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, 2019

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

For the transition period from _____ to _____

Commission File No. 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	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 1, 2019, there were 31,718,601 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 success of our collaboration and services arrangements with third parties;
- 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
- 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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 17,442	$ 11,252
Short-term marketable securities	111,570	111,477
Prepaid expenses	31,356	1,221
Other current assets	2,529	388
Total current assets	162,897	124,338
Long-term marketable securities	20,060	—
Property and equipment, net	13,847	14,841
Right of use asset - operating lease	16,980	—
Restricted cash	1,097	1,097
Other assets	64	64
Total assets	$ 214,945	$ 140,340
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,121	$ 2,421
Accrued expenses	3,688	4,993
Deferred revenue	2,080	268
Deferred rent	—	393
Lease liability - operating lease	2,129	—
Finance lease obligations	273	266
Total current liabilities	11,291	8,341
Long-term liabilities:		
Deferred rent, net of current portion	—	7,691
Lease liability - operating lease, net of current portion	22,759	—
Finance lease obligations, net of current portion	72	210
Total long-term liabilities	22,831	7,901
Commitments and contingencies (Note 11)		
Stockholders' Equity		
Preferred stock, $0.001 par value		
5,000,000 shares authorized, none issued and outstanding as of June 30, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value		
250,000,000 shares authorized as of June 30, 2019 and December 31, 2018. 31,719,719 and 25,401,479 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively.	32	25
Additional paid-in capital	325,778	243,903
Accumulated other comprehensive loss	68	(65)
Accumulated deficit	(145,055)	(119,765)
Total stockholders' equity	180,823	124,098
Total liabilities and stockholders' equity	$ 214,945	$ 140,340

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

SYNLOGIC, INC. AND SUBSIDIARIES

Unaudited Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Revenue	$ 350	$ 254	$ 688	$ 608
Operating expenses:				
Research and development	9,703	10,872	20,087	19,233
General and administrative	3,742	4,734	7,393	8,363
Total operating expenses	13,445	15,606	27,480	27,596
Loss from operations	(13,095)	(15,352)	(26,792)	(26,988)
Other income (expense):				
Interest and investment income	759	776	1,516	1,262
Interest expense	(5)	(12)	(12)	(26)
Other expense	(3)	(3)	(2)	(4)
Other income (expense), net	751	761	1,502	1,232
Net loss	$ (12,344)	$ (14,591)	$ (25,290)	$ (25,756)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.45)	$ (0.59)	$ (0.96)	$ (1.14)
Weighted-average common shares used in computing net loss per share attributable to common shareholders - basic and diluted	27,242,514	24,803,379	26,284,262	22,503,802
Comprehensive loss:				
Net loss	$ (12,344)	$ (14,591)	$ (25,290)	$ (25,756)
Net unrealized gains (losses) on marketable securities	29	36	133	(66)
Comprehensive loss	$ (12,315)	$ (14,555)	$ (25,157)	$ (25,822)

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		Additional paid-in capital	Other accumulated comprehensive income	Accumulated deficit	Total equity
	Shares	Amount				
			For the Three Months Ended June 30, 2019			
Balance at March 31, 2019	25,388,643	$ 25	$ 244,857	$ 39	$ (132,711)	$ 112,210
Proceeds from issuance of common stock, net of issuance costs	6,340,771	7	56,976	—	—	56,983
Proceeds from pre-funded common stock warrants, net of issuance costs	—	—	22,874	—	—	22,874
Cancellation of restricted stock	(9,695)	—	—	—	—	—
Equity-based compensation expense	—	—	1,071	—	—	1,071
Unrealized gain (loss) on securities	—	—	—	29	—	29
Net loss	—	—	—	—	(12,344)	(12,344)
Balance at June 30, 2019	31,719,719	$ 32	$ 325,778	$ 68	$ (145,055)	$ 180,823
			For the Three Months Ended June 30, 2018			
Balance at March 31, 2018	22,172,117	$ 22	$ 211,351	$ (111)	$ (82,495)	$ 128,767
Sale of common stock	3,280,000	3	28,911	—	—	28,914
Cancellation of restricted stock	(19,268)	—	—	—	—	
Equity-based compensation expense	—	—	1,494	—	—	1,494
Unrealized gain (loss) on securities	—	—	—	36	—	36
Net loss	—	—	—	—	(14,591)	(14,591)
Balance at June 30, 2018	25,432,849	$ 25	$ 241,756	$ (75)	$ (97,086)	$ 144,620
			For the Six Months Ended June 30, 2019			
Balance at December 31, 2018	25,401,479	$ 25	$ 243,903	$ (65)	$ (119,765)	$ 124,098
Proceeds from issuance of common stock, net of issuance costs	6,340,771	7	56,976	—	—	56,983
Proceeds from pre-funded common stock warrants, net of issuance costs	—	—	22,874	—	—	22,874
Cancellation of restricted stock	(22,531)	—	—	—	—	—
Equity-based compensation expense	—	—	2,025	—	—	2,025
Unrealized gain (loss) on securities	—	—	—	133	—	133
Net loss	—	—	—	—	(25,290)	(25,290)
Balance at June 30, 2019	31,719,719	$ 32	$ 325,778	$ 68	$ (145,055)	$ 180,823
			For the Six Months Ended June 30, 2018			
Balance at December 31, 2017	16,272,617	$ 16	$ 156,685	$ (9)	$ (71,654)	$ 85,038
Effect of adoption of ASU 2014-09 (ASC 606)	—	—	—	—	324	324
Sale of common stock	9,179,500	9	82,658	—	—	82,667
Cancellation of restricted stock	(19,268)	—	—	—	—	—
Equity-based compensation expense	—	—	2,413	—	—	2,413
Unrealized gain (loss) on securities	—	—	—	(66)	—	(66)
Net loss	—	—	—	—	(25,756)	(25,756)
Balance at June 30, 2018	25,432,849	$ 25	$ 241,756	$ (75)	$ (97,086)	$ 144,620

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, 2019	Six Months Ended June 30, 2018
Cash flows from operating activities:		
Net loss	$ (25,290)	$ (25,756)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,920	1,192
Loss on disposal of property and equipment	—	2
Equity-based compensation expense	2,025	2,413
Accretion/amortization of investment securities	(883)	(531)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(32,275)	(545)
Accounts payable and accrued expenses	(273)	(1,266)
Deferred revenue	1,812	(608)
Operating lease liability and right of use asset	(740)	—
Deferred rent	—	1,095
Other assets	—	169
Net cash used in operating activities	(53,704)	(23,835)
Cash flows from investing activities:		
Purchases of marketable securities	(108,633)	(114,980)
Proceeds from maturity of marketable securities	89,496	27,445
Purchases of property and equipment	(695)	(2,892)
Net cash used in investing activities	(19,832)	(90,427)
Cash flows from financing activities:		
Payments on finance lease obligations	(131)	(217)
Proceeds from sale of common stock, net of issuance costs	56,983	82,666
Proceeds from sale of pre-funded warrants, net of issuance costs	22,874	—
Net cash provided by financing activities	79,726	82,449
Net increase (decrease) in cash, cash equivalents and restricted cash	6,190	(31,813)
Cash, cash equivalents and restricted cash at beginning of period	12,349	59,537
Cash, cash equivalents and restricted cash at end of period	$ 18,539	$ 27,724
Supplemental disclosure of non-cash investing activities:		
Landlord funded allowance for tenant improvements	$ —	$ 1,654
Property and equipment purchases included in accounts payable and accrued expenses	$ (334)	$ 1,447
Assets acquired under operating lease obligation	$ 1,625	$ —
Supplemental disclosure of non-cash financing activities:		
Issuance costs included in accounts payable and accrued expenses	$ 100	$ —
Purchase under finance lease	$ —	$ 12
Cash paid for interest	$ 12	$ 25

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

Synlogic, Inc. ("Private Synlogic" when referred to prior to the Merger (as defined below)) was founded and began operations on March 14, 2014, as TMC Therapeutics, Inc., located in Cambridge, Massachusetts. On July 15, 2014, TMC Therapeutics, Inc. changed its name to Synlogic, Inc. On July 2, 2015, the common and preferred stockholders of Private Synlogic executed the Synlogic, LLC Contribution Agreement (the "Contribution Agreement"), pursuant to which such common and preferred stockholders contributed such stockholders' equity interests in Private Synlogic in exchange for common and preferred units in a newly formed parent company named Synlogic, LLC. In addition, Synlogic IBDCo, Inc. ("IBDCo") was formed as a subsidiary of Synlogic, LLC (the "2015 Reorganization"). In conjunction with the 2015 Reorganization, Private Synlogic entered into a license, option and merger agreement with AbbVie S.à.r.l. ("AbbVie"), for the development of treatments for inflammatory bowel disease ("IBD"). See Note 9, *AbbVie Collaboration Agreement*.

In May 2017, Private Synlogic completed a reorganization (the "2017 Reorganization") pursuant to which Synlogic, LLC merged with and into Private Synlogic, with Private Synlogic continuing as the surviving corporation.

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

Risks and Uncertainties

At June 30, 2019, the Company had approximately $129.0 million in cash, cash equivalents, and short-term marketable securities, $20.1 million of long-term marketable securities, $1.1 million of restricted cash and an accumulated deficit of approximately $145.1 million. Since its inception through June 30, 2019, 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 June 2019, the Company issued to Ginkgo Bioworks, Inc. ("Ginkgo") 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. 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, 2018, and the notes thereto, which are included in the Company's 2018 Annual Report for the year ended December 31, 2018, filed with the Securities and Exchange Commission ("SEC") on March 12, 2019 (the "2018 Annual Report"), have had no material changes during the three and six months ended June 30, 2019, other than our adoption of ASU 2016-02 and ASU 2018-07 (as defined below). The updated accounting policies and the impact of adoption are each discussed in the "Recently Adopted Accounting Pronouncements" section in this note.

Basis of Presentation

The accompanying consolidated financial statements and the related disclosures as of June 30, 2019 and for the three and six months ended June 30, 2019 and 2018 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 2018 and 2017 audited consolidated financial statements and notes included in the Company's 2018 Annual Report. The December 31, 2018 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, 2019 and 2018. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the year ending December 31, 2019 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 February 2016, the FASB issued ASU 2016-02 – Leases (Topic 842), which replaces the existing accounting guidance for leases. This standard requires entities that lease assets to recognize the assets and liabilities for the rights and obligations created by those leases on the balance sheet. The standard is effective for fiscal years and the interim periods within those fiscal years beginning after December 15, 2018. The guidance is required to be applied by the modified retrospective transition approach and early adoption is permitted. In July 2018, the FASB issued ASU 2018-11 Leases – Targeted Improvements, intended to ease the implementation of the new lease standard for financial statement preparers by, among other things, allowing for an additional transition method. In lieu of presenting transition requirements to comparative periods, as previously required, an entity may now elect to show a cumulative effect adjustment on the date of adoption without the requirement to recast prior period financial statements or disclosures presented in accordance with ASU 2016-02. The Company adopted the new standard using the cumulative effect adjustment transition option effective January 1, 2019, which is the initial date of application per ASU 2018-11.

The Company elected the available package of practical expedients which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of our leases, and the treatment of initial direct costs. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet.

The Company adopted ASU 2016-02: Leases (Topic 842) as of January 1, 2019. The Company uses judgement to assess if an arrangement is a lease at contract inception. An arrangement is a lease if the contract involves the use of a distinct identified asset, the lessor does not have substantive substitution rights and the Company obtains control of the asset throughout the period by obtaining substantially all of the economic benefit of the asset and the right to direct the use of the asset. Leases classified as operating leases are included in operating lease right-of-use (ROU) assets, current operating lease liabilities and noncurrent operating lease liabilities in our consolidated balance sheet. Finance leases are included in property and equipment and finance lease obligations, in our consolidated balance sheet.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The Company utilizes its incremental borrowing rate to determine the present value of lease payments. The incremental borrowing rate is the rate incurred to borrow similar funds, on a collateralized basis, over a comparable term in a similar economic environment.

For new and amended leases beginning in 2019 and after, the Company has elected to account for the lease and non-lease components for leases as a single component for classes of all underlying assets and allocate all of the contract consideration to the lease component only. Lease cost for operating leases is recognized on a straight-line basis over the lease term and is included in operating expenses on the statements of operations and comprehensive loss. Variable lease payments are included in lease operating expenses.

The lease term includes options to extend the lease when it is reasonably certain that option will be exercised. Leases with a term of 12 months or less are not recorded on the Company’s consolidated balance sheet.

The adoption had a material impact on the consolidated balance sheet related to the recognition of a transition adjustment on January 1, 2019 of a right-of-use asset of $15.9 million and lease liability of $24.0 million for an operating lease and the derecognition of deferred rent originally accounted for under legacy guidance. The adoption did not have a material impact on the consolidated statement of operations. The Company has designed and implemented changes to related processes, controls and disclosures. Refer to the Commitments and Contingencies footnote for further information on the adoption of this standard and the Company’s accounting for leases.

In February 2018, the FASB issued ASU 2018-02 – Income Statement – Reporting Comprehensive Income (Topic 220), which provides amended guidance on income tax accounting. The amended guidance permits the reclassification of the income tax effect on amounts recorded within other comprehensive income impacted by the Tax Cuts and Jobs Act (the “TCJA”) into retained earnings. The amended guidance is effective for periods beginning after December 15, 2018 and applies only to those amounts remaining in other comprehensive income at the date of enactment of the TCJA. The amended guidance may be adopted on either a retrospective basis or at the beginning of the period of adoption. The amended standard had an immaterial impact on the Company’s consolidated financial statements and as such the Company did not reclassify the income tax effects of the TCJA from other comprehensive income to retained earnings.

In June 2018, the FASB issued ASU 2018-07- Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity’s adoption date of ASC 606. The standard expands the scope of ASC 718 to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. Under the amended guidance, equity-classified share-based payment awards issued to nonemployees will be measured at grant date fair value. Upon transition, the entity is required to remeasure these nonemployee awards at fair value as of the adoption date. The Company adopted the new guidance on January 1, 2019 which had an immaterial impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13 - Fair Value Measurement - Disclosure Framework (Topic 820). The standard modifies the disclosure requirements for fair value measurements. The standard is effective for public companies for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for any removed or modified disclosures. Management is currently assessing the impact adoption will have on the Company, but it is not expected to have a material impact on the Company’s financial statement disclosures.

In August 2018, the FASB issued ASU 2018-15 - Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract. The standard requires implementation costs incurred by customers in cloud computing arrangements to be deferred over the noncancelable term of the cloud computing arrangements plus any optional renewal periods (1) that are reasonably certain to be exercised by the customer or (2) for which exercise of the renewal option is controlled by the cloud service provider. The effective date of this pronouncement is for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted. The standard can be adopted either using the prospective or retrospective transition approach. The Company is currently evaluating the impact of this standard on the Company's consolidated financial statements and disclosures.

In November 2018, the FASB issued ASU 2018-18 - Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the impact of this standard on the Company's consolidated financial statements.

(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 2018 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, 2019 and December 31, 2018, the Company has classified assets measured at fair value on a recurring basis as follows (in thousands):

	Fair Value Measurements at June 30, 2019			
Description	June 30, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds (included in cash and cash equivalents)	$ 5,454	$ 5,454	$ —	$ —
Commercial paper (included in short-term investments)	58,946	—	58,946	—
Corporate debt securities (included short-term investments)	52,624	—	52,624	—
Corporate debt securities (included in long-term investments)	20,060	—	20,060	—
Total	$ 137,084	$ 5,454	$ 131,630	$ —

	Fair Value Measurements at December 31, 2018			
Description	December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds (included in cash and cash equivalents)	$ 265	$ 265	$ —	$ —
Commercial paper (included in short-term investments)	57,453	—	57,453	—
Corporate debt securities (included in short-term investments)	50,052	—	50,052	—
U.S. government agency securities and treasuries (included in short-term investments)	3,972	1,987	1,985	—
Total	$ 111,742	$ 2,252	$ 109,490	$ —

Cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses at June 30, 2019 and December 31, 2018 are carried at amounts that approximate fair value due to their short-term maturities. Finance lease obligations at June 30, 2019 and December 31, 2018 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, 2019 and December 31, 2018 (in thousands):

June 30, 2019	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Commercial paper	$ 58,884	$ 63	$ (1)	$ 58,946
Corporate debt securities	72,678	29	(23)	72,684
Total	$ 131,562	$ 92	$ (24)	$ 131,630

December 31, 2018	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Commercial paper	$ 53,549	$ —	$ (47)	$ 53,502
Corporate debt securities	54,022	4	(23)	54,003
U.S. government agency securities	3,971	1	—	3,972
Total	$ 111,542	$ 5	$ (70)	$ 111,477

The contractual maturity of all securities held at June 30, 2019 was 17 months or less. There were 12 and 37 investments in an unrealized loss position at June 30, 2019 and December 31, 2018, 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, 2019 and December 31, 2018 was $46.3 million and $96.5 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, 2019.

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, 2019	December 31, 2018
Laboratory equipment	$ 7,384	$ 7,111
Computer and office equipment	829	781
Furniture and fixtures	413	413
Leasehold improvements	9,484	9,484
Construction in progress	79	39
	18,189	17,828
Less accumulated depreciation	(4,342)	(2,987)
	$ 13,847	$ 14,841

(6) Accrued Expenses

Accrued expenses consists of the following (in thousands):

	June 30, 2019	December 31, 2018
Payroll related	$ 1,632	$ 2,906
Professional fees	612	306
Research and development	1,327	1,585
Other	117	196
	$ 3,688	$ 4,993

(7) Stockholders' Equity

In June 2019, the Company issued to Ginkgo an aggregate of 6,340,771 shares of common stock at a purchase price per share of $9.00, 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. The net proceeds to the Company were approximately $79.9 million.

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

The Pre-Funded Warrants were classified as a component of permanent equity and were recorded at the issuance date using a relative fair value allocation method. The Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of common shares upon exercise. In addition, such warrants do not provide any guarantee of value or return.

(8) Equity-based Compensation and Equity Incentive Plans

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

Equity Plans

The Company has a number of equity plans, two of which are currently active.

The 2015 Equity Incentive Award Plan (the "2015 Plan") was adopted by Mirna in 2015 and remains active after the Merger, now functioning as the primary equity plan for the Company. The 2015 Plan provides for the granting of a variety of stock-based compensation awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, deferred stock awards, dividend equivalent awards, stock payment awards, performance awards and other stock-based awards. Pursuant to the evergreen provision of the 2015 Plan, which allows for an annual increase in the number of shares of common stock available for issuance, the Company added 1,270,073 shares to the 2015 Plan on January 1, 2019.

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

As of June 30, 2019, there were 1,000,156 shares available for future grant under the Company's two active equity incentive plans, the 2017 Plan and the 2015 Plan.

For a full description of the Company's equity plans, refer to Note 12, *Equity-based Compensation and Equity Incentive Plans* in the Company's 2018 Annual Report.

Stock Options

The following table summarizes stock option activity during the six months ended June 30, 2019 under the 2015 Plan and the 2017 Plan.

	Stock options outstanding			
	Number of options	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate Intrinsic value (a) (in thousands)
Outstanding at December 31, 2018	1,739,884	$ 11.92	9.0	$ —
Granted	1,079,030	8.52		
Exercised	—			
Forfeited	(309,168)	12.85		21,784
Outstanding at June 30, 2019	2,509,746	10.34	9.0	$ 776,565
Vested or expected to vest at June 30, 2019	2,509,746	10.34	9.0	776,565
Exercisable at June 30, 2019	674,817	12.19	8.4	$ 28,837

(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, 2019 and December 31, 2018.

As of June 30, 2019, there was $10.7 million of unrecognized share-based compensation related to unvested stock option grants which is expected to be recognized over a weighted average period of 2.8 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, 2019:

	Restricted stock awards	
	Number of shares	Grant date fair value (per share)
Unvested at December 31, 2018	118,679	$ 13.54
Granted	—	—
Vested	(33,229)	13.53
Forfeited	(22,531)	13.53
Unvested at June 30, 2019	62,919	$ 13.56

As of June 30, 2019, there was approximately $0.1 million of unrecognized share-based compensation related to restricted stock awards granted, which is expected to be recognized over a weighted average period of 1.1 years. The total unrecognized share-based compensation cost will be adjusted for actual forfeitures as they occur.

Equity Compensation

The Company recorded total equity-based compensation expense of $1.1 million and $2.0 million during the three and six months ended June 30, 2019, respectively and $1.5 million and $2.4 million during the three and six months ended June 30, 2018, 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, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 349	$ 352	$ 633	$ 729
General and administrative	722	$ 1,142	1,392	1,684
	$ 1,071	$ 1,494	$ 2,025	$ 2,413

The following table summarizes equity-based compensation expense by type of award for the three and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Stock options	$ 1,047	$ 836	$ 1,973	$ 1,609
Restricted stock awards	24	658	52	804
	$ 1,071	$ 1,494	$ 2,025	$ 2,413

(9) AbbVie Collaboration Agreement

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

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

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

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

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

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

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

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

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

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

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

On February 28, 2019, the JRC concluded that the remaining milestone of $2.5 million under the Second Amendment was achieved upon the achievement of specified research and pre-clinical events under the second phase of the research plan and the advancement to the third phase of the research plan. Revenue associated with performance obligations under the AbbVie Agreement 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 months ended June 30, 2019 and 2018, the Company recognized revenue of $0.4 million and $0.3 million, respectively and for the six months ended June 30, 2019 and 2018, the Company recognized revenue of $0.7 million and $0.6 million, respectively, as collaboration revenue in the Company's consolidated statements of operations and comprehensive loss. Deferred revenue amounted to $2.1 million as of June 30, 2019, all of which is included in current liabilities.

(10) Net Loss per Share

Basic net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the sum of the weighted-average number of shares of common stock outstanding during the period and if dilutive, the weighted-average number of potential shares of common stock, including unvested restricted common stock and outstanding stock options. In June 2019, the Company sold 6,340,771 shares of common stock and Pre-Funded Warrants to purchase an aggregate of 2,548,117 shares of common stock at an exercise price of $9.00 per share, with $8.99 of such exercise price paid at the closing of the offering (see Note 7). 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 computed basic and diluted net loss per share using the two-class method, which gives effect to the impact of outstanding participating securities. As the three and six months ended June 30, 2019 and 2018 resulted in net losses attributable to common stockholders, there is no income allocation required under the two-class method or dilution attributed to weighted-average shares outstanding in the calculation of diluted net loss per share because the preferred stockholders do not participate in losses of the Company. Accordingly, for periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common stock are not assumed to have been issued if their effect is anti-dilutive.

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,	
	2019	2018
Unvested restricted common stock awards	62,919	250,871
Outstanding options to purchase common stock	2,509,746	1,659,614

(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.

In July 2017, the Company entered into an agreement to lease approximately 41,346 square feet of laboratory and office space at 301 Binney Street in Cambridge, Massachusetts. Annual rent is approximately $3.1 million. The ten-year lease commenced in January 2018 and contains provisions for a free-rent period, annual rent increases and an allowance for tenant improvements. Additionally, we have paid for a tenant improvement investment of approximately $1.6 million. The Company was determined to be the accounting owner and recorded tenant improvements as leasehold improvements which reduce the initial measurement of the ROU asset. In conjunction with the lease, we established a letter of credit of approximately $1.0 million. Variable payments based on our portion of the operating expenses, including real estate taxes and insurance, are recorded as a period expense when incurred. The Company has an option to extend the term by five years and an option to terminate the agreement if a similar agreement is executed with the landlord or an affiliate of the landlord. Neither option is reasonably certain of exercise and are excluded from the lease liability calculation.

On December 7, 2018, Synlogic Operating Company, Inc., a wholly-owned subsidiary of Synlogic, Inc., entered into a Statement of Work (the "SOW") with Azzur Group, LLC ("Azzur") pursuant to a Master Contract Services Agreement (the "Master Services Agreement"), dated September 8, 2018, between the Company and Azzur.

Pursuant to the SOW, Azzur has agreed to provide the Company with access to, and the use of, an approximately 700 square foot cleanroom space to be constructed in Waltham, Massachusetts (the "Azzur Suite"), for a period of 44 months, from May 1, 2019 to December 31, 2022 (the "Term"). Azzur has also agreed to provide the Company with storage space and personnel support at the Azzur Suite. The total estimated project cost during the Term for access to, and use of, the cleanroom and storage space, and the personnel support and other services, is up to $4.8 million.

The Company may terminate the SOW on four months' prior written notice at any time during the Term. In addition, either party may terminate the Master Services Agreement (including the SOW) due to a breach by the other party and failure to cure. The Company is reasonably certain not to exercise the termination option through June 30, 2021. Therefore, the Company used a term of May 1, 2019 through June 30, 2021 for purposes of the calculation of the ROU asset and lease liability.

The operating lease right-of-use assets and operating lease liabilities represent the Binney Street and Azzur leases. Finance leases are made up of laboratory and office equipment. Cash paid for amounts included in the present value of operating lease liabilities were $1.0 million and $1.7 million during the three and six months ended June 30, 2019, respectively, which is included in operating cash flows.

The components of lease cost for operating and finance leases were (in thousands):

	For the Three Months Ended	For the Six Months Ended
	June 30, 2019	
Operating leases		
Operating lease cost	$ 830	$ 1,524
Variable lease cost	268	531
	1,098	2,055
Short-term lease cost	39	158
Finance leases		
Depreciation on finance leases	47	94
Interest on finance leases	6	12
	53	106
Total lease cost	$ 1,190	$ 2,319

The right-of-use asset for the operating leases is disclosed on the consolidated balance sheet. The right-of-use asset for finance leases are classified within property and equipment, net. The total right-of-use asset for finance leases is $0.9 million.

The weighted average remaining lease term and the weighted average discount rate for operating and finance leases at June 30, 2019 was:

	Operating Lease	Finance Leases
Weighted average discount rate	8.0%	5.9%
Weighted average remaining lease term (years)	8.7	1.3

The following table reconciles the undiscounted cash flows for the operating and finance leases at June 30, 2019 to the operating and finance lease liabilities recorded on the balance sheet:

Maturity of lease liabilities	Operating Leases	Finance Leases
	(in thousands)	
2019	$ 1,990	$ 143
2020	4,089	214
2021	3,802	2
2022	3,470	—
2023	3,574	—
Thereafter	18,067	—
Total lease payments	34,992	359
Less: imputed interest	10,104	14
Total lease liabilities	$ 24,888	$ 345
Current lease liabilities	2,129	273
Long-term lease liabilities	22,759	72

The aggregate future lease payments for operating and capital leases as of December 31, 2018 are as follows:

	Operating Lease	Capital Leases
	(in thousands)	
2019	$ 3,175	$ 287
2020	3,270	214
2021	3,369	2
2022	3,470	—
2023	3,574	—
Thereafter	18,067	—
Total future minimum lease payments	$ 34,925	$ 503
Less amounts representing interest		27
Capital lease obligations at December 31, 2018		476
Less current portion of capital lease obligations		266
Capital lease obligations, net of current portion		$ 210

(12) Related Party Transactions

In June 2019, the Company issued to Ginkgo an aggregate of 6,340,771 shares of common stock at a purchase price per share of $9.00, 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. The net proceeds to the Company were approximately $79.9 million.

The Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full to the extent that, after giving effect to such issuance after exercise, Ginkgo would not beneficially own in excess of 19.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance. See Note 7 for further details of the transaction.

In 2017, the Company established a technology collaboration with Ginkgo, a privately held high-throughput synthetic biology company, to enable the discovery of new living medicines. 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. 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. The prepayment was recorded to prepaid expenses and will be amortized as the services are performed. Services have not commenced and therefore, the balance is unchanged as of June 30, 2019. Upon the expiration of such initial term and, if applicable, such additional period, any portion of the prepayment that has not been used to purchase services from Ginkgo will be retained by Ginkgo.

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, 2018 and 2017 included in our 2018 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 18 for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. The term "Private Synlogic" refers to Synlogic Operating Company, Inc. (formerly known as Synlogic, Inc.) prior to the consummation of the Merger. Unless otherwise indicated, references to the terms the "combined company", "Synlogic", the "Company", "we", "our" and "us" refer to Private Synlogic prior to the consummation of the Merger and Synlogic, Inc. (formerly known as Mirna Therapeutics, Inc.) and its subsidiaries upon the consummation of the Merger described herein. The term "Mirna" refers to the Mirna Therapeutics, Inc. and its subsidiaries prior to the Merger.

Overview

Business

We are a clinical-stage biopharmaceutical company focused on advancing our proprietary drug discovery and development platform to create Synthetic Biotic™ medicines, which are designed using synthetic biology to genetically reprogram beneficial microbes to treat metabolic and inflammatory diseases and cancer. Synthetic Biotic medicines are generated by applying the principles and tools of synthetic biology to engineer beneficial microbes to perform or deliver critical therapeutic functions. As living medicines, Synthetic Biotic medicines can be designed to sense a local disease context within a patient's body and to respond by metabolizing a toxic substance, compensating for missing or damaged metabolic pathways in patients, or by delivering combinations of therapeutic factors. Our goal is to lead in the discovery and development of Synthetic Biotic therapies as living medicines capable of robust and precise pathway complementation and delivery of therapeutic benefit to patients.

We believe that our Synthetic Biotic platform has potential to address both metabolic and immune-mediated diseases and we are evaluating these medicines at different sites of action via different routes of administration, either orally or via injection. While we have designed and created a number of bacterial strains that could potentially be used therapeutically in a range of diseases, our initial focus is on metabolic diseases that could potentially be treated following oral delivery of a living medicine to the gut. This includes metabolic diseases, which include rare genetic diseases as well as metabolic diseases caused by organ dysfunction. When delivered orally, Synthetic Biotic medicines are designed to act from the gut to compensate for a dysfunctional metabolic pathway that results in the toxic accumulation of a metabolite with the intended consequence of reducing the systemic levels of the metabolite. We believe that success in our lead programs in rare metabolic diseases will enable us to demonstrate the potential of our oral Synthetic Biotic medicines to address metabolic dysfunction while bringing meaningful change to the lives of patients suffering from these debilitating conditions.

Our two lead therapeutic programs are being developed for the treatment of hyperammonemia and phenylketonuria (PKU). SYNB1020, our first therapeutic program to enter clinical trials, is an oral therapy intended for the treatment of hyperammonemia, which includes patients with liver disease such as hepatic encephalopathy (HE) and patients with urea cycle disorders (UCD). In these conditions ammonia accumulates in the body and becomes toxic, leading to neurocognitive crisis and risk of long-term cognitive or behavioral impairment, coma or death. SYNB1020 has received both Fast Track Designation and orphan drug designation for UCD from the U.S. Food and Drug Administration (FDA). We initiated a Phase 1 clinical trial in June 2017 to evaluate the safety and tolerability of SYNB1020 in healthy volunteers. In November 2017, we announced top-line data from this study that demonstrated that SYNB1020 was safe and well-tolerated and achieved proof-of-mechanism. In March 2018, we initiated a clinical trial in patients with cirrhosis and elevated blood ammonia to evaluate the safety and tolerability of SYNB1020 as well as the ability of this Synthetic Biotic medicine to lower systemic levels of ammonia. We expect to have top-line data from this study in the third quarter of 2019. Upon receipt of satisfactory evidence of ammonia lowering in patients with cirrhosis, we will determine the clinical development path for SYNB1020 for the treatment of conditions resulting in hyperammonemia.

SYNB1618, our second program to enter clinical trials, is an oral therapy intended for the treatment of PKU, a rare metabolic disease in which the amino acid phenylalanine (Phe) accumulates in the body as a result of genetic defects. Elevated levels of Phe are toxic to the brain and can lead to neurological dysfunction. 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 FDA. We initiated a Phase 1 / 2a clinical trial for SYNB1618 in April 2018 and announced top-line data from this study in September 2018 that demonstrated that SYNB1618 was safe and well-tolerated and achieved proof-of-mechanism in healthy volunteers. On July 15, 2019, we announced positive top-line clinical data from patient cohorts of the Phase 1/2a study of SYNB1618 indicating that a statistically significant increase in biomarkers of SYNB1618 activity was observed in SYNB1618-treated subjects but not in those treated with placebo. The full data set from the Phase 1/2a study will be discussed in an oral presentation at the upcoming annual symposium of the Society for the Study of Inborn Errors of Metabolism (SSIEM) to be held in Rotterdam, September 3-6, 2019.

We have developed a portfolio of immuno-oncology (IO) programs designed to deliver activities to modify the tumor microenvironment, activate the immune system and result in tumor reduction, and we envision that multiple engineered functions could be combined in one Synthetic Biotic medicine. These products could also be used in combination with other cancer therapies such as check-point inhibitors. In November 2018, we announced the selection of our first Synthetic Biotic clinical IO candidate, SYNB1891, and have advanced it into preclinical studies to enable filing of an IND application with the FDA in the second half of 2019. SYNB1891 is an intratumorally administered Synthetic Biotic medicine designed to act as a dual innate activator of the immune system by stimulation via the *E.coli* Nissle chassis and production of cyclic di-AMP, an activator of the STING pathway.

Our early-stage metabolic pipeline includes discovery-stage product candidates for rare metabolic diseases, GI and immune disorders with high unmet needs. We are also leveraging our proprietary technology platform to develop Synthetic Biotic medicines to treat a broader range of human diseases, including metabolic diseases, inflammation and cancer. Synthetic Biotic medicines can be designed to locally deliver combinations of complementary therapeutics to treat these complex disease states.

To progress our pipeline, we collaborate with key disease experts who have developed robust models of relevant diseases to guide selection of our development candidates and to inform our translational medicine strategy. We focus on indications with clear biomarkers associated with disease progression that enable straightforward, early and ongoing assessment of potential clinical benefit throughout the development process. Our collaboration and intellectual property strategies additionally focus on building or leveraging existing third-party expertise in therapeutic research, preclinical and clinical development, manufacturing and commercialization, while also enhancing our industry-leading position in synthetic biology and metabolic engineering.

We have a collaboration with AbbVie S.à.r.l. (AbbVie) to develop Synthetic Biotic medicines for the treatment of inflammatory bowel disease (IBD) such as Crohn's disease and ulcerative colitis. We have also established a technology collaboration with Ginkgo, a privately held high-throughput synthetic biology company, to enable the discovery of new living medicines. In June 2019 we expanded our collaboration and entered into an agreement with Ginkgo for the research and development of engineered microbial therapeutic products. Under the agreement we made a prepayment to Ginkgo of $30.0 million for its foundry services that will be provided to us over an initial term of five years. Upon the expiration of such initial term and, if applicable, such additional period, any portion of our prepayment that has not been used to purchase services from Ginkgo will be retained by Ginkgo. We may enter into additional strategic partnerships in the future to maximize the value of our programs and our Synthetic Biotic platform.

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 2019, we have received approximately $320.3 million in proceeds to date as we financed our operations through approximately $110.7 million in aggregate net proceeds from the sale of Private Synlogic preferred stock and Synlogic, LLC preferred units, approximately $0.4 million in a convertible promissory note with one of our investors, which was converted into Private Synlogic preferred stock, approximately $6.0 million in payments received under the AbbVie Agreement, approximately $40.4 million from our merger with Mirna, net of transaction costs, approximately $82.7 million in total net proceeds from the sale of our common stock in our common stock offerings in January and April 2018, approximately $79.9 million in total net proceeds from the sale of our common stock and Pre-Funded Warrants in June 2019 and $0.2 million from exercises of stock options.

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 $12.3 million and $25.3 million for the three and six months ended June 30, 2019, respectively and $14.6 million and $25.8 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of approximately $145.1 million, and we expect to incur losses for the foreseeable future as we develop our product candidates. We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, as we:

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

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

Financial Overview

Revenue

Revenue to date is generated from our collaboration agreement with AbbVie. The collaboration agreement contains multiple deliverables, which include an exclusive option for AbbVie to acquire IBDCo and research and development milestones. See Note 9, *AbbVie Collaboration* in the notes to the unaudited consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a full discussion of the arrangement. We expect our revenue to fluctuate for the foreseeable future as it is principally based on the achievement of research and development milestones under our collaboration agreement with AbbVie.

Research and Development Expense

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

- compensation, benefits and other employee related expenses;
- supplies to support our internal research and development efforts;
- research and development related facility and depreciation costs; and
- third-party contract costs relating to research, process and formulation development, preclinical and clinical studies and regulatory operations.

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

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

We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as the competitive landscape and ongoing assessments of such product candidate’s commercial potential. We expect our research and development costs will be substantial for the foreseeable future. We expect costs associated with our SYNB1020, SYNB1618 and SYNB1891 programs to increase as the programs progress through clinical trials and new programs progress toward IND and into development.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
SYNB1020	$ 940	$ 933	$ 1,978	$ 1,358
SYNB1618	1,427	2,111	2,324	3,196
SYNB1891	296	—	1,494	—
External pre-development candidate expenses and unallocated expenses*	791	1,812	1,474	3,296
Internal research and development expenses*	6,249	6,016	12,817	11,383
	$ 9,703	$ 10,872	$ 20,087	$ 19,233

*Lab supplies of $0.8 million and $1.5 million were reclassified from external pre-development candidate expenses and unallocated expenses to internal research and development expenses for the three and six months ended June 30, 2018. Lab supplies are classified as internal research and development expenses for the three and six months ended June 30, 2019.

General and Administrative Expense

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

Other Income (Expense)

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles in the U.S. 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 2018 Annual Report. During the six months ended June 30, 2019, 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, 2019 Compared to Three Months Ended June 30, 2018

	For the three months ended		Change
	June 30, 2019	June 30, 2018	$
	(in thousands)		
Revenue	$ 350	$ 254	$ 96
Operating expenses:			
Research and development	9,703	10,872	(1,169)
General and administrative	3,742	4,734	(992)
Total operating expenses	13,445	15,606	(2,161)
Loss from operations	(13,095)	(15,352)	2,257
Other income (expense):			
Interest and investment income	759	776	(17)
Interest expense	(5)	(12)	7
Other expense	(3)	(3)	—
Other income (expense), net	751	761	(10)
Net loss	$ (12,344)	$ (14,591)	$ 2,247

Revenue

Revenue was $0.4 million for the three months ended June 30, 2019 as compared to $0.3 million for the three months ended June 30, 2018. The revenue for both periods is associated with the AbbVie collaboration. The increase in revenue was due to higher revenue recognition related to time and effort over the performance period for the three months ended June 30, 2019 as compared to June 30, 2018.

Operating Expenses

Research and Development Expense

Research and development expense was $9.7 million for the three months ended June 30, 2019 compared to $10.9 million in the corresponding period in 2018. The decrease in research and development expense was primarily due to a decrease of $1.1 million of clinical development costs for our SYNB1618 program, a decrease of $0.8 million of nonclinical development costs for our programs, a decrease of $0.3 million in compensation, benefits and other employee-related expenses and a decrease of $0.2 million of manufacturing costs for our SYNB1020 program. These decreases were partially offset by increases of $0.5 million of research and development support costs, an increase of $0.2 million in clinical development costs for our SYNB1020 program, an increase of $0.3 million of manufacturing costs for our SYNB1618 program, an increase of $0.1 million in clinical development costs for our SYNB1891 program and an increase of $0.1 million in professional services. Research and development support costs include increased lease cost and depreciation from our 301 Binney Street facility, which we occupied in February 2018.

General and Administrative Expense

General and administrative expense was $3.7 million for the three months ended June 30, 2019 compared to $4.7 million for the corresponding period in 2018. The decrease was primarily due to a decrease of $0.9 million in compensation, benefits and other employee-related expenses and a decrease of $0.2 million in one-time information technology (IT) expenses related to the move and build out of IT infrastructure at 301 Binney Street in 2018. These decreases were partially offset by an increase in professional services of $0.1 million.

Other Income (Expense)

Other income (expense) for the three months ended June 30, 2019 and for the corresponding period in 2018 was $0.8 million.

Six Months Ended June 30, 2019 Compared to Six Months Ended June 30, 2018

	For the six months ended		Change
	June 30, 2019	June 30, 2018	$
	(in thousands)		
Revenue	$ 688	$ 608	$ 80
Operating expenses:			
Research and development	20,087	19,233	854
General and administrative	7,393	8,363	(970)
Total operating expenses	27,480	27,596	(116)
Loss from operations	(26,792)	(26,988)	196
Other income (expense):			
Interest and investment income	1,516	1,262	254
Interest expense	(12)	(26)	14
Other expense	(2)	(4)	2
Other income (expense), net	1,502	1,232	270
Net loss	$ (25,290)	$ (25,756)	$ 466

Revenue

Revenue was $0.7 million for the six months ended June 30, 2019 as compared to $0.6 million for the six months ended June 30, 2018. The revenue for both periods is associated with the AbbVie collaboration. The increase in revenue was due to higher revenue recognition related to time and effort over the performance period for the six months ended June 30, 2019 as compared to June 30, 2018.

Operating Expenses

Research and Development Expense

Research and development expense was $20.1 million for the six months ended June 30, 2019 as compared to $19.2 million for the corresponding period in 2018. The increase in research and development expense was primarily due to an increase of $0.4 million in compensation, benefits and other employee-related expenses associated with increased headcount, an increase of $1.1 million of research and development support costs, an increase of $0.6 million in clinical development costs for our SYNB1020 program, an increase of $0.3 million of manufacturing costs for our SYNB1891 program, an increase of $0.1 million in clinical development costs for our SYB1891 program and an increase of $0.1 million in nonclinical development costs for our programs. Research and development support costs include increased lease cost and depreciation from our 301 Binney Street facility, which we occupied in February 2018. These increases were partially offset by decreases of $0.3 million in manufacturing costs for our SYNB1618 program, and $1.2 million of clinical development costs for our SYNB1618 program and a decrease of $0.2 million in manufacturing costs for our SYNB1020 program.

General and Administrative Expense

General and administrative expense was $7.4 million for the six months ended June 30, 2019 as compared to $8.4 million for the corresponding period in 2018. The decrease was primarily due to a decrease of $0.6 million in compensation, benefits and other employee-related expenses and a decrease of $0.5 million in one-time information technology (IT) expenses related to the move and build out of IT infrastructure at 301 Binney Street in 2018. These decreases were partially offset by an increase of $0.1 million in professional services.

Other Income (Expense)

Other income (expense) for the six months ended June 30, 2019 was $1.5 million compared to $1.2 million for the corresponding period in 2018. The increase in other income (expense) was related to an increase in interest and investment income resulting from higher cash balances and higher interest rates generated by our investment account.

Liquidity and Capital Resources

We have incurred losses since our inception on March 14, 2014 and, as of June 30, 2019, we had an accumulated deficit of approximately $145.1 million. We have financed our operations to date primarily through the sale of preferred stock, common stock, preferred units, payments received under our AbbVie collaboration agreement, interest earned on investments, and cash received in the Merger. In June 2019, we issued to Ginkgo 6,340,771 shares of our common stock at a purchase price per share of $9.00, and Pre-Funded Warrants to purchase an aggregate of 2,548,117 shares of our 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. At June 30, 2019, we had $129.0 million in cash, cash equivalents, and short-term marketable securities and $20.1 million of long-term marketable securities. Our cash and cash equivalents include amounts held in money market funds and corporate debt securities, stated at cost plus unrealized gain and loss, which approximates fair market value. Our available-for-sale securities include amounts held in corporate debt securities and U.S. government agency securities and treasuries. We invest cash in excess of immediate requirements in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve liquidity and capital preservation.

During the six months ended June 30, 2019, our cash, cash equivalents and marketable securities balance increased approximately $26.3 million. This increase was primarily due to the $79.9 million in net proceeds received from Ginkgo related to the issuance of common stock and Pre-Funded Warrants, combined with a decrease of $30.0 million paid to Ginkgo for prepaid foundry services (see Note 12) and a decrease due to the cash used to operate our business, including payments related to, among other things, research and development and general and administrative expenses as we continue to invest in our primary drug candidates and support the development of our proprietary platform. We also made capital purchases and made payments on our finance leases.

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

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Net cash, cash equivalents and restricted cash (used in) provided by:		
Operating activities	$ (53,704)	$ (23,835)
Investing activities	(19,832)	(90,427)
Financing activities	79,726	82,449
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 6,190	$ (31,813)

Cash Flows from Operating Activities

Net cash, cash equivalents and restricted cash used in operating activities was approximately $53.7 million for the six months ended June 30, 2019. The primary use of cash was our net loss of $25.3 million and a decrease in working capital of $31.5 million, primarily related to an increase in prepaid expenses and other current assets primarily as a result of a June 2019 services agreement with Gingko (See Note 12 of the unaudited consolidated financial statements), decreases in accounts payable and accrued expenses, and an increase in operating lease liability, offset by an increase in deferred revenue. Net loss was partially offset by $3.1 million of non-cash items primarily including depreciation and equity-based compensation.

Net cash used in operating activities was $23.8 million for the six months ended June 30, 2018. The primary use of cash was our net loss of $25.8 million and a decrease in working capital of $1.1 million, primarily related to decreases in accounts payable, accrued expenses and deferred revenue, offset by increases in deferred rent from our 301 Binney Street facility. Net loss was partially offset by $3.1 million of non-cash items including depreciation and equity-based compensation.

Cash Flows from Investing Activities

Net cash used in investing activities for the six months ended June 30, 2019 was $19.8 million and resulted primarily from the purchases of marketable securities of $108.6 million and purchases of property and equipment of $0.7 million. These uses were partially offset by the proceeds of maturity of marketable securities of $89.5 million.

Net cash used in investing activities for the six months ended June 30, 2018 was $90.4 million and resulted primarily from the purchases of securities of $115.0 million and the purchases of property and equipment of $2.9 million. These uses were partially offset by proceeds from the maturity of marketable securities of $27.5 million.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2019 totaled $79.7 million related to net proceeds of $79.9 million from the sale of our common stock and Pre-Funded Warrants in June 2019 offset by payments on our finance leases.

Net cash provided by financing activities for the six months ended June 30, 2018 totaled $82.5 million as a result of $53.8 million in net proceeds from the sale of our common stock in January 2018 and $28.9 million in net proceeds from the sale of our common stock in April 2018, partially offset by $0.2 million in payments on our capital leases.

Funding Requirements

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

We have generated revenue from our AbbVie collaboration, but have not generated any product revenue since our inception and do not expect to generate any product revenue unless we receive regulatory approval for our product candidates. We believe that our cash on hand as of June 30, 2019, 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; and
- 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.

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 2018 Annual Report.

Related Party Transactions

In June 2019, we issued to Ginkgo an aggregate of 6,340,771 shares of common stock at a purchase price per share of $9.00, 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. We received net proceeds of approximately $79.9 million.

The Pre-Funded Warrants may be exercised at any time until all of the Pre-Funded Warrants are exercised in full to the extent that, after giving effect to such issuance after exercise, Ginkgo would not beneficially own in excess of 19.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance. See Note 7 of the unaudited consolidated financial statements for further details of the transaction.

In 2017, we established a technology collaboration with Ginkgo, a privately held high-throughput synthetic biology company, to enable the discovery of new living medicines. In June 2019 we expanded our collaboration and entered into an agreement with Ginkgo for the research and development of engineered microbial therapeutic products. Under the agreement we made a prepayment to Ginkgo of $30.0 million for its foundry services that would be provided to us over an initial term of five years. Upon the expiration of such initial term and, if applicable, such additional period, any portion of our prepayment that has not been used to purchase services from Ginkgo will be retained by Ginkgo.

For additional transactions with related parties which may fall outside of the reporting period of this section, please see the section entitled “*Related Party Transactions of Directors and Executive Officers of the Combined Organization – Synlogic Transactions”* in our proxy statement filed with the SEC on April 18, 2019.

Off-Balance Sheet Arrangements

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

JOBS Act

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

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Definition and limitations of disclosure controls

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

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

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control

There have not been any changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of such internal control that occurred during our fiscal quarter ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

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

1A. Risk Factors.

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

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

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

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

We are a clinical-stage biopharmaceutical company focused on the development of Synthetic Biotic medicines and we have incurred significant operating losses since our inception. Our net loss was approximately $12.3 million and $25.3 million for the three and six months ended June 30, 2019 respectively and $14.6 million and $25.8 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of approximately $145.1 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 ready 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 June 2017, we initiated a Phase 1 clinical trial with SYNB1020 in healthy volunteers, 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, and 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, however all of our other therapeutic programs are still in the preclinical development stage. We will need to transition from a company with a research focus to a company capable of supporting clinical development and commercial activities. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes many years to develop one new product candidate from the time it is discovered to the time that it becomes available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may hinder our success in commercializing one or more of our product candidates. Further, drug development is a capital-intensive and highly speculative undertaking that involves a substantial degree of risk. You should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development and clinical trials. Any forward-looking statements regarding our future prospects, plans or viability may not be as accurate as they may be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Risks Related to the Development of Our Product Candidates

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

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

- inability to generate satisfactory preclinical or other nonclinical data, including, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining required institutional review board approval at each clinical trial site;

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

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

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

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

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

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

The clinical trial and manufacturing requirements of the FDA, the European Medicines Agency and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as Synthetic Biotic medicines may be more expensive and take longer than for other, better known or more extensively studied therapeutic modalities. It is difficult to determine how long it will take or how much it will cost to obtain

regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates, even if approved for marketing. Approvals by the European Medicines Agency or national regulatory agencies may not be indicative of what the FDA, and vice versa, may require for approval and different or additional preclinical studies or clinical trials may be required to support regulatory approval in each respective jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

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

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

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

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

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

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

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

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

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

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

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

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 August 2016, the FDA granted orphan drug designation to SYNB1020 for the treatment of UCD and 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 2,000 patients diagnosed with UCD in the United States, and 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.

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 SYNB1020 in June 2017 and 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.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patents may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at universities, academic research institutions and at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have written agreements with and make every effort to ensure that our employees, consultants, collaborators, advisors, independent contractors or other third parties do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to claims that our employees, consultants, collaborators, advisors, independent contractors or other third parties have inadvertently or intentionally used or disclosed confidential information of these third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

We do not independently conduct all aspects of our drug discovery activities, compound development or preclinical studies of product candidates. We currently rely, and expect to continue to rely, on third parties to conduct some aspects of our research and development and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, for product candidates that we develop and commercialize on our own, we will remain responsible for ensuring that each of our studies that support our clinical trial applications and our clinical trials are conducted in accordance with the study plan and protocols for the trial. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us or our strategic alliance partners to select viable product candidates for clinical trial application submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In June 2019, we expanded our collaboration with Ginkgo and entered into an agreement for the research and development of engineered microbial therapeutic products. Under the agreement we made a prepayment to Ginkgo of $30.0 million for its foundry services that will be provided to us over an initial term of five years. Upon the expiration of such initial term and, if applicable, such additional period, any portion of the prepayment that has not been used to purchase services from Ginkgo will be retained by Ginkgo. If Ginkgo ceases operations or otherwise experiences financial difficulties during the period of the agreement, the unused balance of the prepayment may be subject to risk of loss.

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, Acer Therapeutics, Inc., Aeglea BioTherapeutics, Inc., Arcturus Therapeutics Inc., Ultragenyx Pharmaceutical Inc., Horizon Pharma plc, Kaleido Biosciences, Inc., Selecta Biosciences, Inc., Translate Bio, Inc. and Versantis AG have developed or are developing product candidates for the treatment of UCD; Bausch Health Companies Inc., Kaleido Biosciences, Inc., Mallinckrodt plc, Rebiotix, Inc./Ferring, Umecrine Cognition AB, Axcella Health, Versantis AG as well as other preclinical and discovery stage companies have developed or are each developing product candidates for the treatment of HE; and American Gene Technologies International Inc., BioMarin, Inc., Censa Pharmaceuticals, Inc., Nestlé Health Science/Codexis, Inc., Homology Medicines, Inc., MipSalus ApS, Moderna Therapeutics, , Sanofi, Agios Pharmaceuticals, Generation Bio and Rubius Therapeutics, Inc. have developed or are developing product candidates for the treatment of PKU. 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 Intrexon Corp. Further there are several companies working to develop other similar products. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. 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 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, chief executive officer and chief medical officer, chief financial officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of the products we develop.

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

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

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

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

Our executive officers are parties to employment agreements providing for aggregate cash payments of up to approximately $1.4 million at June 30, 2019 for severance and other benefits in the event of a termination of employment in connection with a change of control. The payment of these severance benefits could harm our business, financial condition and results of operations. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with Synlogic.

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 1, 2019, our executive officers and directors, together with holders of 5% or more of our common stock outstanding and their respective affiliates, beneficially own approximately 60.5% of our common stock. Accordingly, these stockholders have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

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

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

If our existing stockholders or holders of our options sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of August 1, 2019, there were a total of 31,718,601 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. Furthermore, our amended and restated certificate of incorporation specifies that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by our stockholders. We believe this provision benefits the company by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

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

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

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

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

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

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

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

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.1	Pre-Funded Warrant		Form 8-K	June 12, 2019	001-37566
10.1	Subscription Agreement, dated as of June 11, 2019, by and between Synlogic, Inc. and Ginkgo Bioworks, Inc.		Form 8-K	June 12, 2019	001-37566
10.2†	Foundry Terms of Service Agreement, dated as of June 11, 2019, by and between Synlogic Operating Company, Inc., and Ginkgo Bioworks, 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 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	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			

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

† Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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 8, 2019

SYNLOGIC, INC.

By: /s/ Aoife Brennan
Aoife Brennan
President, Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

By: /s/ Todd Shegog
Todd Shegog
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 10.2

Confidential
Execution Copy

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

FOUNDRY TERMS OF SERVICE AGREEMENT

THIS FOUNDRY TERMS OF SERVICE AGREEMENT (this "**TSA**") is entered into as of June 11, 2019 (the "**Effective Date**") by and between **Synlogic Operating Company, Inc.**, a corporation organized under the laws of Delaware ("**Customer**") and **Ginkgo Bioworks, Inc.**, a corporation organized under the laws of Delaware ("**Ginkgo**"). Customer and Ginkgo are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Customer is a clinical-stage biopharmaceutical company focused on creating Synthetic Biotic™ medicines, beneficial microbes performing or delivering critical therapeutic functions;

WHEREAS, Ginkgo owns a platform consisting of large-scale genetic engineering facilities, genetic codebase assets, expertise and Intellectual Property for the design and genetic engineering of microbial host cells, enzymes and resulting products;

WHEREAS, the Parties desire to collaborate in the Research and Development of Collaboration Strains or development of Production protocols for Background Customer Strains and enable Customer to Develop, Produce and Commercialize the same as Customer Products in the Licensed Field; and

WHEREAS, in connection with such Research of Collaboration Strains, Customer desires to receive the Technical Services from the Ginkgo foundry, in accordance with the terms and conditions of this TSA;

all capitalized terms used in these recitals are defined in Section 1.

NOW, THEREFORE, in consideration of the respective covenants, representations, warranties and agreements set forth herein, the Parties hereto agree as follows:

1. **Definitions**.

1.1 "**Abandonment**" means, on a Program-by-Program basis, [**], (a) a determination by Customer to permanently discontinue such Program for the Collaboration Strain and corresponding Customer Product designated under the TDP applicable to such Program, or (b) failure by Customer to conduct material Research, Development, Production or Commercialization activities to advance such Program or seek a Third Party Sublicensee, acquiror or other transferee that would continue to advance the Customer Product for such Program, as applicable, for a period of [**]. When used as a verb, "**Abandon**" means Abandonment has occurred with respect to a Program.

1.2 "**Action**" means any claim, action, cause of action, chose in action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), controversy, assessment, arbitration, examination, audit, investigation, hearing, charge, complaint, demand, notice or proceeding to, from, by or before any Governmental Authority or arbitrator(s).

1.3 "**Affiliate**" or "**Affiliates**" means with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or registered investment company now or hereafter existing that is controlled by one or more general partners, managing members or investment adviser of, or shares the same management company or investment adviser with such Person. For the purposes of this TSA, (a) neither Ginkgo nor any of its Affiliates will be considered an Affiliate of Customer or any of its Affiliates, and neither Customer nor any of its Affiliates will be considered an Affiliate of Ginkgo or any of its Affiliates, and (b) no Person will be considered an Affiliate of a Party solely as a result of their right to designate a member of such Party's board of directors.

1.4 "**Applicable Law**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign applicable to the Parties or their respective performance hereunder.

1.5 "**Background Customer Strain**" means a whole cell, intact probiotic microbial strain or other cell line (a) Controlled by Customer as of the Effective Date or during the Term other than as a result of Technical Services performed for Customer under this TSA, and (b) transferred from Customer to Ginkgo under an applicable TDP.

1.6 "**Background IP**" means all Intellectual Property that is (a) owned or Controlled by a Party as of the Effective Date of this TSA or (b) becomes owned or Controlled by a Party during the Term of this TSA outside of work performed under a TDP.

1.7 "**BLA**" means (a) a Biologics License Application as defined in the FD&C Act, as amended, and the regulations promulgated thereunder, (b) a Marketing Authorization Application in the European Union or (c) any equivalent or comparable application, registration or certification in any country or region.

1.8 "**Business Day**" means a day other than a Saturday, Sunday or other day on which commercial banks in Boston, Massachusetts are authorized or required to close.

1.9 "**Calendar Quarter**" means each of the following three (3) month periods during each Calendar Year: January 1 through March 31, April 1 through June 30, July 1 through September 30, and October 1 through December 31; *provided, however,* that the first Calendar Quarter after the Effective Date will commence on the Effective Date and end on December 31, 2018.

1.10 "**Calendar Year**" means the twelve (12) month period from January 1 through December 31.

1.11 "**Candidate Strains**" means those engineered microbial strain lines (a) designed, developed or optimized in accordance with an approved TDP, and/or (b) for which processes are developed and/or scaled up under a TDP, in each case of (a) and (b), meeting certain performance criteria specified in such TDP. Once a Candidate Strain is designated as either a Collaboration Strain or a Back-Up Strain, it will no longer be a Candidate Strain.

1.12 "**Change of Control**" means, with respect to a Party, (a) a merger, consolidation, recapitalization, or reorganization of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger, consolidation, recapitalization, or reorganization, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets to which this TSA relates. Notwithstanding the foregoing, any transaction or series of transactions effected for the purpose of financing the operations of the applicable Party (such as an initial public offering or other offering of equity securities to non-strategic investors) will not be deemed a "Change of Control" for purposes of this TSA.

1.13 "**Collaboration Strain**" means, on a TDP-by-TDP basis, a single Candidate Strain or Back-Up Strain, as applicable, chosen by Customer as the Collaboration Strain pursuant to Section 2.3. For clarity, a Collaboration Strain of a Program that has been Abandoned shall cease to be a Collaboration Strain.

1.14 "**Commercialize**" (and with correlative meaning "**Commercialization**") means to sell, have sold, offer for sale, use, engage in pricing and reimbursement activities, promote, market, commercially distribute, import and export for sale or commercial distribution, and where applicable engage in medical affairs activities following Regulatory Approval for a Customer Product.

1.15 "**Competitive Infringement**" means a Third Party's infringement of any of the Patent Rights within the Foreground IP by such Third Party's development, manufacture, use, marketing, sale or importation of a Competitive Product.

1.16 "**Competitive Product**" means [**].

1.17 "**Confidential Information**" means any confidential or proprietary information related to the Customer Products, any confidential or proprietary information relating to a disclosing Party's business; trade secrets, processes, formulae, data, know-how, improvements and inventions; chemical or biological materials; mutation, sequence and pathway information; techniques or methods for making compounds and target compounds; product development plans, marketing plans, strategies and customer lists; or any other information that has been created, discovered, or developed by such disclosing Party, or has otherwise become known to such disclosing Party, or which proper rights have been assigned to such disclosing Party, as well as any other information and materials that are deemed confidential or proprietary to or by such disclosing Party (including all information and materials of such disclosing Party's customers and consultants and any other Third Party), regardless of whether any of the foregoing are marked as "confidential" or "proprietary" or communicated to the receiving Party by the disclosing Party in oral, written, graphic, or electronic form. Notwithstanding the foregoing, but subject to Section 9.2 and Section 10.2, all information regarding the composition and technological content of Customer Products and Back-Up Strains (so long as they remain Customer Products or Back-up Strains) as well as other information specifically relating to Customer Products and Back-Up Strains (so long as they remain Customer Products or Back-up Strains), including the Collaboration Strain (so long as it remains a Collaboration Strain), shall constitute Customer's Confidential Information and not Ginkgo's Confidential Information, regardless of which Party generates such information or discloses such information to the other Party hereunder.

1.18 "**Confidentiality Agreement**" means that certain Mutual Confidential Disclosure Agreement between Synlogic, Inc. and Ginkgo, made effective as of June 7, 2017.

1.19 "**Control**" means with respect to any Intellectual Property or other data, information or materials, possession of the ability by a Party or its Affiliates (whether by sole or joint ownership, license or otherwise, but in all cases, not including those rights are granted or obtained pursuant to this TSA) to grant a license, sublicense, access or other right to use such Intellectual Property or other data, information or materials as provided for in this TSA without violating the terms of any agreement or other arrangement with any Affiliate or any Third Party in existence as of the time such Party or such Affiliates would be required hereunder to grant, or to permit the grant of, such license, sublicense, access or right to use. Notwithstanding anything in this TSA to the contrary, a Party will be deemed to not Control any Intellectual Property that is owned or controlled by a Third Party described in the definition of "Change of Control," or such Third Party's Affiliates (other than an Affiliate of such Party prior to the Change of Control), (a) prior to the closing of such Change of Control, except to the extent that any such Intellectual Property was developed prior to such Change of Control through the use of such Party's technology, or (b) after such Change of Control to the extent that such Intellectual Property is developed or conceived by such Third Party or its Affiliates (other than such Party) after such Change of Control without using or incorporating such Party's technology. A Party will not need to amend any In-License Agreement existing as of the Effective Date so that such Party "Controls" any Intellectual Property under such given In-License Agreement.

1.20 "**Copyrights**" means copyrights (registered or unregistered), copyright applications, copyrightable works, mask works, data collections and databases.

1.21 "**Cover**" means, (a) as to a method or composition of matter and a Patent Right or Copyright, that, in the absence of a license granted under, or ownership of, such Patent Right or Copyright, the making, using, selling, offering for sale or importation of such method or composition of matter would infringe such Patent Right or Copyright or, as to a pending claim included in such Patent Right, the making, using, selling, offering for sale or importation of such method or composition of matter would infringe such Patent Right if such pending claim were to issue in an issued patent without modification, and (b) as to a method or composition of matter and Technology, the making, using, selling, offering for sale or importation of such method or composition of matter would require the use of such Technology.

1.22 "**Customer Background IP**" means the Background IP of Customer that is necessary for, used for, or otherwise provided to Ginkgo to perform its activities under a TDP.

1.23 "**Customer Competitor**" means a Third Party biotechnology or pharmaceutical company that, itself or together with its Affiliates or collaborators, develops or commercializes drug products for its or their own accounts; provided that, in any event a Customer Competitor shall not include [**].

1.24 "**Customer Product**" means a therapeutic product or product candidate comprising one or more Collaboration Strains. For clarity, a Customer Product of a Program that has been Abandoned shall cease to be a Customer Product.

1.25 "**Designated Competitor(s)**" means any of the entity(ies) listed on Exhibit B.

1.26 "**Develop**" (and with correlative meaning "**Development**") means preclinical and clinical development activities, including: pre-clinical research; stability testing, toxicology, formulation studies, qualification and validation, quality assurance studies and testing, clinical studies and statistical analysis; development of a Production protocol for Production of Customer Products (including fermentation, scale-up and downstream processing); preparation and submission of INDs and NDAs; regulatory affairs with respect to the foregoing; and all other activities necessary, useful, or otherwise requested or required by a Regulatory Authority as a condition of or in support of obtaining Regulatory Approval of a Customer Product. "Development" excludes Research and Commercialization.

1.27 "**[**]**" means [**].

1.28 "**Exclusively Licensed Foreground IP**" means any Patent Rights within the Foreground IP.

1.29 "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.30 "**Foreground IP**" means all Intellectual Property developed, conceived, first reduced to practice or otherwise made or generated, solely or jointly by or on behalf of the Parties or their respective Affiliates, in the performance of activities under a TDP of this TSA, including the [**].

1.31 **"[**]"** means [**].

1.32 "**Ginkgo Background IP**" means, on a TDP-by-TDP basis, the Background IP of Ginkgo [**].

1.33 "**Ginkgo Competitor(s)**" means any of the entity(ies) listed on Exhibit C (and any existing and future affiliates, subsidiaries or successors of any of the entities above), which such Exhibit C may be updated pursuant to Section 2.4; [**].

1.34 "**Governmental Authority**" means any federal, state, local or foreign government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any self-regulated organization or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of law), or any arbitrator, court or tribunal of competent jurisdiction.

1.35 "**In-License Agreement**" means, when used for Customer, an agreement with a Third Party licensor under which Customer or any of its Affiliates obtains Control of any Customer Background IP, and, when used for Ginkgo, an agreement with a Third Party licensor under which Ginkgo or any of its Affiliates obtains Control of any Ginkgo Background IP.

1.36 "**IND**" means an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any amendments thereto, and any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application in the EU).

1.37 "**Intellectual Property**" or "**IP**" means (a) Patent Rights, (b) trade secrets, (c) Technology, (d) Copyrights, and (e) similar rights and privileges, but excluding trademarks, service marks, and goodwill.

1.38 "**Licensed Field**" means the diagnosis, treatment, prevention, and/or palliation of human or veterinary disease.

1.39 "**Non-Exclusively Licensed Foreground IP**" means any Foreground IP that is not Exclusively Licensed Foreground IP.

1.40 "**[**]**" means [**].

1.41 "**Patent Rights**" are any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.

1.42 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, association or other entity.

1.43 "**[**]**" means [**].

1.44 "**Produce**" (and with correlative meaning "**Production**") means activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a Customer Product.

1.45 "**Program**" means, on a TDP-by-TDP basis, the Research, Development, Production and Commercialization activities of Customer or its Affiliates or Sublicensees with respect to the applicable Collaboration Strain and corresponding Customer Product for such TDP.

1.46 "**Regulatory Approval**" means with respect to a regulatory jurisdiction, any and all approvals, clearances, product or establishment licenses, registrations or authorizations of any Regulatory Authority, necessary for the Development, Production or Commercialization of a human therapeutic product in such jurisdiction.

1.47 "**Regulatory Authority**" means any Governmental Authority involved in granting Regulatory Approvals of pharmaceutical or biologic human therapeutic products, including, by way of non-limiting example, the United States Food and Drug Administration, the European Medicines Agency, the European Commission, the Japanese Ministry of Health, Labour and Welfare, the Pharmaceuticals and Medical Devices Agency in Japan, and the China Food and Drug Administration.

1.48 "**Representative**" means, with respect to a Party, any director, manager, officer, employee, consultant, advisor (including any financial advisor, counsel or accountant) and other agent of such Party.

1.49 "**Research**" means any and all activities related to the synthesis, modification, modulation, discovery, identification, screening, optimization or design of biological or pharmaceutical agents; and the design, genetic engineering, culturing, small-scale fermentation, measurement, and/or analysis of organisms, including engineered organisms.

1.50 "**Senior Executives**" means, collectively, (a) for Ginkgo, its Chief Executive Officer or other senior executive having authority to make binding decisions and enter into binding agreements on behalf of Ginkgo, and (b) for Customer, its Chief Executive Officer or other senior executive having authority to make binding decisions and enter into binding agreements on behalf of Customer.

1.51 "**[**]**" means [**].

1.52 "**Strain Transfer Agreement**" means the agreement in the form attached hereto as Exhibit A, pursuant to which Ginkgo or one of its Affiliates transfers a Collaboration Strain to Customer (or to one of Customer's Affiliates), and also provides notice of any relevant In-License Agreements affecting such Collaboration Strain that is the subject of such agreement.

1.53 "**Sublicense**" means to sublicense, grant any other right with respect to, or agree not to assert, directly or indirectly, any Intellectual Property licensed to a Party under this TSA. When used as a noun, "**Sublicense**" means any agreement to Sublicense.

1.54 "**Sublicensee**" means any Third Party other than an Affiliate to whom a Party or an Affiliate of such Party grants a Sublicense.

1.55 "**Technology**" means technology, inventions (whether or not patentable), discoveries, results, know-how, processes, formulas, techniques, methods, procedures, developments, software, hardware, chemical or biological structures, compositions, sequences, functions, targets, biomarkers, pathways, designs, formulae, reports, software, data (including date related to manufacturing, design or testing) and confidential or proprietary information, whether or not recorded in tangible form. All Technology is presumed to be a trade secret unless demonstrated otherwise.

1.56 "**Third Party**" means any Person other than Customer, Ginkgo or any Affiliate of Customer or Ginkgo.

1.57 "**Third Party Obligations**" means any non-financial encumbrances, obligations, restrictions, or limitations imposed by an In-License Agreement, including field or territory restrictions, covenants, diligence obligations or limitations pertaining to enforcement of intellectual property rights.

1.58 "**[**]**" means [**].

1.59 "**United States**" or "**U.S.**" means the fifty states of the United States of America and all of its territories and possessions and the District of Columbia.

1.60 The following additional defined terms have the meanings set forth in the Section indicated in the table below:

Term	Has the meaning ascribed to such term in:
Back-Up Strains	Section 2.3(a)(i)
Bankruptcy Code	Section 14.2(c)
Bankrupt Party	Section 19.4
Claims	Section 13.1
CoC Party	Section 14.2(d)(i)
Customer	First paragraph
Customer CoC Termination Date	Section 14.2(d)(ii)
Customer Materials	Section 5.3
Customer Pricing	Section 7.1
Disclosing Party	Section 11.1(a)
[**]	Exhibit F
Effective Date	First paragraph
Electronic Transmission	Section 19.11
Extended Term	Section 14.1
Force Majeure Event	Section 15
Ginkgo	First paragraph
Ginkgo CoC Termination Date	Section 14.2(d)(iii)
Indemnified Party	Section 13.1
Indemnifying Party	Section 13.1
Initial Term	Section 14.1
IP Subcommittee	Section 3.1
JSC	Section 3.1
Losses	Section 13.1
Massachusetts Court	Section 16.4
Party(ies)	The first paragraph
Product License	Section 10.1(b)
Program Lead	Section 3.2(b)
Program Team	Section 3.2(a)
Prosecution Objectives	Section 9.3(a)(ii)(B)
Receiving Party	Section 11.1(a)
Related Persons	Section 13.1
Survival Period	Section 14.2(d)(i)
Technical Development Plan or TDP	Section 2.1
Technical Services	Section 4.1(a)
Technical Services Charges	Section 7.1
Term	Section 14.1
Third Party Action	Section 9.3(b)(iii)
[**]	Exhibit F
Total Cost	Exhibit F
Transaction Notice	Section 14.2(d)(i)
Transfer Price	Exhibit F
TSA	First paragraph

2. **Collaboration; Technical Development Plans; Implementation**.

2.1 **Collaboration Scope**. Subject to the terms and conditions of this TSA, during the Term, the Parties will collaborate on the Research and Development of one or more Customer Products, with each Customer Product being described in a written technical development plan to be approved by the JSC (each, a "**Technical Development Plan**" or "**TDP**").

2.2 **Process; Technical Development Plans**.

(a) Process. During the Term, the Parties will work together to prepare for JSC approval a TDP for each Customer Product, with Customer initially submitting a written work request to Ginkgo for a specific Customer Product and Ginkgo using commercially reasonable efforts to promptly generate a draft TDP covering such Customer Product for review and discussion with Customer prior to Ginkgo's submission of such TDP to the JSC for formal approval. All TDPs will be in the format attached hereto as Exhibit D (TDP Template). For clarity, each TDP will cover one Collaboration Strain or the development of Production protocols for one Collaboration Strain, as the case may be. For each TDP, upon its approval by the JSC, such TDP will be incorporated herein by reference and be deemed attached hereto as part of Exhibit E (Approved Technical Development Plans). The Parties may collaborate on multiple TDPs at any one time, and TDPs may have different start and end dates.

(b) TDPs.

(i) *TDPs Minimum Content*. Each TDP will set forth the details mutually agreed by the Parties, including: [**], either Party may, [**], enter into agreements with Third Party subcontractors in connection with such subcontractors' performance of any portion of such Party's assigned activities under a specific TDP subject to such subcontractor being bound by confidentiality obligation no less strict than those of Section 11 and invention assignment obligations consistent with the Parties' rights under Section 9.2. [**].

(ii) *Acceptance, Amendment and Termination of TDPs*. The JSC will review and, if it so determines, approve each new proposed TDP. Further, the JSC will review and, if it so determines, approve any amendment or reprioritization proposed by either Party to a JSC-approved and active TDP. Any TDP may be terminated either (A) by Customer upon [**] prior written notice to Ginkgo or (B) at any time by mutual agreement of the Parties through the JSC. Any lack of consensus at the JSC with respect to the approval, amendment, reprioritization or termination of a TDP will be resolved in accordance with the procedures set forth in Section 3; [**].

(iii) *Budget and Budget Overruns*. The initial budget associated with each TDP will be reviewed and approved by the JSC prior to or concurrent with any TDP becoming effective. The Parties acknowledge that the nature of the activities under each TDP shall require adjustment of the budget by the JSC from time to time. Approval for any such adjustments shall be by the JSC in accordance with Section 3. [**].

2.3 **Implementation; Strain Selection**.

(a) Within [**] of the completion of the activities under a given TDP, Customer will have the right to select up to (but not more than) [**] Candidate Strains under such TDP (the "**Selected Strains**") by providing written notice to Ginkgo of the identity of such selected Candidate Strains, each of which Selected Strains will then be available to Customer for future designation as the Collaboration Strain for such TDP in accordance with the remainder of this Section 2.3. Completion of the activities under a given TDP will be deemed to have occurred upon the achievement of certain mutually-agreed criteria set forth in such TDP or as otherwise agreed by the Parties in writing; *provided*, *that*, in any event, completion of the activities under a given TDP shall be deemed to have occurred upon the designation by Customer, its Affiliates or Sublicensees of the Collaboration Strain under such TDP and in no event later than the filing of the first IND by Customer, its Affiliates or Sublicensees for a Candidate Strain arising and selected under such TDP. During its conduct of a Program arising from a given TDP, Customer may designate the Collaboration Strain for such Program as follows:

(i) At any time during its conduct of such Program, Customer will designate one (1) lead strain from the Selected Strains for such Program as the Collaboration Strain by providing written notice to Ginkgo of such designation, with the remaining Selected Strains considered back-up strains (the "**Back-Up Strains**"). During its conduct of such Program, Customer will have the right to substitute a Back-Up Strain for the Collaboration Strain for such Program by delivering written notice to Ginkgo of such substitution, identifying in such written notice the Back-Up Strain being substituted.

(ii) Upon receipt by Ginkgo of any such written substitution notice from Customer, the selected Back-Up Strain will be designated the new Collaboration Strain and the previous Collaboration Strain will be considered a Back-Up Strain.

(iii) For clarity, each Program will have only one Collaboration Strain to be Commercialized by, as applicable, Customer, its Affiliates or Sublicensees. To the extent Customer or any of its Affiliates or Sublicensees desires to advance a Back-Up Strain for a given Program following the approval of a BLA for the Collaboration Strain for such Program, the designation of such Back-Up Strain as a Collaboration Strain must be pursuant to a separate Program arising from a new TDP initiated in accordance with Section 2.2.

2.4 **Competitors**. Ginkgo will have the right to update the list of entities constituting Ginkgo Competitors not more than [**] and by presenting such updated list for discussion (but not approval) at a JSC meeting. For clarity, the JSC will not vote on whether to approve or not such an updated list. Ginkgo agrees to reasonably consider Customer's comments to a proposed updated list, but will have no obligation to implement any changes proposed by Customer before such updated list is deemed to replace the then-current Exhibit C following the JSC meeting at which it was discussed. Notwithstanding the foregoing, in no event shall Ginkgo Competitors include any Third Party that is engaged in the business of commercializing pharmaceuticals (including, for clarity, biopharmaceuticals) that has, together with its Affiliates, a market value or, in the case of a publicly traded company, market capitalization, of at least $[**]; *provided*, *however*, that the foregoing exclusions shall not apply to exclude such a Third Party affiliate, subsidiary, successor or acquiror of a Designated Competitor and Ginkgo will have the right to add such Third Party acquiror to Exhibit C at any time by following the procedures set forth in this Section 2.4.

3. **Governance**.

3.1 **Joint Steering Committee**. A Joint Steering Committee ("**JSC**"), with equal (but not fewer than [**]) representatives from each Party, will be formed within [**] of the Effective Date. Each Party may replace its JSC representatives at any time upon written notice to the other Party. During the Term, the JSC will be responsible for (a) approving new TDPs and its associated budget, (b) approving amendments to TDPs (including to the associated budget), (c) approving the termination by mutual agreement of the Parties of any active TDPs, (d) prioritizing the performance of TDPs in case of multiple active TDPs at a given time and serving as a forum for the Parties to discuss and, in accordance with Section 4.2, agree upon Ginkgo resource and capacity planning as needed to enable the Parties' timely performance of TDPs, (e) developing a service-level process covering activities and timelines for Ginkgo's response to Customer-submitted work requests for Collaboration Strain and TDP preparation, (f) to the extent necessary for a given TDP, forming a Program Team that includes Customer representatives (as well as Ginkgo personnel), (g) monitoring Customer's overall budgeted and actual spend of the Prepayment across all TDPs, including forecasting upcoming work under TDPs discussion of any anticipated cost overruns in accordance with Section 2.2(b)(iii), (h) a forum to discuss (but not approve) any updates to the list of Ginkgo Competitors, (i) a forum to discuss (but not approve) Customer's [**], in accordance with Section 2.2(b)(i), (j) facilitating the disclosure of any Foreground IP arising under any TDPs or any Ginkgo Background IP or Customer Background IP identified under any TDP, and (k) at its discretion, forming a subcommittee (the "**IP Subcommittee**") to handle the activities described in the foregoing clause (j), and to otherwise address any other intellectual property issues that may arise. The JSC will make decisions by consensus, with each Party having one (1) vote. For any matter being submitted to the JSC for decision, the Parties will mutually agree beforehand whether voting by the JSC will take place at a regularly scheduled meeting of the JSC, in which case, at least one (1) representative from each Party must be present at such meeting, or may be handled via email using the general email addresses specified in Section 18. If the JSC cannot reach consensus on a matter or if either Party reasonably requests an escalation, such matter will be escalated to the Senior Executives for resolution through good faith negotiations for a period of up to [**]. If the Senior Executives are unable to resolve the matter within such [**] period (or such longer period as the Parties may agree) after the matter is referred to them in accordance with this Section 3.1, then the matter shall be resolved by binding arbitration in accordance with the process set forth in Schedule 16.1. Notwithstanding the foregoing, the JSC will not have any authority to amend the terms of this TSA, to determine either Party's compliance with the terms thereof, or to waive such compliance by either Party. For clarity, any material changes to the budget may be escalated to the Senior Executives by any representative of the JSC.

3.2 **Program Team and Program Lead**.

(a) For each TDP, subject to the JSC's authority to authorize the formation of a Program Team for a given TDP that includes Customer representatives, Ginkgo will establish a program management team consisting of Ginkgo personnel responsible for the oversight and performance of each TDP (each, a "**Program Team**"). Each Program Team will be constituted of Ginkgo personnel in a number sufficient in Ginkgo's reasonable discretion to perform such activities expected of the Program Team. For clarity, the representatives from Ginkgo named to a Program Team may vary with each TDP.

(b) Within each Program Team, Ginkgo will designate one person to be responsible for managing progress and performance under the applicable TDP (the "**Program Lead**").

(c) Ginkgo will be free to change the composition of its members on any Program Teams or replace any Program Leads at its discretion based on the needs of the applicable TDP; *provided*, *however*, that Ginkgo staffs the Program Team with Ginkgo personnel of comparable requisite scientific skill level and experience to perform the Technical Services.

3.3 **Expenses**. Customer will bear the expense of the participation of its respective JSC members in JSC meetings and the activities of its respective Customer personnel and/or subcontractors in connection with any TDP. Customer will not be permitted to deduct any of the foregoing expenses from, or otherwise offset any of the foregoing expenses against, any Technical Services Charges owed by Customer to Ginkgo under this TSA.

4. **Ginkgo Obligations**.

4.1 **Generally**.

(a) Ginkgo, itself or through a subcontractor, will use commercially reasonable efforts to design and perform Research and Development to create Collaboration Strains in accordance with their applicable TDPs ("**Technical Services**") in the timeframes agreed to in the applicable TDPs; *provided*, *however*, that any failure by Ginkgo to perform the Technical Services as a result of any outage that cannot reasonably be avoided or of a Force Majeure Event affecting the Ginkgo foundry will not be deemed a breach of the foregoing standard of performance. Further, Customer acknowledges and agrees that Ginkgo cannot and does not guarantee the technical or scientific viability (including the ability to successfully construct a strain), safety, usefulness or commercial success of any Collaboration Strains or Customer Products.

(b) The Technical Services will be rendered in material compliance with all Applicable Laws applicable to Ginkgo's operations and the provision of the Technical Services hereunder.

4.2 **Ginkgo Resources and Foundry Capacity**. Subject to the terms and conditions of this TSA, during the Term, the Parties shall reasonably coordinate through the JSC the Ginkgo resource and capacity planning necessary to enable the provision by Ginkgo to Customer of Technical Services during the Term having a value equal to the Prepayment set forth in Section 7.2. Ginkgo shall use commercially reasonable efforts to make available resources and capacity as necessary to timely satisfy the JSC's forecasted demand therefor for Ginkgo's performance of Technical Services hereunder.

4.3 **Maintenance and Updating of the Ginkgo Foundry**.

(a) Ginkgo will be responsible for maintaining the Ginkgo foundry in good condition, repair, and working order.

(b) Ginkgo will be responsible for having and maintaining in full force and effect all licenses, permits, authorizations, registrations and qualifications necessary to operate the Ginkgo foundry.

(c) Ginkgo will be responsible for updating equipment in the Ginkgo foundry as reasonably determined by Ginkgo.

5. **Customer Obligations**.

5.1 **Limitations**. Notwithstanding anything to the contrary under this TSA, Customer acknowledges and agrees that the Technical Services to be performed by Ginkgo for Customer hereunder are personal to Customer, and Customer will not be permitted to subcontract, or (except as permitted under Section 17) assign, transfer or otherwise delegate such rights to any Person.

5.2 **Customer Personnel Visitors**. Customer will seek the written approval of Ginkgo for any employee or contractor of Customer seeking to be granted visitor access to the Ginkgo foundry, by email using the address specified in Section 18 at least [**] in advance of any proposed visit. Provided Ginkgo has granted such approval, each such visitor employee or contractor will execute Ginkgo's standard site-admission nondisclosure agreement before entering the Ginkgo foundry, and will be escorted by a member of the Program Team or another employee of Ginkgo at all times during the visit.

5.3 **Customer Materials**. In the event Customer supplies to Ginkgo any tangible materials, including any Background Customer Strains, ("**Customer Materials**") under and in accordance with the terms of a TDP, Customer will provide such Customer Materials at its sole cost and expense and in a timely manner to Ginkgo at the Ginkgo foundry, together with information specific to such Customer Materials, known to Customer, and reasonably required to enable Ginkgo to properly and safely handle, store, and use such Customer Materials. Ginkgo will properly and safely handle, store, and use such Customer Materials solely in accordance with the applicable TDP (and for no other purpose) and in accordance with Applicable Law. Notwithstanding the foregoing, unless it receives the prior written consent of Ginkgo's Senior Executive, in no event will Customer transfer or provide to Ginkgo any tangible material that includes any direct identifiers or other individually identifiable information, including any "Protected Health Information" as defined in 45 C.F.R. Section 164.501. In all cases, any Customer Materials provided to Ginkgo under a TDP will be de-identified in accordance with 45 C.F.R. Section 164.514(b) before being so provided to Ginkgo.

5.4 **Customer Cooperation**. Customer will cooperate with Ginkgo and use commercially reasonable efforts to provide Ginkgo with information and reasonable assistance (including access to Customer Authorized Personnel and other Customer personnel) as Ginkgo reasonably requests in order to provide to Customer the Technical Services. Without limiting the foregoing, Customer will use commercially reasonable efforts to promptly notify Ginkgo of any material information, fact, problem or delay of which it is aware that is likely to affect the provision of Technical Services.

6. **No Lease or Interest**. This TSA is not intended to lease or to grant to Customer any interest in the Ginkgo foundry.

7. **Customer Pricing; Financial Terms**.

7.1 **Customer Pricing**. Subject to the rest of this Section 7 and Section 8 below, Ginkgo will charge to Customer, and Customer will pay to Ginkgo, the price for the Technical Services as set forth on Exhibit F (Customer Pricing) (such pricing, the "**Customer Pricing**" and such charges, the "**Technical Services Charges**"), which pricing, for the avoidance of doubt, shall be [**], calculated with good faith application of its pricing principles to deliver Technical Services. Such charges shall be made and applied against the pre-payment credit set forth in Section 7.2.

7.2 **Prepayment**.

(a) **Prepayment**. Customer shall pay to Ginkgo in cash on the Effective Date an amount equal U.S. $30,000,000 (the "**Prepayment**"). The Prepayment is non-refundable other than as provided pursuant to the provisions of Section 14.3, and without limiting Customer's rights and remedies hereunder in the case of any breach of this TSA by Ginkgo, and will be applied in accordance with this Section 7 toward Technical Services Charges invoiced to Customer hereunder until such Prepayment amount has been exhausted in full or otherwise becomes subject to forfeiture in accordance with Section 14.3.

(b) **Tax Treatment**. Ginkgo and Customer agree, including as it relates to each Party's U.S. federal income tax reporting, that the Prepayment constitutes an advanced payment by Customer for the Technical Services to be provided by Ginkgo pursuant to this TSA, which shall be applied against the Technical Services Charges in accordance with this Section 7.

7.3 **Order of Payment**. With respect to Customer's payment of each invoice for Technical Services Charges submitted by Ginkgo to Customer in accordance with Section 8.1, the following payment mechanism will apply:

(a) Customer will pay one hundred percent (100%) of any invoice for Technical Services Charges by drawing from the Prepayment balance; and

(b) at such time as the Prepayment balance is insufficient to cover the amount of Technical Services Charges invoiced, Customer will pay to Ginkgo the remaining or the entirety, as the case may be, of the invoiced and owed amount of such Technical Services Charges in cash.

7.4 **Overpayment by Customer**. Subject to Sections 7.1 and 7.3, upon a periodic cost true-up with respect to certain [**] costs within the Technical Services Charges as more specifically set forth in Exhibit F (Customer Pricing), the true costs for the applicable Technical Services Charges will be retroactively applied to the covered period. Amounts overpaid by Customer for the covered period will be refunded in the same method as payment was made by Customer (*i.e.*, applied back to the Prepayment balance or refunded in cash depending on the method of original payment). Overpaid amounts refunded pursuant to such true-up will not be deemed an over-charge or over-payment for purposes of Customer's audit reimbursement rights under Section 8.4.

8. **Payment Terms**.

8.1 **Invoice**. As more specifically set forth in Exhibit F (Customer Pricing), following the end of each calendar month during the Term, Ginkgo will submit to Customer an invoice setting forth the Technical Services Charges to be paid based on the Technical Services provided during such calendar month. Each invoice will include a reasonable amount of detail to enable Customer to verify and identify amounts invoiced. Invoices will be submitted electronically to Customer at the email address specified in Section 18. The foregoing will not limit Ginkgo's right to submit corrective invoices in the event there are unbilled amounts owing for Technical Services provided (including amounts for which Ginkgo is entitled to compensation or reimbursement as permitted hereunder which were not previously invoiced) or in the event there are overbilled amounts with respect to Technical Services provided. Subject to Sections 7.1 and 7.3, following its receipt of a permitted invoice for an unbilled amount, Customer will pay Ginkgo such amount promptly in accordance with the payment mechanism set forth in Section 7 and this Section 8. Any permitted invoice for an overbilled amount sent by Ginkgo to Customer will be accompanied by a refund to Customer of the overpaid amount in the same manner as such payment was initially made to Ginkgo (*i.e.*, as a credit to the balance of the Prepayment or in cash).

8.2 **Payments**. Payment of all amounts owed by Customer hereunder will be remitted on or before [**] from the date the invoice therefor is received by Customer; *provided*, *however*, that if Customer in good faith disputes the validity or amount of any charge on such invoice, then Customer will (a) promptly provide Ginkgo with written notice of such disputed item, which notice will specifically identify the disputed item and explain the reason for such dispute, and (b) remit when due any undisputed amount. In the event of any such dispute, Ginkgo and Customer will promptly discuss and attempt to resolve any differences in good faith. To the extent that agreement is reached within [**] of such dispute arising, Customer will promptly pay (or Ginkgo, at its election with notice to Customer, will promptly refund or credit against the next monthly invoice) such amount, if any, as will be so agreed. To the extent no such agreement is reached within such [**] period, the dispute will be resolved in accordance with Section 16 hereof.

8.3 **Taxes**. All prices and charges under this TSA are exclusive of any taxes on the sale of goods or services (such as value-added tax) that may apply from time to time. Any duty, sales, use or excise taxes imposed by any Governmental Authority on the performance of the Technical Services will be itemized on an invoice to, and, subject to Sections 7.1 and 7.3, borne by, Customer (other than taxes based upon the income of Ginkgo, its Affiliates or its subcontractors, or payroll taxes related to employees of Ginkgo, its Affiliates or their subcontractors).

8.4 **Records and Audit**. Ginkgo will maintain accurate and complete books, records and accounts pertaining to the Technical Services Charges for a period of [**] following the termination of this TSA. Upon the written request of Customer and not more than [**], Ginkgo will permit an independent certified public accounting firm of nationally recognized standing selected by Customer and reasonably acceptable to Ginkgo to have access to such records of Ginkgo as may be reasonably necessary to verify the Technical Services Charges charged by Ginkgo to Customer and the draw-down from the Prepayment for such Calendar Year. Such audit right with respect to any Calendar Year will terminate [**] after the end of such Calendar Year. Audits under this Section 8.4 will be conducted at Ginkgo's principal place of business upon at least [**] prior written notice and during normal business hours, and will be for the sole purpose of verifying the calculation of the Technical Services Charges incurred, the portion of Technical Services Charges paid in cash by Customer, and the portion of Technical Services Charges drawn-down from the Prepayment under this TSA. All information and data reviewed in any audit conducted under this Section 8.4 will be treated as Confidential Information of Ginkgo subject to the terms of this TSA. Customer will cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Ginkgo. The accounting firm will disclose to Customer only whether the calculation of the Technical Services Charges incurred, the cash portion of the Technical Services Charges, and the drawn-down portion from the Prepayment is correct or incorrect, and the specific details concerning any discrepancies. If the audit demonstrates that any cash payment or drawn-down amount from the Prepayment in payment for Technical Services Charges under this TSA has been misstated, then, in the case of an understatement, Customer will pay the balance to Ginkgo within [**] after the result of the audit has been delivered to the Parties in accordance with the payment mechanism set forth in Section 7, and, in the case of an overstatement, Ginkgo will refund Customer the overpaid amount in the same manner as such payment was initially made to Ginkgo (*i.e.*, as a credit to the balance of the Prepayment or in cash) within [**] after the result of the audit has been delivered to the Parties. Customer will bear the cost of any audit conducted pursuant to this Section 8.4, *provided* that, in the event such audit reveals an overpayment by [**] percent ([**]%) or more for any audited period, Ginkgo will reimburse such cost to Customer in cash.

9. **Intellectual Property Matters**.

9.1 **Inventorship**. The inventorship of all patented Intellectual Property, developed, conceived, first reduced to practice or otherwise made after the Effective Date under this TSA, will be determined in accordance with United States patent law.

9.2 **Ownership**.

(a) Background IP and Materials.

(i) As between the Parties, subject to the licenses granted to Customer under this TSA, Ginkgo solely owns and will continue to solely own all right, title and interest in and to the Ginkgo Background IP and any materials introduced by Ginkgo under a TDP.

(ii) As between the Parties, subject to the licenses granted to Ginkgo under this TSA, Customer solely owns and will continue to solely own all right, title and interest in and to the Customer Background IP and the Background Customer Strains, and other Customer Materials provided by Customer to Ginkgo under a TDP.

(b) Foreground IP and Materials.

(i) *By Customer*. Notwithstanding Section 9.1, as between the Parties, Customer will solely and exclusively own all right, title and interest in and to [**] Collaboration Strain [**], such Collaboration Strain, but subject to the rights and license granted to Ginkgo and its Affiliates under Section 10.2 of this TSA. Ginkgo, for itself and on behalf of its Affiliates, licensees and sublicenses, and the employees, subcontractors, consultants and agents of any of the foregoing, hereby assigns to Customer (and, to the extent such assignment can only be made in the future, hereby agrees to assign), all right, title and interest in and to each of the foregoing. Ginkgo will cooperate, and will cause the foregoing persons and entities to cooperate, with Customer to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.

(ii) *By Ginkgo*. Notwithstanding Section 9.1, as between the Parties, Ginkgo will solely and exclusively own all right, title and interest in and to, on a TDP-by-TDP basis, all Candidate Strains, Back-Up Strains and other intermediate strains and materials developed, conceived, first reduced to practice or otherwise made, whether solely by or on behalf of Ginkgo, Customer or jointly by the Parties, in the performance of such TDP, but subject to (A) Customer's selection rights under Section 2.3 of this TSA, and (B) Customer's ownership of the Collaboration Strain pursuant to Section 9.2(b)(i)(C) above. Customer, for itself and on behalf of its Affiliates, licensees and sublicenses, and the employees, subcontractors, consultants and agents of any of the foregoing, hereby assigns to Ginkgo (and, to the extent such assignment can only be made in the future, hereby agrees to assign), all right, title and interest in and to each of the foregoing. Customer will cooperate, and will cause the foregoing persons and entities to cooperate, with Ginkgo to effectuate and perfect the foregoing ownership, including by promptly executing and recording assignments and other documents consistent with such ownership.

(iii) *[**]*. Ginkgo and Customer [**].

9.3 **Prosecution and Enforcement Matters**.

(a) Prosecution.

(i) *By Ginkgo*. As between the Parties, Ginkgo will have the sole responsibility, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of all Patent Rights within the Ginkgo Background IP. For clarity, Customer will not have any right to review or comment on any of the foregoing activities.

(ii) *By Customer*.

(A) As between the Parties, Customer will have the sole responsibility, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of all Patent Rights within the Customer Background IP. For clarity, Ginkgo will not have any right to review or comment on any of the foregoing activities.

(B) As between the Parties, Customer will have the responsibility, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of all Patent Rights within the [**]; *provided*, *however*, that, the Parties will coordinate (through the JSC, or, if so formed by the JSC, the IP Subcommittee) to determine what, if any, [**] will be claimed in a patent application. In making such determination, the JSC or the IP Subcommittee will seek, through commercially reasonable efforts, to maximize the value of any Customer Product that may be Covered by a claim of such proposed patent application (including by optimizing the life cycle of such Customer Product), to reduce the extent to which earlier filings of Patent Rights Covering a Customer Product may be cited as prior art to later filings for Patent Rights, and to reduce any conflicts between [**] ("**Prosecution Objectives**"). Without limiting the rights of Ginkgo under the foregoing proviso clause, Customer will furnish to Ginkgo, 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 the preparation, filing, prosecution and maintenance of Patent Rights within the [**], and such other documents related to such activities, in sufficient time prior to filing such document to allow for review and comment by Ginkgo. Customer will consider in good faith timely comments from Ginkgo thereon. Customer will furnish Ginkgo, via electronic mail or such other method as mutually agreed by the Parties, copies of documents filed with the relevant patent offices with respect to the preparation, filing, prosecution and maintenance of Patent Rights within the [**].

(iii) *By the Parties Jointly*.

(A) Customer and Ginkgo, acting in good faith, will work together to determine a strategy for the preparation, filing, prosecution and maintenance of all Patent Rights within the [**]. Without limiting the foregoing, each Party will furnish to the other Party, 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 the preparation, filing, prosecution and maintenance of Patent Rights within the [**], and such other documents related to such activities, in sufficient time prior to filing such document to allow for review and comment by both Parties. Each Party will consider in good faith timely comments from the other Party thereon. Each Party will furnish the other Party, via electronic mail or such other method as mutually agreed by the Parties, copies of documents filed with the relevant patent offices with respect to the preparation, filing, prosecution and maintenance of Patent Rights within the [**].

(B) The Parties will have joint responsibility for implementing such strategy, with prosecution counsel mutually agreed by the Parties, and the Parties will make commercially reasonable efforts to achieve the Prosecution Objectives. In doing so, the Parties will consult with each other on (1) what subject matter and content to claim in any patent applications for [**], (2) responses to office actions received from patent offices in connection with any such patent applications, and (3) the strategy for restriction and election, terminal disclaimer, foreign filing, and abandonment in connection with any such patent applications and any patents issuing thereon. Ginkgo and Customer will share equally the costs and expenses associated with the foregoing activities with respect to any [**] to the extent Covering subject matter in the Licensed Field and Ginkgo shall solely bear the costs and expenses associated with the foregoing activities with respect to all other [**]. In the event of a dispute between Ginkgo and Customer concerning the filing, prosecution or maintenance of any Patent Rights within the [**], the matter will be escalated to the Senior Executives for resolution through good faith negotiations for a period of up to [**]. If the Senior Executives are unable to resolve the matter within such [**] period (or such longer period as the Parties may agree) after the matter is referred to them in accordance with this Section 9.3(a)(iii)(B), then the matter shall be resolved by binding arbitration in accordance with the process set forth in Schedule 16.1. Customer will have the exclusive right to determine whether to seek a patent term extension for any issued Patent Rights within the Foreground IP and, if so, for which issued Patent Right(s) within the Foreground IP such extension will be sought. [**].

(C) In the event that either Party elects to cease to prosecute any patent application, or cease to maintain any issued patent, within the [**] (any such action, "**Prosecution Abandonment**"), such Party will notify the other Party of such election promptly prior to such Prosecution Abandonment taking effect (the date of such notice, the "**Election Date**"). The non-abandoning Party will have the right (but not the obligation) to assume from and after the Election Date the filing or prosecution of such patent application, or the maintenance of such patent, as applicable, continuing in the joint names of the Parties but at such non-abandoning Party's sole cost and expense.

(b) Enforcement; Defense.

(i) *Notice*. During the Term, if either Party learns of any Third Party infringement of any Patent Rights within the Foreground IP, such Party will notify the other Party within [**] of becoming aware of the same.

(ii) *Enforcement*.

(A) The Parties will [**] any Patent Rights within the Foreground IP to abate any Third Party infringement of the same [**], except in the case of a Competitive Infringement for which Customer will have the rights specified in Section 9.3(b)(ii)(B).

(B) In the case of a Competitive Infringement, Customer will have the [**] right, but not the obligation, at its sole cost and expense and through counsel of its choosing, to seek to abate such Competitive Infringement, or to file suit under any [**] against such Third Party engaging in such Competitive Infringement. [**].

(iii) *Defense*. To the extent either Party receives notice by counterclaim, or otherwise, challenging the invalidity or unenforceability of any Patent Rights within the Foreground IP (a "**Third Party Action**"), it will notify the other Party, including providing all relevant information related to such claim. Where such allegation is made by a Third Party that owns or controls, and is developing, producing or commercializing a Competitive Product that infringes such Patent Rights, Customer will have the first right, but not the obligation, to control the defense of such Third Party Action. If Customer elects not to defend such Third Party Action, or fails to take the requisite actions to defend such Third Party Action within a [**] period or such shorter time if such failure would materially prejudice Customer's right to defend such Third Party Action, Ginkgo will have the right (but not the obligation) to assume and control such defense. With respect to other Third Party Actions, the Parties will jointly control the defense of such Third Party Action.

(iv) *Withdrawal, Cooperation and Participation*. With respect to any infringement action or Third Party Action identified above in this Section 9.3(b), each Party will cooperate with the other. Specifically, (x) in the case of a Competitive Infringement, Ginkgo will cooperate with Customer and (y) in the case of a Third Party Action, the other Party will cooperate with the Party controlling such action, in each case (x) and (y) as reasonably requested by the controlling Party. Such cooperation includes a Party (A) providing access to relevant documents and other evidence, (B) making itself and its Affiliates, licensees and Sublicensees, and all of its and their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (C) if necessary, by bringing such action at the direction of the controlling Party or by being joined as a party plaintiff, subject, for this clause (C), to the controlling Party, if any, agreeing to indemnify such other Party for its involvement in such action and paying those costs and expenses incurred by such other Party in connection therewith. The Party controlling any such action will keep the other Party reasonably updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.

(v) *Settlement*. With respect to any infringement action in a case of Competitive Infringement, Customer will have the sole right to settle or otherwise dispose of such action on such terms and conditions as such Party will determine in its sole discretion; with respect to other infringement actions or Third Party Actions the Parties shall jointly determine whether and on what terms to settle or otherwise dispose of such action; *provided, however*, that, notwithstanding the foregoing, no such settlement or other disposition will (A) impose any monetary restriction or obligation on or admit fault of the other Party, or (B) adversely affect the other Party without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed). For the avoidance of doubt, with respect to any infringement action or Third Party Action for which the Parties are jointly responsible, neither Party shall have the ability to settle or otherwise dispose of such action without the consent of the other Party.

(vi) *Damages*. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in this Section 9.3(b) will be used first to reimburse all out-of-pocket costs and expenses incurred by the Parties in connection therewith (including, without limitation, attorneys' fees). If such recovery is insufficient to cover all such costs and expenses of both Parties, the controlling Party's costs and expenses will be paid in full first before any of the other Party's costs and expenses; provided, that, [**], the Parties shall share equally (50%/50%) with respect to any recovery, even if such recovery in insufficient to cover both Parties' expenses. If after such reimbursement any funds remain from such judgments or settlements, such funds will be (A) shared equally (50%/50%) by the Parties with respect to any action or proceeding for which [**].

10. **Licenses**.

10.1 **Licenses to Customer**. Subject to the terms and conditions of this TSA, for each TDP, Ginkgo hereby grants to Customer:

(a) a non-exclusive, worldwide, fully paid-up, royalty-free license under the Ginkgo Background IP solely as necessary (i) to perform its activities under such TDP, and (ii) to Research, Develop, Produce and Commercialize Customer Products from the Collaboration Strain in the Licensed Field, with the right to grant sublicenses of the license of clause (ii) in accordance with Section 10.3;

(b) a worldwide, fully paid-up, royalty-free license, with the right to grant sublicenses in accordance with Section 10.3, under Ginkgo's rights in the Foreground IP to Research, Develop, Produce and Commercialize Customer Products in the Licensed Field, which license will be (i) exclusive with respect to Exclusively Licensed Foreground IP and (ii) non-exclusive with respect to the Non-Exclusively Licensed Foreground IP (such license, the "**Product License**"); and

(c) a non-exclusive, worldwide, fully paid-up, royalty-free license, with the right to grant sublicenses in accordance with Section 10.3, under its rights in the Foreground IP for all uses in the Licensed Field, subject, however, to the exclusive license granted to Customer under Exclusively Licensed Foreground IP of the Product License set forth in Section 10.1(b)(i).

For clarity, notwithstanding the limitations of the license grant of clause (b) above to Customer Products and, with respect to Non-Exclusively Licensed Foreground IP, Ginkgo shall not grant any license to any Third Party that is inconsistent with any license grants to Customer in this Section 10.1 or with Customer's enforcement rights as set forth in Section 9.3(b).

10.2 **Licenses to Ginkgo**. Subject to the terms and conditions of this TSA, Customer hereby grants to Ginkgo:

(a) a non-exclusive, worldwide, fully paid-up, royalty-free license, with the right to grant sublicenses in accordance with Section 10.3, under the Customer Background IP and Customer's rights in the Foreground IP to perform its activities under each TDP;

(b) a non-exclusive, worldwide, fully paid-up, royalty-free license and right to use and incorporate in Ginkgo's database and associated biomaterials repositories (with the right to grant sublicenses in accordance with Section 10.3) all IP embodied in any Collaboration Strain or Back-Up Strain subject, however, to the Product License and other rights granted to Customer; provided that, notwithstanding the foregoing, this section 10.2(b) does not include any license or right under Customer Background IP, [**]

(c) an exclusive, worldwide, fully paid-up, royalty-free license, with the right to grant sublicenses in accordance with Section 10.3, under its rights in all Foreground IP (other than [**]) for any and all products and uses outside of the Licensed Field; and

(d) a non-exclusive, worldwide, fully paid-up, royalty-free license, with the right to grant sublicenses in accordance with Section 10.3, under its rights in the Foreground IP (other than [**]) for all uses in the Licensed Field, subject, however, to the exclusive license granted to Customer under Exclusively Licensed Foreground IP of the Product License set forth in Section 10.1(b)(i).

For clarity, notwithstanding the foregoing license grants to Ginkgo in this Section 10.2, Ginkgo shall not grant any license to any Third Party that is inconsistent with any license grants to Customer in Section 10.1 or with Customer's enforcement rights as set forth in Section 9.3(b).

10.3 **Sublicensing**.

(a) Customer may grant Sublicenses (through multiple tiers) of, as permitted, the licenses granted to Customer under Section 10.1; provided that in no event will Customer (i) be permitted to grant, or permit the grant of, a Sublicense (whether or not with respect to subcontracting an activity under a TDP) to a Designated Competitor that is a Designated Competitor at the time such Sublicense is granted, or (ii) be permitted to grant, or permit the grant of, a Sublicense to any Third Party that is a Ginkgo Competitor at the time such Sublicense is granted.

(b) Ginkgo may grant Sublicenses (through multiple tiers) of the licenses granted to Ginkgo under Section 10.2; provided that, Ginkgo shall not grant any license to any Third Party that is inconsistent with any license grants to Customer in Section 10.1 or with Customer's enforcement rights as set forth in Section 9.3(b).

(c) Each Sublicense granted pursuant to this Section 10.3 will be subject and subordinate to, and consistent with, the terms and conditions of this TSA, and will require each Sublicensee thereunder to comply with all applicable terms of this TSA and all Third Party Obligations. Notwithstanding the grant of any Sublicense, the granting Party will remain primarily liable to the other Party for the performance of all of such granting Party's obligations under, and such granting Party's compliance with all provisions of, this TSA. Within [**] after entering into any Sublicense of Commercialization rights, Customer shall provide Ginkgo [**].

10.4 **Ginkgo Retained Rights**. Notwithstanding the exclusive license under the Exclusively Licensed Foreground IP granted to Customer under Section 10.1(b)(i), Ginkgo for itself and for its Affiliates and for any of its or their subcontractors, reserves the rights under the Exclusively Licensed Foreground IP to perform itself, and have performed by any such Affiliates and subcontractors, the activities assigned to Ginkgo or its Affiliates in TDPs under this TSA in accordance herewith.

10.5 **No Implied Licenses**. All rights of each Party and its Affiliates in and to any Intellectual Property not expressly licensed to the other Party under this TSA are hereby retained by such Party or its Affiliates, as applicable. Except as expressly provided in this TSA, no Party will be deemed by estoppel or implication to have granted the other Party any licenses or other right with respect to any Intellectual Property it owns or Controls.

10.6 **Customer Abandonment**.

(a) On a Program-by-Program basis, in the event an Abandonment occurs with respect to such Program (an "**Abandoned Program**"), Ginkgo will have the right to trigger the consequences set forth in Section 10.6(b) upon written notice to Customer specifying in reasonable detail the basis for such claim and identifying the clause in the definition of Abandonment corresponding to such claim (such notice, the "**Abandonment Notice**"); provided, that, but only where Ginkgo's Abandonment Notice refers to clause (b) of the definition of Abandonment as the basis for its claim, (i) within [**] of receipt of an Abandonment Notice, Customer will have the right to request a meeting with Ginkgo to discuss Ginkgo's abandonment claim ("**Abandonment Dispute Notice**"), (ii) following such meeting, if the Parties are unable to reach agreement on whether abandonment under this Section 10.6 occurred prior to the Abandonment Notice, either Party may refer the matter for dispute resolution in accordance with Section 16.1, and (iii) the consequences set forth in Section 10.6(b) shall not be effective until an adjudicator has determined that such abandonment has occurred.

(b) Consequences of Customer Abandonment. Following Ginkgo's delivery of the Abandonment Notice in connection with a Program, and for such Program, (i) where Ginkgo's Abandonment Notice refers to clause (a) of the definition of Abandonment as the basis for Ginkgo's claim, effective immediately upon Customer's receipt of such Abandonment Notice, and (ii) where Ginkgo's Abandonment Notice refers to clause (b) of the definition of Abandonment as the basis for Ginkgo's claim, effective upon (1) the expiration of the [**] period set forth in Section 10.6(a), to the extent Customer does not timely provide an Abandonment Dispute Notice within such time period, (2) the Parties' mutual agreement that an abandonment under this Section 10.6 has occurred in respect of the Program referenced in the Abandonment Notice, or (3) the determination of an adjudicator of any dispute with respect to Abandonment of a Program in accordance with Section 16.1:

(i) All exclusive licenses granted to Customer under Section 10.1, and all other exclusive rights granted to Customer under this TSA, with respect to the Candidate Strains, Back-Up Strains, Collaboration Strain and Customer Product for such Program (each, an "**Abandoned Product**") shall immediately become non-exclusive, without any further action of either Party; and

(ii) Customer's right to enforce and defend Patent Rights within the Foreground IP with respect to Competitive Infringement relating to any Competitive Product of each such Abandoned Product, as set forth in Section 9.3(b)(ii)(B) and Section 9.3(b)(iii), shall immediately terminate, with any such enforcement or defense thereafter governed by the terms of Section 9.3(b)(ii)(A).

(c) Customer Annual Reports. On a Program-by-Program basis, during the Term and thereafter until such time as Customer or any of its Affiliates or Sublicensees has obtained a Regulatory Approval for a Customer Product under such Program, within [**] after the end of each Calendar Year, Customer shall submit to Ginkgo a [**] written report [**]. For clarity, such reports shall include [**].

11. **Confidentiality**.

11.1 **Confidentiality**.

(a) Each Party acknowledges that during the Term, each such Party (the "**Receiving Party**") may have access to and become acquainted with Confidential Information belonging to the other Party and its Affiliates, licensors or licensees (the "**Disclosing Party**"). In addition, each Receiving Party acknowledges that: (i) the Disclosing Party has invested, and continues to invest, substantial time, expense and specialized knowledge in developing its Confidential Information; (ii) the Confidential Information provides the Disclosing Party with a competitive advantage over others in the marketplace; and (iii) the Disclosing Party would be irreparably harmed if the Confidential Information were disclosed to competitors or made available to the public. No Receiving Party will, directly or indirectly, disclose or use at any time, including use for personal, commercial or proprietary advantage or profit, either during their association with the other Party or thereafter, any Confidential Information of the Disclosing Party which the Receiving Party is or becomes aware. Each Receiving Party in possession of Confidential Information of the Disclosing Party will take measures it normally takes with respect to information of a like type to safeguard such information and to protect it against unauthorized disclosure, misuse, espionage, loss and theft, which measures shall be no less than a reasonable standard of care. The terms of this TSA will be deemed to be the Confidential Information of both Parties. The Parties acknowledge that Confidential Information has been exchanged between the Parties prior to the Effective Date pursuant to the Confidentiality Agreement. The Parties agree that as of the Effective Date the Confidentiality Agreement is hereby terminated without further force and effect and is superseded by this TSA, and all obligations between the Parties relating to all such Confidential Information exchanged before the Effective Date will be governed by this Article 11.

(b) Nothing contained in Section 11.1(a) will prevent a Receiving Party or any of its Affiliates and Representatives from disclosing (and in the case of clauses (v), (vi) and (vii), below, using) Confidential Information of the Disclosing Party: (i) upon the order of any court or administrative agency; (ii) upon the request or demand of any regulatory agency or authority having jurisdiction over such Party or, in the case of Customer, otherwise reasonably necessary to seek Regulatory Approval for Customer Products in the Licensed Field; (iii) to the extent compelled by legal process; (iv) to such Receiving Party's Affiliates and its and their Representatives, who, in the reasonable judgment of such Receiving Party, have a need to know such information for purposes of assisting the Receiving Party in performing its obligations or exercising its rights hereunder, and are under binding (whether fiduciary, statutory or otherwise) obligations to maintain its confidentiality which are at least as stringent as those set forth herein (but of duration customary in confidentiality agreements entered into for a similar purpose); (v) to such Receiving Party's bona fide actual or prospective acquirers, underwriters, investors, lenders or other financing sources, subcontractors, collaborators, licensors, sublicensees, licensees, or strategic partners, and to employees, directors, agents, consultants, and advisers of any such Third Parties, who, in the reasonable judgment of such Receiving Party, have a need to know such information for purposes of assisting the Receiving Party in performing its obligations or exercising its rights hereunder, and are under binding (whether fiduciary, statutory or otherwise) obligations to maintain its confidentiality which are at least as stringent as those set forth herein (but of duration customary in confidentiality agreements entered into for a similar purpose); (vi) to exercise such Receiving Party's rights and licenses granted under this TSA; and (vii) to perform such Receiving Party's obligations to the Disclosing Party or its

Affiliates under this TSA; *provided*, *however*, that in the case of clause (i), (ii) and (iii), if legally permitted, such Receiving Party will notify the Disclosing Party of the proposed disclosure as far in advance of such disclosure as practicable and use reasonable efforts to ensure that any Confidential Information of the Disclosing Party so disclosed is accorded confidential treatment reasonably satisfactory to the Disclosing Party, when and if available. For the avoidance of doubt, Customer Materials provided by Customer to Ginkgo hereunder or under any TDP shall be used by Ginkgo solely to perform the Technical Services for Customer and for no other purpose, notwithstanding any license grant hereunder.

(c) The restrictions of Section 11.1(a) will not apply to Confidential Information of a Disclosing Party that: (i) is or becomes generally available to the public other than as a result of a disclosure by the Receiving Party in violation of this TSA; (ii) is or becomes available to such Receiving Party or any of its Affiliates or Representatives on a non-confidential basis prior to its disclosure to such Receiving Party and any of its Affiliates or Representatives in compliance with this TSA; (iii) is or has been independently developed or conceived by such Receiving Party without use of Confidential Information of such Disclosing Party; or (iv) becomes available to such Receiving Party or any of its Affiliates or Representatives on a non-confidential basis from a source other than such Disclosing Party or any of its Affiliates or Representatives; *provided*, *however*, that such source is not known by the recipient of the Confidential Information of such Disclosing Party to be bound by a confidentiality agreement with such Disclosing Party or its Affiliates or Representatives.

(d) During the Term, each Party will, and will cause its Affiliates to, submit to the other Party for review and approval any proposed academic, scientific and medical publication or public presentation to the extent it includes Confidential Information of the other Party or its Affiliates. In each such instance, such review and approval will be conducted for the purposes of preserving the value of the rights granted under this TSA and determining whether any portion of the proposed publication or presentation containing such Confidential Information should be modified or deleted. Notwithstanding anything to the contrary, a Party may require, in its reasonable discretion, that the other Party redact any Confidential Information of the reviewing Party from any such proposed publication or presentation. Each Party hereby agrees to comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication.

(e) No Disclosing Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this TSA, or any of its confidential or proprietary information to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties: (i) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (ii) may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (iii) intend that such privileges and protections remain intact should any Party become subject to any actual or threatened proceeding to which the Disclosing Party's information covered by such protections and privileges relates; and (iv) intend that after the Effective Date both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges.

(f) The provisions of this Section 11.1 will continue to apply to the Parties until the date which is [**] following the expiration of the Term or termination of this TSA; *provided*, *however*, that, with respect to any scientific or technical information constituting Confidential Information of a Party, such provisions will continue to apply to the Parties in perpetuity.

11.2 **Publicity**. Neither Party, nor any of its Affiliates or Representatives, will issue any press release or make any other public announcement with respect to this TSA or the transactions contemplated herein, without obtaining the prior written approval of the other Party, except in case of public announcements required under the rules of any stock exchange on which the equity interests of a such Party or its Affiliates (or any successor entity) are listed or any Applicable Law or governmental requirement. Notwithstanding anything to the contrary in this TSA, either Party (or its Affiliates) may disclose (a) this TSA (and a summary thereof) and (b) information specifically relating to the progress of Development or Commercialization of (i) Customer Products and Back-Up Strains (so long as they remain Customer Products or Back-Up Strains), with respect to Customer, or (ii) products within the scope of Ginkgo's licenses or retained rights, with respect to Ginkgo, in securities filings with the U.S. Securities and Exchange Commission or an equivalent foreign agency to the extent required by Applicable Law, *provided*, *however*, *that* neither Party shall make any such disclosure that would put at risk either Party's right to seek, file, prosecute, maintain, defend

or enforce Patent Rights as permitted by this TSA without the prior written consent of the other Party. In such event, such Party seeking such disclosure will prepare such summary and a proposed redacted version of this TSA to request confidential treatment for such agreements, and the other Party may promptly (and in any event, no less than [**] after receipt of such summary and proposed redactions) provide its comments. The Party seeking such disclosure will reasonably consider any such comments provided by the other Party within such [**] period. The initial press release regarding this TSA shall be jointly issued on a timing agreed by the Parties following the Effective Date, but in any event prior to or simultaneous with any obligation by Customer to disclose such press release in a current report on Form 8-K.

12. **Representations and Warranties**.

12.1 **Representations and Warranties of the Parties**. Each of Customer and Ginkgo hereby represents and warrants to the other as of the Effective Date that:

(a) It is duly organized, validly existing and in good standing under the laws of the jurisdiction of its formation.

(b) It (i) has the requisite power and authority and the legal right to enter into this TSA and to perform its obligations hereunder, and (ii) has taken all requisite action on its part to authorize the execution and delivery of this TSA and the performance of its obligations hereunder.

(c) Its execution, delivery and performance of this TSA (i) will constitute a legal, valid, binding and enforceable obligation on it, and (ii) will not constitute a default under or conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, or violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

(d) It has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons or entities required to be obtained by it in connection with the execution and delivery of this TSA.

12.2 **Additional IP Representations and Warranties of the Parties**. Each of Customer and Ginkgo hereby represents and warrants to the other as of the Effective Date that:

(a) it owns or has the right to use, in the case of Customer, the Customer Background IP existing as of the Effective Date, and, in the case of Ginkgo, the Ginkgo Background IP, existing as of the Effective Date, free and clear of any liens, charges and encumbrances (other than licenses granted to Third Parties that are not inconsistent with the rights and licenses granted to the other Party hereunder and other than the licenses granted to the other Party hereunder); *provided*, *however*, that the foregoing is not a representation of non-infringement of the Intellectual Property of another Person.

12.3 **Covenants**.

(a) By Each Party. Each Party hereby covenants to the other Party that, except as expressly permitted under this TSA, during the Term, it will not amend, modify or terminate any In-License Agreements to which it is a party in a manner that would have a material adverse effect on such other Party's rights under this TSA. Each Party shall comply, and will ensure that its Affiliates and Sublicensees, and each of its and their respective employees, contractors and agents, comply, with all local, state and international laws, rules and regulations relating to the Development, Production and Commercialization of the Customer Products and use of the Collaboration Strains, including all export control laws, anti-corruption laws, anti-kickback laws and data or patient privacy laws.

(b) By Ginkgo.

(i) Ginkgo shall not incorporate into any Collaboration Strain or Back-Up Strain generated by Ginkgo under any TDP hereunder any Intellectual Property of a Third Party, whether or not Controlled by Ginkgo, without Customer's prior written consent.

(ii) Ginkgo shall not use in any capacity in connection with the performance of its obligation under a TDP, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction. Ginkgo shall inform Customer in writing promptly upon learning that it or any Person that is performing, or has performed, activities under a TDP on behalf of Ginkgo or any of its Affiliates is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or if any action, suit, claim, investigation or legal or administrative proceeding is pending or is threatened, relating to the debarment or conviction of Ginkgo, any of its Affiliates or any such Person.

(iii) Ginkgo will reasonably cooperate with Customer to provide Confidential Information, including chemical and biological materials, reasonably necessary for Customer to seek Regulatory Approval for Customer Products in the Licensed Field.

(c) By Customer. Customer shall not use, in any capacity, in connection with the performance of its obligations under a TDP or the exercise of its rights or licenses granted hereunder, any Person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction. Customer shall inform Ginkgo in writing promptly upon learning that it or any Person that is performing, or has performed, activities under a TDP, or in connection with the exercise by Customer or any of its Affiliates of Customer's rights or licenses granted hereunder, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or is threatened, relating to the debarment or conviction of Customer, any of its Affiliates or any such Person.

12.4 **Disclaimer of Warranties**. EXCEPT FOR THOSE WARRANTIES EXPRESSLY MADE IN THIS TSA, NEITHER PARTY MAKES, AND EACH PARTY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EITHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO THE CUSTOMER LICENSED IP, THE GINKGO LICENSED IP, THE PROVISION OF TECHNICAL SERVICES, THE GINKGO FOUNDRY, OR THE PROVISION OF ANY BIOLOGICAL OR OTHER MATERIALS PROVIDED BY OR ON BEHALF OF A PARTY, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NON-INFRINGEMENT.

13. **Indemnification**.

13.1 **Third Party Claims**. Each Party (the "**Indemnifying Party**") will defend, indemnify and hold the other Party (the "**Indemnified Party**") and its Affiliates and its and their directors, officers, employees, agents and consultants and legal, financial, accounting and other advisors ("**Related Persons**") harmless from and against any and all liabilities and damages (including reasonable attorneys' fees) ("**Losses**") resulting from any claims, demands, suits or proceedings by a Third Party ("**Claims**") to the extent arising out of or based upon: (a) in the case that Customer is the Indemnifying Party, (i) the Customer Materials, including their presence or use at the Ginkgo foundry or the Ginkgo facilities, and (ii) the Research, Development, Production and Commercialization of Customer Products in the Licensed Field by or on behalf of Customer or any of its Affiliates, licensees or Sublicensees or the exercise by Customer or any of its Affiliates, licensees or Sublicensees of any license granted by Ginkgo to Customer hereunder, and (b) in the case that Ginkgo or Customer is the Indemnifying Party, (i) a breach of any representation, warranty or covenant made or given under this TSA by such Indemnifying Party, or (ii) the negligence, recklessness or willful misconduct of such Indemnifying Party or any of its Related Persons during the course of activities carried out in connection with this TSA, and (c) in the case that Ginkgo is the Indemnifying Party, the operation of the Ginkgo foundry by Ginkgo (except to the extent covered by subclause (a)(i) of this Section 13.1) or any of its Affiliates, licensees or Sublicensees or the exercise by Ginkgo or any of its Affiliates, licensees or Sublicensees of any license granted by Customer to Ginkgo hereunder for any purpose other than to perform Technical Services for Customer hereunder. The indemnification obligations set forth in this Section 13.1 do not apply to the extent that the Losses arise in whole or in part from (A) the negligence, recklessness or willful misconduct of the Indemnified Party or any of its Related Persons, (B) the material breach of any representation, warranty or covenant made or given under this TSA by the Indemnified Party or any of its Related Persons, or (C) a failure to comply with Applicable Laws by the Indemnified Party or any of its Related Persons.

13.2 **Defense**. Each Party will notify the other Party promptly upon learning of a Claim that is subject to indemnification pursuant to Section 13.1; *provided*, *however*, that any failure by the Indemnified Party to provide prompt notice to the Indemnifying Party will not relieve such Indemnifying Party from, or reduce its, indemnification obligation under Section 13.1, unless any delay in providing notice results in actual prejudice to the Indemnifying Party. The Indemnifying Party may control, at its own expense, the defense of the Claim in good faith with counsel of its choice as long as such counsel is reasonably acceptable to the Indemnified Party. The Indemnified Party will use reasonable efforts to cooperate in the defense and may participate at its own expense using its own counsel. No compromise or settlement of any Claim may be made by the Indemnifying Party without the Indemnified Party's written consent (such consent not to be unreasonably withheld, conditioned or delayed) unless (a) there is no finding or admission of any violation of Applicable Law or any violation of the rights of any Person, (b) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party, and (c) the Indemnified Party's rights under this TSA are not adversely affected.

13.3 **Limitations of Liability**.

(a) NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY CLAIMS FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, PUNITIVE, BUSINESS INTERRUPTION, EXEMPLARY OR INDIRECT DAMAGES OR LOST PROFITS, ARISING UNDER STATUTE, IN TORT OR CONTRACT OR OTHERWISE IN CONNECTION WITH OR RESULTING FROM THE PARTIES' PERFORMANCE UNDER THIS TSA. THE FOREGOING LIMITATION WILL NOT LIMIT EITHER PARTY'S LIABILITY WITH RESPECT TO (I) A PARTY'S BREACH OF THE CONFIDENTIALITY AND NON-USE PROVISIONS IN SECTION 11, (II) A PARTY'S FRAUD OR WILLFUL MISCONDUCT, AND (III) THE OBLIGATIONS OF EACH PARTY FOR THE INDEMNIFICATION OF THIRD PARTY CLAIMS UNDER SECTION 13.

(b) EXCEPT FOR (I) A PARTY'S BREACH OF THE CONFIDENTIALITY AND NON-USE PROVISIONS IN SECTION 11, (II) A PARTY'S FRAUD OR WILLFUL MISCONDUCT, (III) A PARTY'S BREACH OF ITS ASSIGNMENT OBLIGATION OF FOREGROUND IP UNDER THIS TSA, AND (IV) THE OBLIGATIONS OF EACH PARTY FOR THE INDEMNIFICATION OF THIRD PARTY CLAIMS UNDER SECTION 13.1, IN NO EVENT WILL EITHER PARTY'S AGGREGATE LIABILITY TO THE OTHER FOR ALL CLAIMS OF ANY KIND (INCLUDING NEGLIGENCE) FOR ANY LOSS OR DAMAGE ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM THIS TSA OR FROM PERFORMANCE OR BREACH THEREOF EXCEED [**].

13.4 **Insurance**. Each Party will obtain and maintain, during the Term and for a period of [**] thereafter, with a reputable, solvent insurer, general liability insurance (including liability for property damage, product liability, personal injury and contractual liability) adequate to cover its obligations under this TSA and consistent with normal business practices of prudent companies similarly situated as such Party. Upon request, a Party will provide the other Party with evidence of the existence and maintenance of such insurance coverage.

14. **TSA Term and Termination.**

14.1 **TSA Term**. Unless earlier terminated in accordance with the provisions of Section 14.2, this TSA is effective as of the Effective Date and will terminate upon the first to occur of (a) exhaustion of the Prepayment in full or (b) the fifth (5^{th}) anniversary of the Effective Date (the "**Initial Term**"), *provided* that if, the Initial Term expires pursuant to the foregoing clause (b) and the Prepayment balance as of the fifth (5^{th}) anniversary of the Effective Date is greater than zero U.S. Dollars (US$0.00), this TSA will automatically extend beyond the Initial Term for up to three (3) years after the expiration of the Initial Term, one (1) Calendar Quarter at a time, so long as both (A) the Prepayment balance at the commencement of such Calendar Quarter is greater than zero U.S. Dollars (US$0.00) and (B) the total quarterly usage for Technical Services under this TSA during the immediately preceding Calendar Quarter exceeded [**] U.S. Dollars (US$[**]) (any such extension, the "**Extended Term**" and, together with the Initial Term, the "**Term**"). For clarity, in the event the provisions of the foregoing proviso apply, Customer will have the right to propose, for approval by the JSC in accordance with Section 3, new TDPs during such three (3) year period (or a shorter time period depending on Customer's satisfaction of the foregoing clause (B) requirement).

14.2 **Termination Rights**.

(a) Termination by Mutual Agreement. At any time during the Term, the Parties may mutually agree in writing to terminate this TSA in its entirety, for any reason or no reason.

(b) Termination for Convenience by Customer. Following the one (1) year anniversary of the Effective Date, Customer will have the right to terminate this TSA in its entirety for its convenience upon ninety (90) days' prior written notice to Ginkgo.

(c) Termination for Insolvency. If, at any time during the Term (i) a case is commenced by or against either Party under Title 11, United States Code, as amended (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within sixty (60) days after the commencement thereof, (ii) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (iii) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (iv) a receiver or custodian is appointed for either Party's business, or (v) a substantial portion of either Party's business is subject to attachment or similar process; then, in any such case ((i), (ii), (iii), (iv) or (v)), the other Party may terminate this TSA upon written notice to the extent permitted under Applicable Law.

(d) Termination for Party Change of Control.

(i) If, at any time during the Term, either Party intends to complete a Change of Control with a Third Party (the "**CoC Party**"), the CoC Party will deliver a written notice to the other Party (such notice, the "**Transaction Notice**") at least [**] before completing or closing such Change of Control or, if earlier, prior to disclosing an unredacted form of this TSA, which Transaction Notice will include the name of the applicable acquiror. In addition, if the CoC Party completes or closes a Change of Control, such CoC Party will so notify the other Party within [**] of such closing. Without limiting the foregoing, if any such Change of Control is structured as a sign and close, the CoC Party will provide to the other Party a Transaction Notice promptly after signing and in any event at least [**] before completing or closing such Change of Control.

(ii) Notwithstanding anything to the contrary in Section 14.2(d)(i), in the event that Customer intends to complete a Change of Control with a Third Party that is a Ginkgo Competitor, including, for the avoidance of doubt, with a Designated Competitor, Ginkgo will have the right to terminate this TSA in its entirety upon written notice to Customer at any time during the period beginning on the date that Ginkgo receives a Transaction Notice from Customer and ending on the earlier of (i) the date that is [**] after the date Ginkgo receives notice of the closing of the Change of Control that is the subject of such Transaction Notice, or (ii) the date on which Customer notifies Ginkgo that such Change of Control will not be completed or will not be closed. Such termination shall be effective [**] after such termination notice is delivered to Customer by Ginkgo; *provided* that, if Ginkgo exercises its termination right prior to the occurrence of such Change of Control being completed or closing, such termination by Ginkgo will be effective only upon the date such Change of Control is completed or closed, or if later, [**] after such Ginkgo termination letter is delivered ("**Customer CoC Termination Date**").

(iii) Notwithstanding anything to the contrary in Section 14.2(d)(i), in the event that Ginkgo intends to complete a Change of Control with a Third Party that is a Customer Competitor, Customer will have the right to terminate this TSA in its entirety upon written notice to Ginkgo at any time during the period beginning on the date that Customer receives a Transaction Notice from Ginkgo and ending on the earlier of (i) the date that is [**] after the date Customer receives notice of the closing of the Change of Control that is the subject of such Transaction Notice, or (ii) the date on which Ginkgo notifies Customer that such Change of Control will not be completed or will not be closed. Such termination shall be effective [**] after such termination notice is delivered to Ginkgo by Customer; *provided* that, if Customer exercises its termination right prior to the occurrence of such Change of Control being completed or closing, such termination by Customer will be effective only upon the date such Change of Control is completed or closed, or if later, [**] after such Customer termination letter is delivered ("**Ginkgo CoC Termination Date**").

(e) Termination for Non-Use of Technical Services. Within [**] following the third (3rd) anniversary of the Effective Date, Customer will have a one-time right to terminate this TSA in its entirety upon [**] prior written notice to Ginkgo, if, and only if, on the third (3rd) anniversary of the Effective Date, Ginkgo has failed to either (a) initiate an aggregate of [**] TDPs under this TSA, if at least [**] TDPs have been approved by the JSC as of such date or (b) file, and/or co-own with Customer, at least [**] Patent Rights arising from the Foreground IP. To the extent one of the preceding conditions has been met and Customer fails to deliver Ginkgo with a notice to terminate under this Section 14.2(e) within such [**] period, Customer's right to terminate under this Section 14.2(e) shall cease.

14.3 **Effects of Termination**.

(a) Upon expiration of the Term of this TSA:

(i) subject to Customer's continued payment for Technical Services Charges associated therewith, any active TDPs as of the date of such expiration will be completed, including any such active TDPs that may have been added by Customer pursuant to its rights under the last sentence of Section 14.1 but provided no such continued activities will continue later than the eighth (8th) anniversary of the Effective Date unless mutually agreed in writing by the Parties; ***provided***, ***that*** for any such active TDP as of the date of such eighth (8th) anniversary for which Candidate Strains have been identified and Developed thereunder, for a period of [**] from the date of such eighth (8th) anniversary, Customer shall have the right to designate one (1) Collaboration Strain for each such TDP and up to, but no more than, [**] Back-Up Strains for each TDP and the procedures set forth in Section 2.3 shall apply;

(ii) (A) all licenses granted under Section 10.1 by Ginkgo to Customer will survive and become perpetual, irrevocable and non-terminable, unless and until an Abandonment in which case such licenses will convert to non-exclusive for the Program that is the subject of such Abandonment, and (B) all licenses granted under Section 10.2 by Customer to Ginkgo will survive and become perpetual, irrevocable and non-terminable, ***provided***, ***however***, that, in case of (A) and (B), such licenses will be limited to Intellectual Property of such granting Party existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iii) upon the occurrence of the eighth (8th) anniversary of the Effective Date, Ginkgo will retain the balance, if any, of the Prepayment remaining on such date;

(iv) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(a)(ii), each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(v) the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, ***provided***, ***however***, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

(b) Upon termination of this TSA by Customer pursuant to Section 14.2(b) (Termination for Convenience by Customer) or Section 14.2(e) (Termination for Non-Use of Technical Services) or by the Parties pursuant to Section 14.2(a) (Termination by Mutual Agreement):

(i) any and all active TDPs as of the date of such termination will terminate and an orderly wind-down of any work being performed thereunder will be undertaken;

(ii) (A) all licenses granted under Section 10.1 by Ginkgo to Customer will survive and become perpetual, irrevocable and non-terminable, unless and until an Abandonment in which case such licenses will convert to non-exclusive for the Program that is the subject of such Abandonment, and (B) all licenses granted under Section 10.2 by Customer to Ginkgo will survive and become perpetual, irrevocable and non-terminable, *provided*, *however*, that, in case of (A) and (B), such licenses will be limited to Intellectual Property of such granting Party existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iii) Ginkgo will retain the balance, if any, of the Prepayment remaining on the date of such termination, except, if such termination is by Customer pursuant to Section 14.2(e), in which case Ginkgo will repay to Customer, promptly following the date of such termination, any remaining unused balance of the Prepayment up to a maximum of U.S. $10,000,000;

(iv) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(b)(ii), each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(v) the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, *provided*, *however*, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

(c) Upon termination of this TSA by Customer pursuant to Section 14.2(c) (Ginkgo's Insolvency):

(i) any and all active TDPs as of the date of such termination will terminate immediately and an orderly wind-down of any work being performed thereunder will be undertaken; *provided*, *that* for any such active TDP as of the date of such termination for which Candidate Strains have been identified and Developed thereunder, for a period of [**] from the effective date of termination, Customer shall have the right to designate one (1) Collaboration Strain for each such TDP and up to, but no more than, [**] Back-Up Strains for each TDP and the procedures set forth in Section 2.3 shall apply;

(ii) all licenses granted under Section 10.1 by Ginkgo to Customer will survive and become perpetual, irrevocable and non-terminable, *provided*, *however*, that such licenses will be limited to Intellectual Property of Ginkgo existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iii) all licenses granted under Section 10.2 by Customer to Ginkgo will become perpetual, irrevocable and non-terminable and will survive and become perpetual, irrevocable and non-terminable, provided, that, such licenses will be limited to Intellectual Property of Customer existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iv) to the extent the Prepayment balance, as of the effective date of termination, is greater than zero U.S. Dollars (US$0.00), Ginkgo will pay to Customer the amount of such balance in cash promptly following the date of such termination; *provided*, *however*, that such repayment will be made after Customer has paid for any and all Technical Services Charges that have accrued as of such effective date of termination and which are to be paid for by drawing-down from the Prepayment;

(v) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(c)(ii) or Section 14.3(c)(iii), as applicable, each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(vi) at Customer's election by written notice to Ginkgo, the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, *provided*, *however*, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

(d) Upon termination of this TSA by Customer pursuant to Section 14.2(d) (Ginkgo's Change of Control):

(i) any and all active TDPs as of the date of such termination will terminate on the Ginkgo CoC Termination Date and an orderly wind-down of any work being performed thereunder will be undertaken during the period preceding the Ginkgo CoC Termination Date; *provided*, *that* for any such active TDP as of the date of such termination for which Candidate Strains have been identified and Developed thereunder, for a period of [**] from the Ginkgo CoC Termination Date, Customer shall have the right to designate one (1) Collaboration Strain for each such TDP and up to, but no more than, [**] Back-Up Strains for each TDP and the procedures set forth in Section 2.3 shall apply;

(ii) (A) all licenses granted under Section 10.1 by Ginkgo to Customer will survive and become perpetual, irrevocable and non-terminable, unless and until an Abandonment, in which case such licenses will convert to non-exclusive for the Program that is the subject of such Abandonment, and (B) all licenses granted under Section 10.2 by Customer to Ginkgo will survive and become perpetual, irrevocable and non-terminable, *provided*, *however*, that, in case of (A) and (B), such licenses will be limited to Intellectual Property of such granting Party existing as of the Ginkgo CoC Termination Date (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iii) to the extent the Prepayment balance, as of the effective date of termination, is greater than zero U.S. Dollars (US$0.00), Ginkgo will pay to Customer the amount of such balance in cash promptly following the date of such termination; *provided*, *however*, that such repayment will be made after Customer has paid for any and all Technical Services Charges that have accrued as of such effective date of termination and which are to be paid for by drawing-down from the Prepayment;

(iv) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(d)(ii), each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(v) at Customer's election by written notice to Ginkgo, the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, *provided*, *however*, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

(e) Upon termination of this TSA by Ginkgo pursuant to Section 14.2(c) (Customer's Insolvency):

(i) any and all active TDPs as of the date of such termination will terminate immediately and an orderly wind-down of any work being performed thereunder will be undertaken;

(ii) all licenses granted under Section 10.1 by Ginkgo to Customer will become perpetual, irrevocable and non-terminable and will survive and become perpetual, irrevocable and non-terminable, unless and until an Abandonment, in which case such licenses will convert to non-exclusive for the Program that is the subject of such Abandonment, ***provided***, ***that***, such licenses will be limited to Intellectual Property of Ginkgo existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights); ***provided***, ***further***, ***that***, notwithstanding the foregoing, [**];

(iii) all licenses granted under Section 10.2 by Customer to Ginkgo will survive and become perpetual, irrevocable and non-terminable, ***provided***, ***however***, that, such licenses will be limited to Intellectual Property of Customer existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iv) Ginkgo will retain the balance, if any, of the Prepayment remaining on the date of such termination;

(v) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(e)(ii) or Section 14.3(e)(iii), as applicable, each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(vi) the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, ***provided***, ***however***, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

(f) Upon termination of this TSA by Ginkgo pursuant to Section 14.2(d) (Customer's Change of Control):

(i) any and all active TDPs as of the date of such termination will terminate on the Customer CoC Termination Date and an orderly wind-down of any work being performed thereunder will be undertaken during the period preceding the Customer CoC Termination Date; ***provided***, ***that*** to the extent Ginkgo terminates this TSA pursuant to Section 14.2(d) due to a Change of Control, or proposed Change of Control, of Customer with a Designated Competitor, all active TDPs shall terminate immediately upon the Customer CoC Termination Date without any wind-down work required to be undertaken thereunder;

(ii) all licenses granted under Section 10.1 by Ginkgo to Customer will survive and become perpetual, irrevocable and non-terminable, unless and until an Abandonment in which case such licenses will convert to non-exclusive for the Program that is the subject of such Abandonment, ***provided***, ***however***, that such licenses will be limited to Intellectual Property of Ginkgo existing as of the Customer CoC Termination Date (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights); and, further ***provided***, ***however***, that, if Ginkgo terminated this TSA pursuant to such Section 14.2(d) due to a Change of Control, or proposed Change of Control, of Customer with a Designated Competitor, then all licenses granted under Section 10.1 by Ginkgo to Customer shall terminate immediately on the Customer CoC Termination Date, with no further action required by the Parties;

(iii) all licenses granted under Section 10.2 by Customer to Ginkgo will survive and become perpetual, irrevocable and non-terminable, *provided*, *however*, that, such licenses will be limited to Intellectual Property of Customer existing as of the effective date of such termination (but will include, for clarity, as to Patent Rights, within such Intellectual Property Rights, any other patents or patent applications that claim priority, directly or indirectly, to any such preexisting Patent Rights);

(iv) Ginkgo will retain the balance, if any, of the Prepayment remaining on the date of such termination;

(v) except in the case of any Confidential Information of the other Party that is the subject of a Party's surviving licenses pursuant Section 14.3(f)(ii) or Section 14.3(f)(iii), as applicable, each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing such destruction) all of such other Party's Confidential Information provided by or on behalf of such other Party that is in the possession or control of such Party (or any of its Affiliates, Sublicensees or subcontractors), except that such Party will have the right to retain one (1) copy of intangible Confidential Information of such other Party, only for legal purposes; and

(vi) the JSC and, if one was established, the IP Committee or each Program Team, will be dissolved as of the expiration date, *provided*, *however*, that, for any surviving provisions requiring action or decision by the JSC, IP Committee or Program Team, each Party hereby appoints its respective Senior Executive to perform such action or make such decision.

14.4 **Additional Effects of Expiration or Termination; Survival**.

(a) Additional Effects of Expiration or Termination. Expiration or termination for any reason of this TSA will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or under Applicable Law or in equity.

(b) Survival. In addition to the termination consequences set forth in Section 14.3 (and any Sections referenced therein) and this Section 14.4, the following provisions of this TSA will survive expiration or termination of this TSA for any reason: Section 1 (Definitions) (to the extent the definitions are used in other surviving provisions), Section 7 (solely with respect to amounts accrued but not yet paid prior to termination or expiration), Section 8 (solely with respect to amounts accrued but not yet paid prior to termination or expiration), Section 9 (Intellectual Property Matters), Section 10.6(c) (Customer Annual Reports); Section 11 (Confidentiality) (for the time period set forth therein), Section 12.4 (Disclaimer of Warranties), Sections 13.1-13.3 (Indemnification) (inclusive), Section 13.4 (for the time period set forth therein), Section 15 (Force Majeure), Section 16 (Dispute Resolution), Section 17 (Assignment), Section 18 (Notices), and Section 19 (Miscellaneous).

15. **Force Majeure**. No failure or omission by either Party in the performance of any obligation of this TSA will be deemed a breach of this TSA or create any liability if the same will arise from a Force Majeure Event; *provided*, *however*, that the Party affected by such cause promptly notifies the other Party and uses diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of one or more of the above mentioned causes. "**Force Majeure Event**" means, with respect to a Party, an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of such Party (which may include acts of God, acts of any government, any rules, regulations or orders issued by any Governmental Authority or by any officer, department, agency or instrumentality thereof, fire, storm, flood, earthquake, shortage, accident, war, rebellion, insurrection, riot, terrorism and invasion) that interferes with the normal business operations of such Party.

16. **Dispute Resolution**.

16.1 Disputes. The Parties agree that, except for (a) disputes arising under Section 3.1 that have been escalated to the Senior Executives and not been resolved and (b) any matter as to which a Party seeks immediate equitable relief, all controversies or claims arising out of or relating to this TSA, or the interpretation, performance, breach, termination, or validity thereof, will be referred to the Senior Executives for good faith negotiation towards a resolution for a period of up to [**]. If the Senior Executives cannot reach an agreement within such [**] period (or such longer period as the Parties may agree), either Party may, at its sole discretion, seek resolution of such dispute in accordance with Section 16.4.

16.2 Attorneys' Fees. If any Action at law or in equity (including, arbitration) is necessary to enforce or interpret the terms of this TSA, including claims for fraud and/or fraudulent inducement, the prevailing Party will be entitled to seek reasonable attorneys' fees, costs and necessary disbursements, in addition to any other relief to which such Party may be entitled.

16.3 Governing Law. The Parties agree that this TSA will be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts.

16.4 Jurisdiction. Except as otherwise set forth in Section 3.1 and Schedule 16.1, each Party to this TSA, by its execution hereof, unless otherwise prohibited by Applicable Law (a) hereby irrevocably submits to the exclusive jurisdiction of the state courts of the Commonwealth of Massachusetts in Suffolk County and to the United States District Court for the District of Massachusetts (each a "**Massachusetts Court**") for the purpose of any Action among the Parties, (b) hereby waives and agrees not to assert, by way of motion, as a defense or otherwise, in any such Action, any claim that it is not subject personally to the jurisdiction of such Massachusetts Courts, that any such Action brought in such Massachusetts Court should be dismissed on grounds of *forum non conveniens*, should be transferred or removed to any forum other than a Massachusetts Court, or should be stayed by reason of the pendency of some other proceeding in any court other than such Massachusetts Court, or that this TSA or the subject matter hereof may not be enforced in or by such Massachusetts Court, and (c) to the extent that an Action can be commenced in a court, agrees not to commence any such Action in any court other than a Massachusetts Court. Notwithstanding the previous sentence, a Party hereto may commence any Action in a court other than a Massachusetts Court for the purpose of enforcing an order or judgment issued by a Massachusetts Court or an award issued by an arbitrator in accordance with Schedule 16.1.

16.5 Specific Performance. Each of the Parties hereto acknowledges and agrees that the other Party would be damaged irreparably in the event any of the provisions of this TSA are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, each of the Parties hereto agrees that, without posting a bond or other undertaking, the other Party may seek an injunction or injunctions to prevent breaches or violations of the provisions of this TSA and to enforce specifically this TSA and the terms and provisions hereof in any Action instituted in any Massachusetts Court. An Action for specific performance as provided herein will not preclude a Party hereto from pursuing any other remedy to which such Party may be entitled in accordance with the terms of this TSA. Each Party hereto further agrees that, in the event of any action for specific performance in respect of such breach or violation, it will not assert as a defense that a remedy at law would be adequate; *provided*, *however*, that each Party hereto also agrees that any Party hereto can assert any other defense it may have other than the defense of adequate remedy at law.

17. **Assignment**. None of the rights, interests and obligations created herein will be transferred or assigned to any Third Party and such rights and interests will not inure to the benefit of any other person, including any trustee in bankruptcy, receiver or other successor of either of the Parties, whether by operation of Applicable Law, transfer of assets, merger, liquidation or otherwise, without the prior written consent of the other Party. Any purported or actual transfer or assignment of any such rights, interests or obligations without the prior written consent of the other Party is and will be null and void *ab initio*; *provided*, *however*, that either Party may, without prior consent of the other Party, assign its respective rights and obligations under this TSA (a) to a successor company of such Party as the result of a Change of Control, or (b) to an Affiliate of such Party; *provided* that, in each case, the assigning Party will remain liable for its obligations hereunder.

18. **Notices**. All notices, requests, consents, claims, demands, waivers and other communications hereunder will be in writing and will be deemed to have been given: (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient; or (d) on the third (3rd) day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the applicable Party at the following addresses (or at such other address for such Party as will be specified in a notice given in accordance with this Section 18):

To Ginkgo:	Ginkgo Bioworks, Inc. 27 Drydock Ave., Floor 8 Boston, MA 02210 Attention: Chief Executive Officer and General Counsel Email: [**]
With a copy to: (which will not constitute notice)	Goodwin Procter LLP 100 Northern Avenue Boston, MA 02210 Attention: Rob E. Puopolo and Karen A. Spindler Email: rpuopolo@goodwinlaw.com and kspindler@goodwinlaw.com
and	
To Customer:	Synlogic Operating Company, Inc. 301 Binney St., Suite 402 Cambridge, MA 02142 Attention: Chief Executive Officer and General Counsel
With a copy to: (which will not constitute notice)	WilmerHale LLP 60 State Street Boston, MA 02109 Attention: Steven D. Barrett, Esq. Email: steven.barrett@wilmerhale.com

19. **Miscellaneous**.

19.1 No provision of this TSA may be amended or modified, or compliance otherwise waived, except by a writing executed by each Party.

19.2 The Parties have participated jointly in the negotiation and drafting of this TSA. In the event an ambiguity or question of intent or interpretation arises, this TSA will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this TSA. Any reference to any federal, state, local or foreign statute or law will be deemed also to refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

19.3 Every day commences at 12:00 a.m. and ends at 11:59 p.m. (midnight) Massachusetts time. Any reference in this TSA to a number of days "in" which an action or notice is to be taken or given, will be interpreted in such way that the term commences the day after the date taken as reference and that the action or notice will be validly taken or given at the last day. Any reference in this TSA to a "day" or a number of "days" without explicit qualification of "business" will be interpreted as a reference to a calendar day or number of calendar days. If any action or notice is to be taken or given on or by a particular calendar day, and such calendar day is not a Business Day, then such action or notice will be deferred until, or may be taken or given on, the next Business Day.

19.4 All rights and licenses granted under or pursuant to this TSA by Ginkgo or Customer, as applicable, are, and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this TSA, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "**Bankrupt Party**") under the Bankruptcy Code, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the Bankrupt Party elects to continue to perform all of its obligations under this TSA or (b) if not delivered under clause (a), following the rejection of this TSA by the Bankrupt Party upon written request therefor by the other Party.

19.5 This TSA constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter.

19.6 The headings in this TSA are inserted for convenience or reference only and are in no way intended to describe, interpret, define, or limit the scope, extent or intent of this TSA or any provision of this TSA.

19.7 If any term or provision of this TSA is held to be invalid, illegal or unenforceable under Applicable Law in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other term or provision of this TSA or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties hereto will negotiate in good faith to modify this TSA so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

19.8 Any mistaken reference to Articles, clauses, Sections, Schedules, Exhibits or paragraphs of this TSA will be amended according to common sense and good faith rules. When a reference is made in this TSA to an Article, clause, Section, Schedule, Exhibit or paragraph, such reference will be to an Article, clause, Section, Schedule, Exhibit or paragraph of this TSA, unless otherwise indicated.

19.9 No waiver by any Party of any default, misrepresentation or breach of warranty or covenant hereunder, whether intentional or not, will be deemed to extend to any prior or subsequent default, misrepresentation or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent such occurrence. No single or partial exercise of any right, power or privilege will preclude any other or further exercise thereof, or the exercise of any other right, power or privilege unless explicitly provided for in this TSA.

19.10 Subject to the terms of and restrictions in this TSA, the reference to any Party will include its successors or permitted assignees or transferees that have legally acquired its rights, obligations and/or duties. This TSA will be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assignees and transferees and nothing herein, express or implied, is intended to or will confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever, unless otherwise specified therein.

19.11 This TSA may be executed in counterparts, each of which will be deemed an original, but all of which together will be deemed to be one and the same agreement. A signed copy of this TSA delivered by e-mail or other means of Electronic Transmission will be deemed to have the same legal effect as delivery of an original signed copy of this TSA. For purposes of this Section 19.11, "**Electronic Transmission**" means any form of communication not directly involving the physical transmission of paper that creates a record that may be retained, retrieved and reviewed by a recipient thereof and that may be directly reproduced in paper form by such a recipient through an automated process.

19.12 Whenever the words “include,” “includes” or “including” are used in this TSA, they will be deemed to be followed by the words “without limitation” or “but not limited to”. The words “hereof,” “herein” and “hereunder” and words of similar import when used in this TSA will refer to this TSA as a whole and not to any particular provision of this TSA. All terms used herein with initial capital letters have the meanings ascribed to them herein and all terms defined in this TSA will have such defined meanings when used in any certificate or other document made or delivered pursuant hereto unless otherwise defined therein. The definitions contained in this TSA are applicable to the singular as well as the plural forms of such terms. Any agreement, instrument or statute defined or referred to herein, or in any agreement or instrument that is referred to herein, means such agreement, instrument or statute as from time to time amended, modified or supplemented, including (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein.

19.13 Both Parties are independent contractors under this TSA. Nothing herein contained will be deemed to create an employment, agency or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party, except to the extent specifically agreed to in a written agreement signed by the Parties. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

[*SIGNATURE PAGE FOLLOWS*]

* - * - * - *

IN WITNESS WHEREOF, the Parties have caused this TSA to be executed by their representatives thereunto duly authorized as of the Effective Date.

SYNLOGIC OPERATING COMPANY, INC.		**GINKGO BIOWORKS, INC.**	
By:	/s/ Aoife Brennan	By:	/s/ Jason Kelly
Name:	Aoife Brennan	Name:	Jason Kelly
Title:	CEO	Title:	Chief Executive Officer

[*Signature Page to Foundry Terms of Service Agreement***]**

Exhibit F
Customer Pricing

Customer Pricing will be calculated based on a mark-up on total operating costs for providing the services, under the definitive agreement, as amended from time to time.

The remuneration to be paid by Customer shall cover (i) the total costs incurred by Ginkgo in connection with the Technical Services provided to Customer, as defined below (the "**Total Cost**") and (ii) a [**]% arm's length mark-up on such Total Cost, [**] (collectively, the "**Transfer Price**").

The Total Cost shall be determined by full cost accounting in accordance with a recognized cost calculation method applying the principles of US GAAP. The Total Cost shall be calculated on the basis of all actual direct and indirect costs incurred by Ginkgo in providing the Technical Services to Customer.

[**]

Ginkgo will invoice Customer [**].

On a quarterly basis upon close of Ginkgo's fiscal quarter, a true-up calculation will be performed on [**] and any needed billing adjustments issued. The purpose of the true-up calculation is to establish that quarterly amounts billed reflect actual [**] allocable to a Work Order. Ginkgo reserves the right to change to an annual true-up calculation.

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 8, 2019

/s/ Aoife Brennan
Aoife Brennan
President, Chief Executive Office and Chief Medical 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, Todd Shegog, 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 8, 2019

/s/ Todd Shegog
Todd Shegog
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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Aoife Brennan, President. Chief Executive Officer and Chief Medical 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, Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

August 8, 2019

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, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Todd Shegog, 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/ Todd Shegog
Todd Shegog
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

August 8, 2019

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.