or Third Party's or person's permitted successors and assigns,

(f) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof,

(g) all references herein to Articles, Sections or Appendices shall be construed to refer to Articles, Sections or Appendices of this Agreement, and references to this Agreement include all Appendices hereto,

(h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and

(i) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or".

13.8 Entire Understanding
This Agreement shall constitute the entire understanding between the parties with respect to the subject matter hereof and may only be modified by written agreement of both parties.

13.9 Amendments
No amendments of the terms and conditions of this Agreement shall be binding upon either Party hereto unless in writing and signed by both Parties.

13.10 Notice
All notices that are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to Synlogic, to:	Synlogic, Inc. Attn: Chief Executive Officer 301 Binney St., Suite 402 Cambridge, MA 02142
and:	Attn: Legal Department
if to Roche, to:	F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 4070 Basel Switzerland Attn: Legal Department
and:	Hoffmann-La Roche Inc. 150 Clove Road Suite 8 Little Falls, New Jersey 07424 U.S.A. Attn. Corporate Secretary

13.11 Governing Law; Arbitration
This Agreement shall be governed by and construed in accordance with the laws of New York, New York, without reference to its conflict of laws principles.

All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") by three arbitrators appointed in accordance with the said rules. The Emergency Arbitrator Provisions shall not apply.

Each Party shall nominate one arbitrator each of whom has at least [***] years of relevant experience in the pharmaceutical or biotechnology industry , each of whom will be impartial and independent as required by the applicable Rules of Arbitration of the ICC. Should the claimant fail to appoint an arbitrator in the request for arbitration within [***] days of being requested to do so, or if the respondent should fail to appoint an arbitrator in its answer to the request for arbitration

within [***] days of being requested to do so, the other Party shall request the ICC Court to make such appointment.

The arbitrators nominated by the Parties shall, within [***] days from the appointment of the arbitrator nominated in the answer to the request for arbitration, and after consultation with the Parties, agree and appoint a third arbitrator, who will act as a chairman of the Arbitral Tribunal. Should such procedure not result in an appointment within the [***] day time limit, either Party shall be free to request the ICC Court to appoint the third arbitrator.
If any Party-appointed arbitrator or the third arbitrator resigns or ceases to be able to act, a replacement shall be appointed in accordance with the arrangements provided for in this clause.

Paris, France shall be the seat of the arbitration. The language of the arbitration shall be English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with an English translation.

13.12 Counterparts
This Agreement may be executed in two or more counterparts, including by facsimile, electronic Signature, or PDF signature pages, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

13.13 Further Assurances
The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.

F. Hoffmann-La Roche Ltd

By:	/s/ VIKAS KABRA	By:	/s/ HANNAH BOEHM
Name:	Vikas Kabra	Name:	Hannah Boehm
Title:	Global Head Transaction Excellence	Title:	Legal Counsel

16 June 2021

Date

Hoffmann-La Roche Inc.

By: /s/ JOHN PARISE
Name: John Parise
Title: Authorized Signatory

16 June 2021

Date

Synlogic Operating Company, Inc.

By: /s/ AOIFE BRENNAN
Name: Aoife Brennan
Title: CEO

16 June 2021

Date

Appendix 1

Study Plan

[***]

Appendix 2 to the Pilot Collaboration and Option Agreement (“PCO Agreement”)
Synlogic, Inc. (“Synlogic”)
–
Hoffmann-La Roche Inc. and F. Hoffmann-La Roche Ltd (collectively “Roche”)
Term Sheet for a Collaboration and License Agreement (“CLA”)

[***]

EXHIBIT 31.1

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: August 12, 2021

/s/ AOIFE BRENNAN
Aoife Brennan
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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: August 12, 2021

/s/ GREGG BELOFF
Gregg Beloff
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

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

In connection with the Quarterly Report of Synlogic, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 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
Aoife Brennan
President and Chief Executive Officer
(Principal Executive Officer)

August 12, 2021

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.

EXHIBIT 32.2

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

In connection with the Quarterly Report of Synlogic, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 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
Gregg Beloff
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

August 12, 2021

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.